
REGULATORY OVERVIEW

This section sets forth a summary of the principal laws, rules and regulations in the PRC that are relevant to our business and operation.

MAJOR REGULATORY AUTHORITIES AND RELEVANT ORGANIZATIONS

The operations of the Company in the PRC are mainly supervised and regulated by the following authorities, in addition to the authorities generally administering the companies in the PRC:

National Medical Products Administration (NMPA)

The NMPA, which is subordinate to and supervised by the State Administration of Market Supervision, is the primary regulatory agency responsible for the supervision and management of pharmaceutical products and businesses, formulating laws, regulations, regulatory policies and standards, organizing the drafting of laws and regulations, managing drug standards, organizing the formulation of national pharmacopoeia and other industry standards, establishing classified management system, and supervising the implementation. The NMPA is also in charge of drug registration management, including formulating the registration management system, strictly conducting review and approval the listing, managing post-marketing risks of drugs, undertaking the emergency management of drug safety according to applicable laws, organizing and guiding drug supervision and inspection, investigating and handling illegal activities in drug registration and production according to its statutory responsibilities, and guiding the supervision of local governments on drugs. As an integrated CDMO service provider focusing on the macromolecular biologics market, the company is managed and supervised by NMPA and local drug regulatory authorities.

National Development and Reform Commission (NDRC)

The NDRC is a component of the PRC State Council, which implements the principles, policies, and decision-making arrangements for development and reform. It is mainly responsible for formulating and organizing the implementation of laws, regulations and policies relating to national economic and social development, economic system reform and opening up, which has a great impact on drug research and development, production and service industries. As the Company has established a subsidiary overseas, it is also subject to NDRC's supervision in regard to overseas investment.

Ministry of Commerce of the PRC (MOFCOM)

The MOFCOM is the department in charge of the PRC's domestic & international trade and international economic cooperation. It is responsible for formulating development strategies and policies for domestic and foreign trade and international economic cooperation, drafting laws and regulations and formulating departmental rules and regulations on domestic and foreign trade, foreign investment, outward foreign investment and outward foreign economic cooperation; formulating foreign investment policies and reform programmes and organizing their implementation; and approving, in accordance with the law, the establishment of and changes in foreign-invested enterprises. It also approves the establishment and changes of foreign-invested enterprises in accordance with the law and approves the contracts and articles of association of major foreign-invested projects and major changes as specifically as stipulated by the law.

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General Administration of Customs of the PRC

The General Administration of Customs of the PRC is a directly affiliated institution of the State Council which is responsible for customs supervision, collection and management of import and export duties and other taxes, entry-exit health quarantine, statutory inspection of import and export commodities, national import and export trade and other customs statistics, and comprehensive national anti-smuggling work. The company is subject to the management and supervision of the customs department when importing and exporting goods.

LAWS AND REGULATIONS OF THE PRC

Drug Research and Development & Registration Services

Regulations on Research and Development of New Drugs

Pursuant to the Drug Administration Law of the PRC (《中華人民共和國藥品管理法》, the “**DAL**”) which was promulgated by the Standing Committee of the National People’s Congress (the “**SCNPC**”) on September 20, 1984, became effective on July 1, 1985 and last amended on August 26, 2019, activities engaged in the development, production, operation and use of drugs shall comply with laws, regulations, rules, standards and norms, and ensure that information on the entire process is true, accurate, complete and traceable. Those engaged in drug development activities shall comply with the code of practice for the quality management of non-clinical studies of drugs and code of practice for the quality management of clinical trials of drugs and ensure that the whole process of drug development continuously meets the statutory requirements.

