Our business operations are primarily in the PRC and subject to regulation by the PRC government. This section summarizes the major PRC regulatory authorities and PRC laws and regulations that we believe are relevant to our business and operations in the PRC.

REGULATORY AUTHORITIES

NMPA and CDE

The National Medical Products Administration (國家藥品監督管理局) ("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 (國家藥品監督管理局藥品審評中心) ("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) (formerly known as the National Health and Family Planning Commission (國家衛生和計劃生育委員會) (the "NHC"), is primary national regulator for national public health and medical system.

It is primarily responsible for drafting national health policies, supervising and regulating public health, healthcare services, and health emergency systems, coordinating the reform of medical and health system, organizing the formulation of national drug policies and national essential medicine system, launching an early warning mechanism for the monitoring of the use and clinical comprehensive evaluation of medicine as well as the drug shortage, giving suggestions on the pricing policy of national essential medicine, and regulating the operation of medical institutions and practicing of medical personnel.

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 January 16, 2026, and effective since May 15, 2026, 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, clinical 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.

The China Food and Drug Administration issued several technical guidelines on March 20, 2003, including the Technical Guideline for Preclinical Research of Preventive DNA Vaccines (《預防用DNA疫苗臨床前研究技術指導原則》), the Technical Guideline for Quality Control of Human Recombinant DNA Products (《人用重組DNA製品質量控制技術指導原則》), and the Technical Guideline for Quality Control and Clinical Research of Human Gene Therapy (《人基因治療研究和制劑質量控制技術指導原則》). These guidelines clarified the requirements for preclinical research and quality control of DNA vaccines.

The China Food and Drug Administration issued the Technical Guideline for Vaccine Clinical Trials (《疫苗臨床試驗技術指導原則》) on December 3, 2004, which clarified the requirements for preclinical studies and lab evaluations, the uniqueness of vaccines, selection of subjects, safety, immunogenicity, vaccine efficacy, criteria for determining protective effects, Adverse Event monitoring, and reporting. Clinical trials are divided into four phases: Phase I, II, III, and IV. The focus of Phase I is primarily on safety; Phase II aims to observe or evaluate whether the vaccine achieves its expected outcomes (usually referring to immunogenicity) and general safety information in the target population; Phase III evaluates the overall efficacy and safety of the vaccine; Phase IV clinical trials are conducted post-market approval to comprehensively assess the vaccine's safety and effectiveness in actual use populations. Clinical trials must ensure the rights, safety, and health of participants, and all research must be reviewed and approved by an independent ethics committee.

On October 14, 2005, the China Food and Drug Administration issued additional guidelines such as the Technical Guideline for Preclinical Research of Preventive Vaccines (《預防用疫苗臨床前研究技術指導原則》) (revised on April 22, 2010), the Technical Guideline for Management of Changes in Biologics Manufacturing Processes (《生物製品生產工藝過程變更管理技術指導原則》), the Technical Guideline for Preclinical and Clinical Research of Combined Vaccines (《聯合疫苗臨床前和臨床研究技術指導原則》), the Technical Guideline for Production and Quality Control of Peptide Vaccines (《多肽疫苗生產及質控技術指導原則》), and the Technical Guideline for Quality Control and Clinical Research of Conjugate Vaccines (《結合疫苗質量控制和臨床研究技術指導原則》). These guidelines clarified the requirements for preclinical research, changes in manufacturing processes, and quality control during clinical stages to ensure the safety and efficacy of vaccines.

The China Food and Drug Administration issued the Technical Guideline for Stability Studies of Biological Products (Trial) (《生物製品穩定性研究技術指導原則(試行)》) on April 15, 2015, which clarified the design and analysis of stability studies for biological product raw materials, finished products, or intermediates.

The CDE issued the Technical Guideline for Aluminum-Adjuvanted Preventive Vaccines (《預防用含鋁佐劑疫苗技術指導原則》) on December 9, 2019, which clarified the technical requirements for pharmacology, preclinical research, clinical research, and post-marketing production quality control related to aluminum-adjuvanted vaccines.

The CDE issued the Regulations for the Assessment and Management of Safety Information During Drug Clinical Trials (Trial) (《藥物臨床試驗期間安全信息評估與管理規範(試行)》) and the Management Regulations for Development Safety Update Reports During Research and Development (Trial) (《研發期間安全性更新報告管理規範(試行)》) on July 1, 2020. After obtaining approval for clinical trials, applicants must submit rapid reports on suspected and unexpected serious adverse reactions (SUSAR) and other potential serious safety risk information during the clinical trial period, as well as DSURs.

