

REGULATORY OVERVIEW

OVERVIEW OF LAWS AND REGULATIONS IN THE PRC

Our business is primarily in the PRC and is subject to PRC laws and regulations and extensive government supervision. This section sets out a summary of the main laws, regulations, and government supervision relevant to our business in the PRC, but in no event should it be considered as a full account or a comprehensive summary of laws and regulations relating to our Group’s operation and business.

MAJOR REGULATORY AUTHORITIES

The major regulatory authorities of China’s pharmaceutical industry include the NMPA, the National Health Commission (國家衛生健康委員會) (“NHC”) and the National Healthcare Security Administration (國家醫療保障局) (“NHSA”).

NMPA

The NMPA is mainly responsible for the management of safety supervision, standards, registration, quality, post-marketing risks, and supervision and inspection of drugs, cosmetics and medical devices, as well as the supervision of external exchange and cooperation and guidance for the work of local drug supervision and management departments. In March 2018, the State Council Institutional Reform Proposal (國務院機構改革方案) passed by the First Session of the Thirteenth National People’s Congress (“NPC”) decided the China Food and Drug Administration (國家食品藥品監督管理總局) (“CFDA”) shall cease to exist, and the NMPA was established to undertake the duties of the former CFDA.

NHC

The NHC is mainly responsible for formulating national health policies, coordinating to deepen the reform of the medical and health system, organizing the formulation of a national essential drugs system, and supervising and managing medical services.

NHSA

The NHSA is mainly responsible for formulating and organizing the implementation of policies, plans and standards for medical insurance, maternity insurance, medical aid and other medical security systems, organizing the formulation and adjustment of prices and charging standards for drugs and medical services, and formulating and supervising the implementation of the bidding and procurement policies for drugs and medical consumables.

MAJOR REGULATORY LAWS AND REGULATIONS

Our business in the PRC is subject to a variety of laws, rules and regulations which relate to R&D, registration, production, sales, labor, intellectual property rights, taxation and other areas of drugs.

Laws and Regulations in relation to the Pharmaceutical Industry

Drug Administration Laws and Regulations

The Drug Administration Law of the PRC (《中華人民共和國藥品管理法》) (the “**Drug Administration Law**”), which was promulgated by the NPCSC and last amended on August 26, 2019 and took effect on December 1, 2019, as well as the Implementing Rules for the Drug Administration Law of the PRC (《中華人民共和國藥品管理法實施條例》), with the current effective version in force since May 15, 2026 together establish the legal framework for the administration of drugs, which govern the R&D, manufacturing, distribution and use of drugs in the PRC and the supervision and administration activities thereof.

Non-Clinical Study and Animal Testing

According to the Drug Administration Law, drug research and development activities shall comply with the Good Laboratory Practice for Non-Clinical Studies (《藥物非臨床研究質量管理規範》) (“GLP”), and the entire drug research and development process shall continuously comply with statutory requirements. The GLP, which was promulgated by the former CFDA on August 6, 2003 and amended on July 27, 2017, prescribes quality management requirements concerning the operation and management of non-clinical safety evaluation research institutions and the entire process of non-clinical safety evaluation research project trial protocol design, organization and implementation, execution, inspection, record-keeping, archiving and reporting.

According to the Measures for Administration of Certification of the Good Laboratory Practice for Non-clinical Laboratory Studies (《藥物非臨床研究質量管理規範認證管理辦法》) promulgated by the NMPA on January 19, 2023 which took effect on July 1, 2023, institutions that intend to conduct non-clinical safety evaluation studies in the PRC for drug registration applications are required to

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obtain GLP certification. The NMPA oversees national GLP certification, while provincial drug authorities supervise local non-clinical safety study institutions. The GLP Certificate will be issued by the NMPA with its approval if the relevant requirements for the GLP are satisfied by the applicant. The valid period for the GLP certificate lasts for 5 years. Any entity without such certification must engage a qualified third party to conduct such non-clinical studies regulated under relevant laws and regulations.

According to the Administrative Regulations on Experimental Animals (《實驗動物管理條例》), as well as the Administrative Measures on Good Practice of Experimental Animals (《實驗動物質量管理辦法》), and the Administrative Measures on the Certificate for Experimental Animals (Trial) (《實驗動物許可證管理辦法(試行)》), using and breeding experimental animals shall be subject to certain rules, and performing experiments on animals requires a Certificate for Use of Experimental Animals. Any entity without such certification must engage a qualified third party to conduct such non-clinical studies regulated under relevant laws and regulations.