Pursuant to the DAL and the Regulations of Implementation of the Drug Administration Laws of the PRC (《中華人民共和國藥品管理法實施條例》) which was promulgated by the State Council on August 4, 2002, became effective on September 15, 2002 and last amended on January 16, 2026 and took effect as of May 15, 2026, respectively, clinical trials, the production and the import of drugs shall be examined and approved by the drug supervision and administration department of the State Council; The pharmaceutical supervisory and administrative department of the State Council may entrust the pharmaceutical supervisory and administrative departments of the people’s governments of provinces, autonomous regions and municipalities directly under the Central Government to review the development and conditions of the declared drugs, review the application materials in form, and test the trial-produced samples. The pharmaceutical supervisory and administrative department shall supervise and inspect the development, production, marketing and use of drugs according to law.

Drug Manufacturing

Pursuant to the DAL, a drug manufacturing enterprise is required to obtain a Drug Manufacturing License (《藥品生產許可》). According to the Measures for the Supervision and Administration of Pharmaceutical Production (《藥品生產監督管理辦法》), the “**Pharmaceutical Production Measures**”) which was promulgated by CFDA on August 5, 2004 with effect from the same date, and last amended on January 22, 2020 respectively, to produce preparations, active pharmaceutical ingredients (the “**APIs**”), an applicant shall, in the light of Pharmaceutical Production Measures and the requirements of NMPA for application materials, file an application with the medical products administrative department of the province where it is located. The Drug Manufacturing License is valid for five years and shall be renewed at least six months prior to its expiration date upon a re-examination by the relevant authority.

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According to the Announcement of the NMPA on Strengthening Supervision and Administration of Contract Manufacturing of Drugs (《國家藥監局關於加強藥品受託生產監督管理工作的公告》) issued by the NMPA on December 30, 2025 with effect from the same date, an entrusted manufacturer must maintain facilities, personnel and equipment commensurate with the entrusted products. The contract manufacturers of sterile biologics shall possess relevant production experience, including prior commercial manufacturing experience for the same category of products, as determined by the NMPA on a product-specific basis.

Pursuant to the DAL, undertaking drug manufacturing shall comply with drug manufacturing quality management norms, establish and improve upon a drug manufacturing quality management system, ensure the whole drug manufacturing process continuously comply with statutory requirements. The legal representative and the key person-in-charge of a drug manufacturing enterprise shall be fully responsible for the enterprise’s drug manufacturing activities. The Good Manufacturing Practice for Pharmaceutical Products (《藥品生產質量管理規範》, the “GMP”) which was promulgated on December 28, 1992 with effect from the same date and last amended on January 17, 2011, comprises a set of detailed standard guidelines governing the manufacture of the 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.

According to the Announcement on Implementing the Drug Administration Law of PRC (《關於貫徹實施中華人民共和國藥品管理法有關事項的公告》) issued by NMPA on November 29, 2019, the GMP certification was cancelled on December 1, 2019, GMP certification applications would no longer be accepted and GMP certificates would no longer be issued. However, according to the DAL, drug manufacturers still have to abide by GMP, establish and improve GMP system, and ensure that the whole drug production process always conforms to the legal provisions.

On May 24, 2021, NMPA promulgated the Measures for the Administration of Drug Inspection (for Trial Implementation) (《藥品檢查管理辦法(試行)》) (which came into effect on the same day, and was amended on July 19, 2023). The Measures for the Administration of Drug Inspection (for Trial Implementation) stipulate that drug manufacturers applying for a Drug Manufacturing License for the first time shall carry out on-site inspections in accordance with the GMP requirements. For an application for re-issuance of a Drug Manufacturing License, the examination shall be carried out in light of the enterprise’s compliance with laws and regulations on drug administration, GMP and operation of quality system under the principles of risk management, and GMP conformity inspection may be conducted if necessary. The GMP conformity inspection shall be conducted in case of new construction, reconstruction or expansion of a workshop or production line at the original address or at another place.

Drug Registration

Pursuant to the Measures for the Administration of Drug Registration (《藥品註冊管理辦法》) promulgated by State Administration for Market Regulation (the “SAMR”) on January 22, 2020, the Measures shall apply to those engaging in drug development and registration within the territory of the PRC. The term “drug registration” shall mean the activities of drug registration applicants (applicant(s)) applying for clinical trial of drugs, drug marketing authorization, re-registration etc. as well as supplementary applications, in accordance with the statutory procedures and the relevant requirements, and the drug administrative authorities

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conducting examination of safety, effectiveness and quality control etc. based on laws and regulations and the current scientific knowledge, and deciding on approval or non-approval of the applications.