The CDE issued the Technical Guideline for Pharmaceutical Research and Change Management During Clinical Trials (Trial) (《臨床試驗期間生物製品藥學研究和變更技術指導原則(試行)》) on June 7, 2024, which clarified the requirements for pharmaceutical changes and updates during clinical trials to ensure the safety and efficacy of vaccines.

Post-approval Studies of Vaccines

The CDE issued the Technical Guideline for Post-Marketing Pharmaceutical Changes of Biological Products (Trial) (《已上市生物製品藥學變更研究技術指導原則(試行)》) on June 25, 2021. The MAH must establish a post-marketing change control system for biological products and be responsible for all post-marketing pharmaceutical changes, self-assessment of research results, and continuous dynamic change management.

The CDE issued the Technical Guideline for Post-Marketing Pharmaceutical Changes of Vaccines (Trial) (《已上市疫苗藥學變更研究技術指導原則(試行)》) on June 7, 2024. The MAH should strengthen the construction of vaccine quality systems and be responsible for all post-marketing pharmaceutical changes, self-assessment of research results, and continuous dynamic change management. Additionally, they should continuously optimize production processes to maintain advanced production and control methods.

The NMPA issued the Management Measures for Post-Marketing Changes of Drugs (Trial) (《藥品上市後變更管理辦法(試行)》) on January 12, 2021. MAHs should proactively conduct post-marketing studies to achieve full lifecycle management of drugs. Post-marketing anges must not adversely affect the safety, efficacy, or quality control of the drugs.

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. 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 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 POV designated thereby.

Based on the above, the prices of vaccines are determined by the MAHs in accordance with the law, without upper limit on profit margins.

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

Environment Protection

The Environmental Protection Law of the PRC (《中華人民共和國環境保護法》) ("the Environmental Protection Law"), which was promulgated by the SCNPC on December 26, 1989, came into effect on the same day and last amended on April 24, 2014, outlines the authorities and duties of various environmental protection regulatory agencies. The Ministry of Ecology and Environment is authorized to issue national standards for environmental quality and emissions, and to monitor the environmental protection scheme of the PRC. Meanwhile, local environment protection authorities may formulate local standards which are more rigorous than the national standards, in which case, the concerned enterprises must comply with both the national standards and the local standards.

Environmental Impact Appraisal

According to the Administration Rules on Environmental Protection of Construction Projects (《建設項目環境保護管理條例》), which was promulgated by the State Council on November 29, 1998, amended on July 16, 2017 and became effective on October 1, 2017, depending on the impact of the construction project on the environment, an construction employer shall submit an environmental impact report or an environmental impact statement, or file a registration form. As to a construction project, for which an environmental impact report or the environmental impact statement is required, the construction employer shall, before the commencement of construction, submit the environmental impact report or the environmental impact statement to the relevant authority at the environmental protection administrative department for approval. If the environmental impact assessment documents of the construction project have not been examined or approved upon examination by the approval authority in accordance with the law, the construction employer shall not commence the construction. According to the Environmental Impact Appraisal Law of PRC (《中華人民共和國環境影響評價法》) ("the Environmental Impact Appraisal Law"), which was promulgated by the SCNPC on October 28, 2002, amended on July 2, 2016 and December 29, 2018, for any construction projects that have an impact on the environment, an entity is required to produce either a report, or a statement, or a registration form of such environmental impacts depending on the seriousness of effect that may be exerted on the environment.

Completion and Acceptance

The Interim Measures for Acceptance of Environmental Protection upon Completion of Construction Projects (《建設項目竣工環境保護驗收暫行辦法》), promulgated and implemented by the former Ministry of Environmental Protection (now the MEE) on November 20, 2017, regulate the procedures and standards for environmental protection acceptance by construction entities upon the completion of construction projects.

Fire Prevention

According to the Fire Prevention Law of the PRC (《中華人民共和國消防法》), promulgated by the SCNPC on April 29, 1998 and last amended with effect from April 29, 2021, design and construction of the fire control facilities for a construction work shall comply with the national fire control technical standards. The developer, designer, constructors and project supervisor of a construction project shall be responsible for the quality of the design and construction of the fire control facilities for the construction work according to the relevant laws. If the design of fire control of a construction project has not been examined pursuant to the relevant laws or failed to pass the examination, the construction of such project is not allowed. If a completed construction project has not gone through the fire safety inspection or failed to satisfy the requirements of fire safety upon inspection, such project is not allowed to be put to use or business.