Drug Clinical Trial

According to the Provisions for Drug Registration (《藥品註冊管理辦法》), which was promulgated by State Administration for Market Regulation (國家市場監督管理總局) (“SAMR”) on January 22, 2020, and took effect on July 1, 2020, the drug clinical trial refers to the drug research carried out in human body to determine the safety and effectiveness of drugs for the purpose of drug marketing and registration, which shall be carried out in the drug clinical trial institutions that have the corresponding conditions and are filed in accordance with the provisions. All activities related to drug clinical trials shall comply with the Good Practice for Clinical Trials of Drugs (“GCP”) (藥物臨床試驗質量管理規範), which was promulgated by the NMPA and the NHC on April 23, 2020, and amended on May 21, 2026, scheduled to take effect on September 1, 2026.

According to the Provisions for Drug Registration, drug clinical trials are divided into phase I clinical trials, phase II clinical trials, phase III clinical trials, phase IV clinical trials and bioequivalence trials. Having completed the pharmaceutical, pharmacological and toxicological studies supporting drug clinical trials, to file a drug clinical trial application, the applicant shall submit relevant study data as per requirements on application dossiers. The application shall be accepted when the application dossiers pass preliminary review. The CDE shall organize pharmaceutical, medical and other technical personnel to evaluate the drug clinical trial application accepted. The decision on whether to approve the drug clinical trial shall be made within 60 days upon acceptance, and the applicant shall be informed of the review and approval result via the CDE website; where no notice has been issued within the specified timeline, the application shall be deemed approved, and the applicant may carry out the drug clinical trial as per the submitted protocol. To carry out a bioequivalence trial, the applicant shall file the bioequivalence trial at the CDE website as required before carrying out relevant studies as per the filed protocol. Drug clinical trials shall be subject to review and approval by an ethics committee. When the drug clinical trial application is approved, the sponsor shall formulate the corresponding drug clinical trial protocols and have them reviewed and approved by the ethics committee before carrying out the subsequent phases of clinical trial, and submit the corresponding protocols and supporting dossiers on the CDE website.

According to the GCP, drug clinical trials shall comply with the principles of the World Medical Association’s Declaration of Helsinki (世界醫學會《赫爾辛基宣言》) and relevant ethical requirements. The rights, safety, and well-being of trial subjects shall be the primary considerations, taking precedence over interests of science and society. Ethical review and informed consent are essential measures to protect the rights and interests of trial subjects.

International Multi-center Clinical Trials

The Notice on Issuing the International Multi-Center Clinical Trial Guidelines (Trial) (《關於發佈國際多中心藥物臨床試驗指南(試行)的通告》), which was promulgated by the former CFDA on January 30, 2015 and took effect on March 1, 2015, provides guidance for, regulates and supervises the application, implementation and management of international multi-center clinical trials in China, and encourages Chinese applicants to conduct international multi-center drug clinical trials as a way to speed up the internationalization of drug research and development in the PRC. Where the applicants plan to implement the international multi-center drug clinical trials in China, they shall comply with relevant laws and regulations, observe the GCP of the PRC, make reference to universal international principles such as the International Council for Harmonisation of Technical Requirements for Pharmaceuticals for Human Use Guideline for Good Clinical Practice (人用藥品註冊技術國際協調會議臨床試驗品質管制規範) (“ICH-GCP”), and abide by the laws and regulations of relevant countries.

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Drug Registration

According to the Drug Administration Law, drugs to be marketed in the territory of the PRC shall be subject to the approval by the drug regulatory department under the State Council to obtain the Drug Registration Certificate (藥品註冊證書), except for Chinese medicinal materials (中藥材) and prepared slices of Chinese crude drugs (中藥飲片) which are not subject to review and approval administration. To apply for drug registration, data, documents, and samples that are true, adequate, and credible shall be provided to prove the safety, efficacy, and quality management of the drug.

According to the Provisions for Drug Registration, the NMPA is in charge of the administration of drug registration nationwide and is responsible for establishing the systems, policies and practices for drug registration administration, and for organizing review and approval of drug registration and relevant supervision and administration in accordance with the law. The CDE is responsible for evaluating drug clinical trial applications, drug marketing authorization applications, supplementary applications, and registration renewal applications of drugs manufactured overseas, etc. The National Institutes for Food and Drug Control (NIFDC) (中國食品藥品檢定研究院), the Chinese Pharmacopoeia Commission (CPC) (國家藥典委員會), the Center for Food and Drug Inspection of NMPA (CFDI) (國家藥品監督管理局食品藥品審核查驗中心), the Center for Drug Reevaluation of NMPA (CDR) (國家藥品監督管理局藥品評價中心), the Center for Administrative Services and Complaints & Reports of NMPA (國家藥品監督管理局行政事項受理服務和投訴舉報中心), the Center for Information of NMPA (NMPAIC) (國家藥品監督管理局資訊中心), and other specialized technical institutions for drugs shall undertake such work as drug registration testing, generic name approval, inspection, monitoring and evaluation, making and delivery of certificates, as well as establishing and managing the corresponding information system needed for the administration of drug registration in accordance with the law.