Regulations on Pathogenic Microorganism Laboratories

According to the Regulations on Administration of Bio-safety in Pathogenic Microorganism Laboratories (《病原微生物實驗室生物安全管理條例》), which were promulgated by the PRC State Council on November 12, 2004 and last amended on December 6, 2024 and effective from January 20, 2025, the pathogenic microorganism laboratory is classified into four levels, namely Bio-safety Level 1, 2, 3 and 4 in terms of the national standard on biosafety of the laboratory. A laboratory of Bio-safety Level 1 or 2 shall not conduct laboratory activities related to highly pathogenic microorganisms. The construction, alteration or expansion of a laboratory of Bio-safety Level 1 or 2 shall be reported for the record to competent health authorities. The establisher of a laboratory shall develop a scientific and strict management system, regularly inspect the implementation of the regulations on bio-safety, and regularly inspect, maintain and update the facilities, equipment and materials in the laboratory, to ensure its compliance with the national standards.

Regulations on Product Liability

The Product Quality Law of the PRC (《中華人民共和國產品質量法》) promulgated by the SCNPC on February 22, 1993, became effective on September 1, 1993, and last amended on December 29, 2018, is the principal law governing the supervision and administration of product quality. According to the PRC Product Quality Law, if a defect in a product causes physical injury or damage to property other than the defective product (third party property), the producer shall bear liability for compensation, unless one of the following circumstances can be proven: (i) the product has not been put into circulation; (ii) the defect causing the damage did not exist when the product was put into circulation; (iii) when the product was put into circulation, the level of science and technology at the time was not sufficient to detect the existence of the defect. Where a product is defective due to a mistake made by the seller and such defect causes physical injury or damage to third party property, the seller shall bear liability for compensation. A seller that is unable to identify the producer of a defective product and is also unable to identify the supplier thereof shall bear liability for compensation.

Pursuant to the Civil Code of the PRC or the PRC Civil Code (《中華人民共和國民法典》), which was promulgated by the National People's Congress on May 28, 2020 and effective from January 1, 2021, where a defective product causes damage to others, the manufacturer shall bear tort liability. The infringed may claim compensation from either the manufacturer or the seller of the products. Where the product defect is caused by the producer, the seller may, after paying compensation, claim the same from the producer, and vice versa where the product defect is caused by the fault of the seller. In the event of product defects which endanger the personal and property security of others, the injured party is entitled to request the manufacturer and the seller to assume tortious liability such as cessation of infringement, removal of obstruction, elimination of danger, etc.

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Regulations on Environmental Protection, Health and Safety

Environmental Protection

The Environmental Protection Law of the PRC (《中華人民共和國環境保護法》), promulgated by the SCNPC on December 26, 1989 with effect from the same date and last amended on April 24, 2014, summarizes the rights and responsibilities of environmental protection regulatory authorities. The competent department of environmental protection in the State Council is responsible for formulating national environmental quality standards and pollutant discharge standards, and the people's governments of provinces, autonomous regions and municipalities directly under the Central Government may formulate local standards that are more stringent than the national standards. In this case, the company concerned must comply with national and local standards.

Environmental Impact Assessment

According to the Environmental Impact Assessment Law of the PRC (《中華人民共和國環境影響評價法》), promulgated by the SCNPC on October 28, 2002, became effective on September 1, 2003, amended on July 2, 2016 and December 29, 2018, respectively, and the Regulations on the Administration of Construction Project Environmental Protection (《建設項目環境保護管理條例》), promulgated by the State Council on November 29, 1998 with effect from the same date and last amended on July 16, 2017, for construction projects that have an impact on the environment, entities shall prepare an environmental impact report, environmental impact statement or registration form in accordance with the severity of the impact that the project may have on the environment and submit the relevant document to the competent administrative authority of environmental protection for approval before the commencement of the construction. If the environmental impact assessment documents of a construction project have not been reviewed by the competent administrative authority in accordance with the law or have not been granted approval after the review, the construction entity shall be prohibited from commencing construction works of such project.