Management of Waste Discharge

Pursuant to the Catalog of Classified Management of Pollutant Discharge Permits for Stationary Pollution Sources (2019 Version) (《固定污染源排污許可分類管理名錄(2019年版)》) issued by the Ministry of Ecology and Environment of the PRC and became effective on December 20, 2019, the State implements the primary management, simplified management and registration management of pollutant discharge permits based on the pollutant production, emission amount and the extent of environmental impact of the pollutant discharge entities. A pollutant discharge unit under registration management does not need to apply for a pollutant discharge license.

Pursuant to the Regulations on the Administration of Pollutant Discharge Permits (《排污許可管理條例》) promulgated by the State Council on January 24, 2021 and became effective on March 1, 2021, based on the quantity of pollutants generated and discharged, their impacts on the environment and other factors, categorical administration of pollutant discharge permit system is implemented to regulate pollutant-discharging entities: (1) key administration of pollutant discharge permits shall be implemented for pollutant discharging entities which generate and discharge relatively large quantities of pollutants or have a relatively serious impact on the environment; and (2) administration of pollutant discharge permits shall be simplified for pollutant-discharging entities which generate and discharge relatively small quantities of pollutants and have a relatively small impact on the environment. The entities that generate and discharge relatively small quantities of pollutants and have a relatively small impact on the environment shall fill in the waste discharge registration form (排污登記表) and are no longer required to obtain a waste discharge license (排污許可證). Entity that is required to fill in the waste discharge registration form shall report the basic information, waste discharge destination, waste discharge standards implemented, waste prevention and control measures adopted and other information to the national waste discharge license information platform. If the information reported is changed, it shall be changed in the platform within 20 days as of the date when such change occurs.

Laws and Regulations Relating to Data Compliance

Cyber and Data Security

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, most recently amended on October 28, 2025 and effective since January 1, 2026, 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.

Personal Information Protection

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.

Cross-border Data Transfer

Pursuant to the Measures for Security Assessment of Data Export (《數據出境安全評估辦法》), issued by the Cyberspace Administration of China on July 7, 2022, and implemented since September 1, 2022, data handlers must apply for a security assessment through their local provincial cyberspace administration to the national cyberspace administration before exporting data under any of the following circumstances: (i) the data handler intends to export important data; (ii) critical information infrastructure operators and data handlers processing personal information of more than one million individuals intend to export such personal information; (iii) since January 1 of the previous year, the data handler has cumulatively exported personal information of 100,000 individuals or sensitive personal information of 10,000 individuals and intends to continue exporting such information; and (iv) other situations as specified by the national cyberspace administration that require a security assessment for data export.

Pursuant to the Regulations for Promoting and Regulating Cross-border Data Flows (《促進和規範數據跨境流動規定》), issued and implemented by the Cyberspace Administration of China since March 22, 2024, data handlers must identify and report important data in accordance with relevant regulations. If the data has not been designated or publicly announced as important data by relevant authorities or regions, data handlers are not required to report it for a data export security assessment as important data.

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.

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 came into effect on January 1, 2021. According to the Civil Code of the PRC, 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.

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 was amended on August 27, 2009 and October 25, 2013 to protect consumers' rights when they purchase or use goods and accept services. All business operators must comply with this law when they manufacture or sell goods and/or provide services to customers. Where the goods or services provided by a business operator do not satisfy quality requirements, the consumer may require the business operator to perform replacement or repair obligations.

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

Labor Contract Law

According to the Labor Law of the PRC (《中華人民共和國勞動法》) promulgated by the SCNPC on July 5, 1994 and last amended on December 29, 2018, enterprises and institutions shall establish and improve their system of workplace safety and sanitation, strictly abide by state rules and standards on workplace safety, educate labourers in labor safety and sanitation in the PRC. Labor safety and sanitation facilities shall comply with state-fixed standards. Enterprises and institutions shall provide labourers with a safe workplace and sanitation conditions which are in compliance with state stipulations and the relevant articles of labor protection. The PRC Labor Contract Law (《中華人民共和國勞動合同法》) which was promulgated by the SCNPC on June 29, 2007 and amended on December 28, 2012, is primarily aimed at regulating employee/employer rights and obligations, including matters with respect to the establishment, performance and termination of labor contracts. Pursuant to the PRC Labor Contract Law, labor contracts shall be concluded in writing if labor relationships are to be or have been established between enterprises or institutions and the labourers. Enterprises and institutions are forbidden to force labourers to work beyond the time limit and employers shall pay labourers for overtime work in accordance with the laws and regulations. In addition, labor wages shall not be lower than local standards on minimum wages and shall be paid to labourers in a timely manner.