Drug-Device Combination Products

According to the Announcement on Relevant Matters Concerning the Registration of Drug-Device Combination Products (《關於藥械組合產品註冊有關事宜的通告》), which was promulgated by the NMPA and on 23 July 2021 and implemented on the same day, drug-device combination products where the pharmaceutical effect is primary shall be registered in accordance with the relevant requirements for pharmaceuticals; drug-device combination products where the medical device effect is primary shall be registered in accordance with the relevant requirements for medical devices. The applicant shall fully assess the attributes of the drug-device combination product for which it intends to apply for registration. Where the regulatory classification of a drug-device combination product cannot be determined, the applicant shall apply to the Center for Medical Device Standard Administration of the NMPA (國家藥品監督管理局醫療器械標準管理中心) to determine the classification of the drug-device combination product prior to registration. The NMPA published an Interpretation of the Notice on Registration Matters for Drug-Device Combination Products (《〈關於藥械組合產品註冊有關事宜的通告〉解讀》) on July 27, 2021, which stipulates that if the product's regulatory attribute can be ascertained by referencing previously registered combination products or published property determination outcomes, the applicant may proceed with registration under the determined classification.

Prioritized Review and Approval for Registration of Drugs

On July 7, 2020, the NMPA promulgated the Working Procedures for Review of Breakthrough Therapy Drugs (Interim) (《突破性治療藥物審評工作程式(試行)》), the Working Procedures for Review and Approval of Applications for Conditional Approval of Drug Marketing (Interim) and Working Procedures for Priority Review (《藥品附條件批准上市申請審評審批工作程式(試行)》) and the Approval of Drug Marketing Authorization (Interim) (《藥品上市許可優先審評審批工作程式(試行)》) to encourage the research and innovation of new drugs and to standardize the review and approval system of drugs.

According to the Approval of Drug Marketing Authorization (Interim), at the time of application for drug marketing authorization, drugs with significant clinical value in the following categories may apply for the prioritized review and approval procedure:

- (i) innovative drugs and improved new drugs addressing clinically needed shortage drugs, as well as for the prevention and treatment of major infectious diseases, rare diseases, and other conditions;
- (ii) new varieties, dosage forms, and specifications of pediatric drugs that align with children's physiological characteristics;
- (iii) vaccines urgently needed for disease prevention and control, as well as innovative vaccines;
- (iv) drugs included in the Breakthrough Therapy Drugs program;
- (v) drugs eligible for conditional approval;

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- (vi) other circumstances specified by the NMPA for prioritized review and approval.

Drug Marketing Authorization Holder System

According to the Drug Administration Law, the marketing authorization holder system is implemented in the PRC for drug administration. The drug marketing authorization holder refers to an enterprise or drug research institution that has obtained the drug registration certificate, which is legally responsible for the safety, efficacy, and quality control of the drug throughout the entire process of research, development, production, distribution, and utilization processes in accordance with laws. The drug marketing authorization holder bears overall responsibility for non-clinical study, clinical trial, manufacturing and business operation, post-market launch study, monitoring, reporting and handling of adverse reactions of the pharmaceuticals. The legal representative and the key person-in-charge of a drug marketing authorization holder shall be fully responsible for the quality of drugs.

The drug marketing authorization holders may produce drugs by itself or entrust drug manufacturers with the production of such drugs. If the drug marketing authorization holder produce drugs by itself, it shall obtain the drug production license in accordance with the provisions of the Drug Administration Law. The production of blood products, narcotic drugs, psychotropic substances, toxic drugs for medical use, and drug precursors are in principle not allowed to be produced through entrustment unless otherwise specified by the drug regulatory department of the State Council.

The drug marketing authorization holders may sell drugs covered by its drug registration certificate on its own or through entrusting qualified drug operating enterprises. If the drug marketing authorization holders engages in drug retailing, it shall obtain the drug supply license.