Social Insurance

Enterprises in China are required by PRC laws and regulations to participate in certain employee benefit plans, including social insurance funds, namely a pension plan, a medical insurance plan, an unemployment insurance plan, a work-related injury insurance plan and a maternity insurance plan, and a housing provident fund, and contribute to the plans or funds in amounts equal to certain percentages of salaries, including bonuses and allowances, of the employees as specified by the local government from time to time at locations where they operate their businesses or where they are located. In accordance with the Social Security Law of the PRC (《中華人民共和國社會保險法》) which was last amended on December 29, 2018 and other applicable laws and regulations, employers who fail to promptly contribute social security premiums in full amount shall be ordered by the social security premium collection agency to make or supplement contributions within a stipulated period, and shall be subject to a late payment fine computed from the due date at the rate of 0.05% per day; where payment is not made within the stipulated period, the relevant administrative authorities shall impose a fine ranging from one to three times of the amount in arrears.

The Notice of the State Administration of Taxation on Implementing Measures to Further Support and Serve the Development of Private Economy (《國家税務總局關於實施進一步支持和服務民營經濟發展若干措施的通知》) issued on November 16, 2018 and the Notice on Promulgation of the Comprehensive Plan for the Reduction of Social Insurance Premium Rate (《關於印發<降低社會保險費率綜合方案>的通知》), promulgated by the General Office of the State Council on April 1, 2019, also emphasize that the historical unpaid arrears of enterprises shall be properly treated, or in the process of the reform of the collection system, it is not allowed to conduct self-collection of historical unpaid arrears from enterprises in a centralized manner.

Housing Provident Fund

In accordance with the Regulations on the Management of Housing Funds (《住房公積金管理條例》) which was promulgated by the State Council on April 3, 1999 and last amended on March 24, 2019, employers shall register at the competent managing center for housing provident funds and upon the examination by such managing center of housing provident funds, these enterprises shall complete procedures for opening an account at the relevant bank for the deposit of employees' housing provident funds. Employers are also required to pay and deposit housing provident funds on behalf of their employees in full and in a timely manner. With respect to employers who violate the above regulations and fail to complete housing provident fund contribution registration or open housing provident fund accounts for their employees, such employers shall be ordered by the competent managing center of housing provident funds to complete such procedures within prescribed period. Those who fail to complete such procedures within the prescribed period shall be subject to a fine from RMB10,000 to RMB50,000. For overdue or underpayment of housing provident fund in violation of the provisions of such regulations, the managing center of housing provident funds shall order relevant employers to make contribution within prescribed period, failing which an application may be made to a people's court for compulsory enforcement.

Laws and Regulations Relating to Foreign Investment

On March 15, 2019, the Foreign Investment Law of the PRC (《中華人民共和國外商投資法》) (the "Foreign Investment Law") was promulgated by the NPC. The Foreign Investment Law took effect on January 1, 2020, and the Sino-Foreign Equity Joint Ventures Law of the PRC (《中華人民共和國中外合資經營企業法》), the Wholly Foreign-Owned Enterprises Law of the PRC (《中華人民共和國外資企業法》) and the Sino-Foreign Cooperative Joint Ventures Law of the PRC (《中華人民共和國中外合作經營企業法》) were abolished at the same time. Since then, the Foreign Investment Law has become the basic law regulating foreign-invested enterprises wholly or partially invested by foreign investors, while the organization form, institutional framework and standard of conduct of foreign-invested enterprises shall be subject to the provisions of the Company Law of the PRC (《中華人民共和國公司法》) and other laws.

The PRC implements a pre-access national treatment plus negative list management system for foreign investment, which means that foreign investors and their investments are given treatment no less favorable than that accorded to domestic investors and their investments at the stage of investment access; the so-called negative list refers to the special access management measures that the State has stipulated to be applied to foreign investment in specific areas, and the State grants national treatment to foreign investment that is not on the negative list.

The Catalog of Industries Encouraging Foreign Investment (2022 Version) (《鼓勵外商投資產業目錄(2022年版)》) issued by the NDRC and the MOFCOM on October 26, 2022 (effective January 1, 2023), and the Special Administrative Measures for Foreign Investment Entry (Negative List) (2024 Version) (《外商投資准入特別管理措施(負面清單)(2024年版)》) issued by the NDRC and the MOFCOM on September 26, 2024 (the "Negative List"), which became effective on November 1, 2024) together constitute the catalog of industries encouraging foreign investment and the special administrative measures for foreign investment access to industries restricted or prohibited for foreign investment, of which the Negative List has uniformly listed the special administrative measures in respect of foreign investment access, such as shareholding requirements and senior management requirements. Fields outside the Negative List are managed in accordance with the principle of consistency between domestic and foreign investments. Domestic enterprises

engaging in businesses in the areas of investment prohibited by the Negative List that issue shares abroad and list them for trading shall be subject to the examination and consent of the relevant competent state authorities. Foreign investors shall not participate in the operation and management of the enterprise, and the proportion of their shareholding shall be implemented with reference to the relevant provisions on the management of domestic securities investment by foreign investors.

While strengthening investment promotion and protection, the Foreign Investment Law further regulates foreign investment management and proposes the establishment of a foreign investment information reporting system that replaces the original foreign investment enterprise approval and filing system of the MOFCOM. The foreign investment information reporting shall be subject to the Foreign Investment Information Reporting Method (《外商投資信息報告辦法》) jointly developed by the MOFCOM and the SAMR, which came into effect on January 1, 2020. According to the Foreign Investment Information Reporting Method, foreign investors who directly or indirectly carry out investment activities in China shall submit investment information to the competent commercial department through the enterprise registration system and the National Enterprise Credit Information Publicity System, and the reporting methods include initial reports, change reports, cancelation reports, and annual reports.

Laws and Regulations Relating to Overseas Securities Offering and Listing

The Securities Law of the PRC (《中華人民共和國證券法》) (the "PRC Securities Law") which was latest revised on December 28, 2019 and came into effect on March 1, 2020, is divided into 14 chapters and 226 articles, regulating, among other things, the issue and trading of securities, the listing of securities and takeovers of listed companies. Article 224 of the PRC Securities Law provides that domestic enterprises which, directly or indirectly, issue securities or list and trade their securities outside the PRC shall comply with the relevant regulations of the State Council. Currently, the issue and trading of foreign issued securities (including shares) are principally governed by the regulations and rules promulgated by the State Council and the CSRC.

On February 17, 2023, the CSRC issued 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》) (the "Overseas Listing Measures") and five relevant guidelines, which took effect on March 31, 2023. The Overseas Listing Measures comprehensively reformed the regulatory regime for overseas offering and listing of PRC domestic companies' securities, either directly or indirectly, into a filing-based system. According to the Overseas Listing Measures, the PRC domestic companies that seek to offer and list securities in overseas markets, either in direct or indirect means, are required to fulfill the filing procedure with the CSRC and report relevant information. Direct overseas offering and listing by domestic companies refers to such overseas offering and listing by a joint-stock company incorporated domestically. Indirect overseas offering and listing by domestic companies refers to such overseas offering and listing by a company in the name of an overseas incorporated entity, whereas the company's major business operations are located domestically and such offering and listing is based on the underlying equity, assets, earnings or other similar rights of a domestic company.

On February 24, 2023, CSRC and other three relevant government authorities issued the Provisions on Strengthening Confidentiality and Archives Administration of Overseas Securities Offering and Listing by Domestic Companies (《關於加強境內企業境外發行證券和上市相關保密和檔案管理工作的規定》) (the "Confidentiality and Archives Administration Provisions"), which took effect on March 31, 2023. According to the Confidentiality and Archives Administration Provisions, a domestic company that seeks overseas offering and listing shall strictly abide by applicable PRC laws and regulations, enhance legal awareness of keeping state secrets and strengthening archives administration, institute a sound confidentiality and archives administration system, and take necessary measures to fulfill confidentiality and archives administration obligations. The "domestic company" may refer to either one of the following entities: a joint-stock company incorporated domestically that conducts direct overseas offering and listing, or a domestic operating entity of a company that conducts indirect overseas offering and listing.