With the approval of the drug regulatory department of the State Council, the drug marketing authorization holder may transfer the drug marketing authorization. The transferee shall possess the capabilities in quality management, risk prevention and control, and liability compensation to ensure the drug's safety, efficacy, and quality control, and shall fulfill the obligations of the marketing authorization holders.

Drug Manufacturing

According to the Drug Administration Law and the Provisions for the Supervision and Administration of Drug Manufacturing (《藥品生產監督管理辦法》) promulgated by the SAMR on January 22, 2020 and took effect on July 1, 2020, the undertaking of drug manufacturing shall obtain a Drug Manufacturing License (藥品生產許可證) granted by the drug regulatory authority of the people's government of the province, autonomous region, or municipality directly under the central government at the place where the enterprise is located. No drugs may be manufactured without the license.

The Drug Manufacturing License has a validity period of five years upon issuance. Undertaking of drug manufacturing shall be subject to the following requirements: (i) having legally qualified pharmaceutical professionals, engineering professionals and the necessary technical workers, a legal representative, principal of the company, person in charge of production management (“**production responsible person**”), the persons in charge of quality management (“**quality responsible person**”), qualified persons and other relevant personnel complied with the conditions stipulated in the Drug Administration Law or the Vaccine Administration Law; (ii) having the premises, facilities, equipment and hygienic environment required for drug manufacturing; (iii) having the institutions and personnel capable of quality control and testing for the drugs to be manufactured; (iv) having instruments and equipment essential for quality management and testing for drugs to be manufactured; (v) having rules and regulations to ensure the quality of drugs, and in compliance with the requirements of the Good Manufacturing Practice for Pharmaceutical Products. In addition, pursuant to the Announcement of the National Medical Products Administration on the Issuance of the Appendices on Pharmaceutical Excipients and Pharmaceutical Packaging Materials to the Good Manufacturing Practice for Pharmaceutical Products (2010 Revision) — drug manufacturers shall, from January 1, 2026, ensure that the production and use of pharmaceutical excipients and pharmaceutical packaging materials comply with the quality management requirements set forth therein, including establishing a sound quality management system, strict change control, supplier audit, and quality review procedures.

A drug marketing authorization holder entrusting others for manufacturing drug products shall comply with the conditions specified in items (i), (iii) and (v) above, sign an entrustment agreement and quality agreement with a drug manufacturer that meets relevant conditions, submit related agreements and application documents of the actual manufacturing site to the drug regulatory department of the province, autonomous region or municipality directly under the central government where the drug marketing authorization holder is located and apply for the Drug Manufacturing Certificate according to these Provisions.

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Drug Distribution

According to the Drug Administration Law, the undertaking of drug wholesale is subject to approval of the local drug regulatory department of the people’s government of the province, autonomous region, or municipality directly under the central government and requires a Drug Distribution Certificate (藥品經營許可證). The undertaking of drug retail is subject to approval of the drug regulatory department of the local people’s government at or above the county level and requires the said certificate. No drugs may be distributed without the certificate.

According to the Measures for the Supervision and Administration of the Quality of Drug Distribution and Use (《藥品經營和使用質量監督管理辦法》) promulgated by the SAMR on September 27, 2023 which took effect on January 1, 2024, any entity engaged in drug distribution shall comply with the GSP, and shall sell and store drugs at the address approved by the drug regulatory department, in accordance with the business model and scope specified in the Drug Supply Certificate. It must ensure that the entire drug distribution process complies with statutory requirements. Further, it shall establish a quality management system that covers the entire drug supply process. All records, including purchasing and sales, storage conditions, transportation processes, and quality control, shall be complete and accurate. Falsification or alteration of records is prohibited.

Drug Post-marketing Changes

According to the Measures for the Administration of Drug Post-marketing Changes (Trial) (《藥品上市後變更管理辦法(試行)》) promulgated by the NMPA on January 12, 2021, the categories of changes include changes in marketing authorization holder, changes in drug manufacturing site, and changes to other drug registration matters. Based on the potential impact level of the changes on drug safety, efficacy, and quality controllability, changes are classified into approval-type changes, filing-type changes, and reporting-type changes, implementing hierarchical and categorized management.

OTHER LAWS AND REGULATIONS AFFECTING OUR BUSINESS ACTIVITIES IN THE PRC

Laws and Regulations on Corporation and Foreign Investment

The establishment, operation and management of corporate entities in the PRC are governed by the PRC Company Law (《中華人民共和國公司法》), which was promulgated by the NPCSC on December 29, 1993 and came into effect on July 1, 1994, and was last amended on December 29, 2023 and became effective on July 1, 2024.

According to the Foreign Investment Law of the PRC (《中華人民共和國外商投資法》) (“**Foreign Investment Law**”) became effective on January 1, 2020, China has adopted a system of national treatment which includes a negative list with respect to foreign investment administration. The national treatment refers to granting to foreign investors and their investments, in the stage of investment access, the treatment no less favorable than that granted to domestic investors and their investments. The negative list will be issued, amended or released upon approval by the State Council, from time to time. The Special Administrative Measures (Negative List) for the Access of Foreign Investment (2024 Version) (《外商投資准入特別管理措施(負面清單) (2024年版)》) (“**Negative List**”), which was promulgated by the National Development and Reform Commission (“**NDRC**”) and the MOFCOM on September 6, 2024 and became effective on November 1, 2024, and the Catalog of Industries for Encouraging Foreign Investment (2025 Version) (《鼓勵外商投資產業目錄(2025年版)》) (“**Encouraging Catalog**”), which was promulgated by the NDRC and the MOFCOM on December 15, 2025 and became effective on February 1, 2026, listed the categories of encouraged, restricted, and prohibited industries. Any industry not included in the Negative List shall be administered under the principle of equal treatment to domestic and foreign investment.

During the Track Record Period and up to the Latest Practicable Date, the business of our Company does not belong to any restricted or prohibited industries listed in the Negative List.

Laws and Regulations on Information Security and Data Privacy

On November 7, 2016, the NPCSC promulgated the Cybersecurity Law of the PRC (《中華人民共和國網絡安全法》) (“**Cybersecurity Law**”), which took effect on June 1, 2017 was last amended on October 28, 2025 and took effect on January 1, 2026. In accordance with the Cybersecurity Law, network operators must comply with applicable laws and regulations and fulfill their obligations to safeguard network security in conducting business and providing services. Network service providers must take technical and other necessary measures as required by laws, regulations and mandatory requirements to safeguard the operation of networks, respond to network security incidents effectively, prevent illegal and criminal activities, and maintain the integrity, confidentiality and usability of network data.

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On August 20, 2021, the NPCSC promulgated the Personal Information Protection Law of the PRC (《中華人民共和國個人信息保護法》), which took effect on November 1, 2021. The Personal Information Protection Law integrates the scattered rules with respect to personal information rights and privacy protection.

On June 10, 2021, the NPCSC promulgated the Data Security Law of the PRC (《中華人民共和國數據安全法》) (“**Data Security Law**”), which took effect on September 1, 2021. In accordance with the Data Security Law, the conduct of data processing activities shall be in compliance with the provisions of laws and administrative regulations, establishing and completing a data security management system for the entire workflow, organizing and conducting data security education and training, adopting corresponding technical measures and other necessary measures to ensure data security, strengthening risk monitoring, taking immediate disposition measures and promptly reporting to relevant authorities when data security incidents occur.

On September 24, 2024, the State Council promulgated the Regulations on Network Data Security Management (《網絡數據安全管理條例》), which took effect on January 1, 2025. The Regulations on Network Data Security Management prescribes several key obligations, including requiring network data handlers to specify the purpose and method of personal information processing, as well as the types of personal information involved, before any personal information is processed. It also clarifies definitions for important data, outlines the obligations of those handling important data, establishes broader contractual requirements for data sharing between data handlers, and introduces a new exemption for regulatory obligations regarding cross-border data transfers. The regulation also provides that network data processors conducting any data processing activities that affect or may affect national security shall undergo national security review in accordance with relevant national regulations.

Laws and Regulations on Customs Declaration

Our import and export activities are subject to PRC laws and regulations, including the Customs Law of the PRC (《中華人民共和國海關法》), the Administrative Provisions on the Record-Filing of Customs Declaration Entities of the PRC (《中華人民共和國海關報關單位備案管理規定》), the Foreign Trade Law of the PRC (《中華人民共和國對外貿易法》) and the Regulations on the Administration of Import and Export of Goods (《中華人民共和國貨物進出口管理條例》).

Under these laws and regulations, all transports, goods and articles entering or exiting the PRC must pass through a designated customs office. Customs declaration and duty payment may be handled by the consignees or consignors of imported and exported goods, or their entrusted customs clearing enterprises. Such entities must file records with customs and, where applicable, complete foreign trade dealer filing, with applicants required to have market entity status. Unless otherwise provided by law, goods may be freely imported and exported. Import and export goods are classified as prohibited, restricted, or freely permitted: prohibited goods may not be traded; restricted goods may be subject to quotas, licensing, or tariff-rate quota administration; and freely permitted goods require an automatic import or export license for customs clearance.

Laws and Regulations on Work Safety

Pursuant to the Work Safety Law of the PRC (《中華人民共和國安全生產法》) (“**Work Safety Law**”), promulgated by the NPCSC on June 29, 2002 and last amended on June 10, 2021, which took effect on September 1, 2021, entities shall strengthen the management, establish and improve responsibility systems and policies, improve conditions, strengthen the standardized and information technology development of work safety and improve the production level to ensure their production safety. The principal persons in charge of the production and operation entities are fully responsible for the production safety of their entities. Violation of the Work Safety Law may result in fines and penalties, suspension of operation, an order to cease operation, or even criminal liability in severe cases.

Laws and Regulations on Environmental 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 NPCSC on December 26, 1989 and amended on April 24, 2014, which became effective on January 1, 2015, any entity which releases or will release pollutants during the 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.

On March 12, 2026, the NPCSC promulgated the Ecological Environment Code of the PRC (《中華人民共和國生態環境法典》), which is scheduled to come into effect on August 15, 2026, and will repeal the current Environmental Protection Law of the PRC. As a comprehensive and fundamental legal framework for ecological and environmental protection, the Ecological Environment Code

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systematically integrates existing environmental laws and regulations. It strengthens the legal mechanisms for environmental impact assessments, pollution control, and the promotion of green and low-carbon transformation.

Pursuant to the Environmental Impact Assessment of the PRC (《中華人民共和國環境影響評價法》) promulgated by the NPCSC on October 28, 2002, and last amended and took effect on December 29, 2018, for construction projects that have an impact on the environment, entities shall prepare an environmental impact report, report form or registration form in accordance with the severity of the impact that the project may have on the environment.

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, which became effective on March 1, 2021, entities that generate or release significant volumes of pollutants, or which cause a substantial environmental impact, shall apply for pollutant discharge permits. Entities that generate and release only minor volumes of pollutants and cause a limited environmental impact, shall fill out pollutant discharge registration forms, and are not required to apply for a pollutant discharge permit.

Laws and Regulations on Employment and Social Welfare

Employment

The major PRC laws and regulations that govern employment relationships are the PRC Labor Law (《中華人民共和國勞動法》) (“**Labor Law**”), the PRC Labor Contract Law (《中華人民共和國勞動合同法》) (“**Labor Contract Law**”) and its implementation regulations, which impose stringent requirements on the employers in relation to entering into employment contracts, hiring of part-time employees and dismissal of employees.

According to the Interpretation (II) of the Supreme People’s Court on Issues Concerning the Application of Law in the Trial of Labor Dispute Cases (《最高人民法院關於審理勞動爭議案件適用法律問題的解釋(二)》), which was promulgated by the Supreme People’s Court on July 31, 2025, and came into force on September 1, 2025, where an employer and an employee agree, or an employee undertakes to the employer, that social insurance premiums need not be paid, the people’s court shall determine such agreement or undertaking to be invalid. Where an employer fails to pay social insurance premiums in accordance with the law, and an employee claims to terminate the labor contract and demand the employer to pay economic compensation in accordance with the Labor Contract Law, the people’s court shall support such claim in accordance with the law. Under the circumstances specified in the preceding paragraph, if the employer has paid the social insurance premiums retroactively in accordance with the law and then claims that the employee shall return the compensation for social insurance premiums already paid, the people’s court shall support such claim in accordance with the law.

Social Insurance

The PRC Social Insurance Law (《中華人民共和國社會保險法》) (“**Social Insurance Law**”) was issued by the NPCSC on October 28, 2010 and last amended and took effect on December 29, 2018, and has established social insurance systems of basic pension insurance, basic medical insurance, work-related injury insurance, unemployment insurance and maternity insurance. According to the Social Insurance Law and the Provisional Regulations on Collection and Payment of Social Insurance Premiums (《社會保險費徵繳暫行條例》) promulgated by the State Council on January 22, 1999 and last amended and implemented on March 24, 2019, enterprises shall register for social insurance with local social insurance and pay or withhold relevant social insurance for or on behalf of their employees. Any employer who fails to make social insurance contributions may be ordered to rectify the non-compliance and pay the required contributions within a prescribed time limit and be subject to a late fee. If the employer still fails to rectify the failure to make the relevant contributions within the prescribed time, it may be subject to a fine ranging from one to three times the amount overdue.

Housing Provident Fund

Pursuant to the Regulations on Management of Housing Provident Fund (《住房公積金管理條例》), which was promulgated by the State Council on April 3, 1999 and last amended and took effect on March 24, 2019, employers in China shall provide their employees with housing provident fund. Employers who fail to contribute to the above housing provident funds may be ordered to make full payment within a prescribed time period by the housing provident fund management center. If an employer fails to make the payment towards the housing provident fund within a prescribed time limit, an application may be made to the people’s court for enforcement.

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Laws and Regulations on the Management of Lease Housing

Pursuant to the Law on Administration of Urban Real Estate of the PRC (《中華人民共和國城市房地產管理法》) and the Administrative Measures on Leasing of Commodity Housing (《商品房屋租賃管理辦法》), when leasing premises, the lessor and lessee are required to enter into a written lease contract. Both the lessor and the lessee shall complete property leasing registration and filing formalities within 30 days from the execution of the property lease contract with the real estate administration department where the leased property is located. If the lessor and lessee fail to go through the registration and filing procedures, both lessor and lessee may be subject to fines.

Laws and Regulations on Intellectual Property Rights

Trademark

The Trademark Law of the PRC (《中華人民共和國商標法》) was last amended on June 26, 2026, with scheduled implementation from January 1, 2027. The Regulations for the Implementation of the Trademark Law of the PRC (《中華人民共和國商標法實施條例》) were last amended on April 29, 2014, with implementation from May 1, 2014. According to these laws and regulations, the validity period of a registered trademark is 10 years from the date of approval. Each renewal extends the validity period for 10 years, starting from the day following the expiration of the last validity period.

Patent

The Patent Law of the PRC (《中華人民共和國專利法》) was last amended on October 17, 2020, with implementation from June 1, 2021. The Detailed Rules for the Implementation of the Patent Law of the PRC (《中華人民共和國專利法實施細則》) last amended on December 11, 2023, with implementation from January 20, 2024. According to these laws, regulations and detailed rules, patents in China are categorized into three types: invention patents, utility model patents and design patents. The term of an invention patent right is 20 years, the term of a utility model patent is 10 years, and the term of a design patent is 15 years, all of which are calculated from the filing date.

Copyright

The Copyright Law of the PRC (《中華人民共和國著作權法》) (the “**Copyright Law**”) was last amended on November 11, 2020, with implementation from June 1, 2021. According to the Copyright Law, Chinese citizens, legal entities or other organizations own copyright in their copyrightable works (whether published or not), including ingenious intellectual achievements in the fields of literature, art and science that are original and can be expressed in certain forms.

Domain Name

The Internet Domain Name Management Measures (《互聯網域名管理辦法》) were issued on August 24, 2017, and implemented on November 1, 2017. According to these management measures, domain name registration is conducted through domain name root servers and their operating institutions, domain name registration management institutions and domain name registration service institutions established in accordance with the relevant regulations.

Laws and Regulations on Foreign Exchange

Pursuant to the Foreign Exchange Administrative Regulations of the PRC (《中華人民共和國外匯管理條例》) (the “**Foreign Exchange Administration Regulations**”), which was promulgated by the State Council on January 29, 1996, effective on April 1, 1996 and last amended on August 5, 2008, all international payments and transfers were classified into current items and capital items. Most of the current items are not subject to the approval of foreign exchange administration agencies, while capital items are subject to such approval. The PRC will not impose any restriction on international current payments and transfers.

Laws and Regulations on Taxation

Enterprise Income Tax (“EIT”)

According to the Enterprise Income Tax Law of the PRC (《中華人民共和國企業所得稅法》) (“**EIT Law**”) which was promulgated by the NPCSC on March 16, 2007 and last amended on December 29, 2018, a unified income tax rate of 25% will be applied to foreign investment and foreign enterprises which have set up institutions or facilities in the PRC as well as PRC enterprises. Under the EIT Law, enterprises established outside of China whose “de facto management bodies” are located in China are considered “resident enterprises” and will generally be subject to the unified 25% enterprise income tax rate as to their global income.

According to the Administrative Measures for the Determination of High and New Tech Enterprises (《高新技術企業認定管理辦法》) issued by the Ministry of Science and Technology (科學技術部), the MOF and the STA on April 14, 2008 and amended on January 29, 2016 and implemented on

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January 1, 2016, enterprises that are recognized as high and new technology enterprises are entitled to enjoy a preferential EIT rate of 15%, under which the validity period of the high and new technology enterprise qualification shall be three years from the date of issuance of the certificate.

Value-Added Tax (“VAT”)

According to the Provisional Regulations on Value-Added Tax of the PRC (《中華人民共和國增值稅暫行條例》) (“**VAT Provisional Regulations**”) the Notice on the Adjustment of Value-added Tax Rates (《財政部、國家稅務總局關於調整增值稅稅率的通知》) (Cai Shui [2018] No. 32), and the Announcement on Relevant Policies for Deepening the Value-added Tax Reform (《關於深化增值稅改革有關政策的公告》), the applicable value-added tax rates for general taxpayers are 13%, 9% and 6% respectively, and the applicable value-added tax rate for small-scale taxpayers is 3%.

According to Value-Added Tax Law of the PRC (《中華人民共和國增值稅法》) and its implementing regulations, which became effective on January 1, 2026 and replace the Provisional Regulations on Value-Added Tax of the PRC, entities and individuals that sell goods, services, intangible assets, real estate, and import goods within the territory of China are regarded as value-added tax payers and shall pay value-added tax in accordance with said Law. The term “selling goods, services, intangible assets, and real estate” refers to the transfer of ownership of goods and real estate for consideration, the provision of services, and the transfer of ownership or the right to use intangible assets. The value-added tax rates are set at 13%, 9%, 6%, and 0%, depending on the nature of the transactions. The tax rate applicable under the simplified tax calculation method is 3%.

OTHER LAWS AND REGULATIONS THAT MAY AFFECT OUR BUSINESS ACTIVITIES IN THE U.S.

The U.S. BioSecure Act

Section 851 of the National Defense Authorization Act for Fiscal Year 2026 (the “**BioSecure Act**”) prohibits U.S. executive agencies from from: (i) procuring biotechnology equipment or services from a “biotechnology company of concern”; and (ii) entering into, extending or renewing federal contracts with any entity that uses the biotechnology equipment or services of a “biotechnology company of concern” in the performance of such contracts. As confirmed by our U.S. legal advisors, (i) none of the members of our Group has been designated as a “biotechnology company of concern” during the Track Record Period and up to the Latest Practicable Date; (ii) none of the members of our Group has entered into any contract, procurement arrangement, service arrangement or other business relationship with any U.S. federal government agency during the Track Record Period and up to June 30, 2026 (being the latest practicable date for preparing the list of customers, suppliers, third-party service providers or other collaborating partners); (iii) none of our five largest customers in each year during the Track Record Period and up to June 30, 2026 is a U.S. federal contractor or a recipient of U.S. federal funding in connection with the products or services provided by our Group and (iv) none of our customer, supplier, third-party service provider or other collaborating partner during the Track Record Period and up to June 30, 2026 have been designated or identified as a “biotechnology company of concern” under the BioSecure Act framework and any of its predecessor legislative drafts. Accordingly, our U.S. legal advisors are of the view that the BioSecure Act is not applicable to the Group in any material respect during the Track Record Period and up to the Latest Practicable Date, and the BioSecure Act has not had any material impact on the business operations of our Group during the Track Record Period and up to the Latest Practicable Date. Our Group has not been required to suspend, modify or terminate any material customer relationship, supplier relationship, collaboration, product sale, research activity or other business arrangement as a result of the BioSecure Act.

Regulations on Combination Products

The FDA regulates products that comprise two or more different types of regulated components (e.g., a drug and a medical device) as “Combination Products” under section 3.2(e) of Title 21 of the Code of Federal Regulations.

A combination product is assigned to a lead FDA Center that will have primary jurisdiction over the product’s pre-market review and regulation. This assignment is based on the FDA’s determination of the product’s Primary Mode of Action (“**PMOA**”), the mode of action expected to make the greatest contribution to the product’s overall intended therapeutic effect.

- Center for Drug Evaluation and Research (“**CDER**”) Lead: If the PMOA is pharmacological and attributable to a drug component, the FDA’s CDER will generally serve as the lead center. In such cases, marketing authorization may involve submission of an NDA or abbreviated NDA (for generics).

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- Center for Devices and Radiological Health (“**CDRH**”) Lead: If the PMOA is primarily mechanical or physical and attributable to a device component, the FDA’s CDRH will generally serve as the lead center. In such cases, marketing authorization may involve submission of a premarket approval (“**PMA**”) application or a premarket notification under Section 510(k) of the Federal Food, Drug, and Cosmetic Act.

Regardless of which FDA Center is assigned to lead PMA, FDA will take into account the questions and considerations associated with each constituent part in its review of the combination product as a whole and its constituent parts.