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.

Pollution Discharge

Pursuant to 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, and the Measures for the Administration of Pollutant Discharge Permit (《排污許可管理辦法》) promulgated by Ministry of Ecology and Environment on April 1, 2024 (effective on July 1, 2024), enterprises, public institutions and other producers and business operators that are subject to pollutant discharge permit administration in accordance with laws shall apply for and obtain a pollutant discharge permit according to laws and discharge pollutants in accordance with the provisions of such permits. The entities that fail to obtain a pollutant discharge permit shall not discharge any pollutants.

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Pursuant to the Notice of the General Office of the State Council on Issuing the Implementation Plan for the Control of Pollutant Release Permit System (《國務院辦公廳關於印發控制污染物排放許可制實施方案的通知》) promulgated on November 10, 2016 and the Classification Administration List of Pollutant Discharge Permitting for Fixed Pollution Sources (2019) (《固定污染源排污許可分類管理名錄》(2019年版)) promulgated by the MEE on December 20, 2019, the state implements a focused management and a simplification of emission permits based on the pollutant-discharging enterprises and other manufacturing businesses' amount of pollutants, emissions and the extent of environmental damage. The manufacturing of drug substance and manufacturing dose for chemical drugs are industries that shall obtain the discharge permit in accordance with the prescribed time limit.

According to the Regulations on Urban Drainage and Sewage Treatment (《城鎮排水與污水處理條例》), promulgated by the State Council on October 2, 2013 with effect from January 1, 2014, urban entities and individuals shall dispose of sewage through urban drainage facilities covering their geographical area in accordance with the law. Companies or other entities engaging in industrial activities shall apply for a sewage disposal drainage license (《污水排入排水管網許可證》) before disposing sewage into urban drainage facilities. Sewage-disposing entities and individuals shall pay sewage treatment fees in accordance with the law.

According to the Measures for the Bio-safety Environmental Management of Pathogenic Microbe Laboratories (《病原微生物實驗室生物安全環境管理辦法》), promulgated by the former State Environmental Protection Administration (now the MEE) on March 8, 2006 with effect from May 1, 2006, where a laboratory intends to discharge waste water or waste gas, it shall comply with the relevant provisions issued by the former Ministry of Environmental Protection (now the MEE) and implement an internal system for reporting and conduct the pollutant discharge registrations.

The Law of the PRC on Prevention and Treatment of Water Pollution (《中華人民共和國水污染防治法》), promulgated by the SCNPC on May 11, 1984, became effective on November 1, 1984 and last amended on June 27, 2017, requires that new construction projects and reconstruction or expansion projects and other installations on water that directly or indirectly discharge pollutants to water bodies shall be subject to environmental impact assessment in accordance with the law. The facilities for prevention and control of water pollution shall be designed, constructed and put to use simultaneously with the main parts of a construction project. The facilities for prevention and control of water pollution shall conform to the requirements of the approved or filed environmental impact assessment documents.

Regulations on Work Safety

Work Safety

According to the Safety Production Law of the PRC (《中華人民共和國安全生產法》), promulgated by the SCNPC on June 29, 2002 and effect from November 1, 2002 and last amended on June 10, 2021, a producers and business operators shall abide by this Law and other laws and regulations concerning work safety, strengthen work safety management, establish and improve the all-staff work safety responsibility system and work safety rules and regulations, increase investment in funds, materials, technologies and personnel for work safety, improve the conditions for work safety, strengthen the standardized and information technology development of work safety, establish a dual prevention mechanism of graded management and control of safety risks and the screening and handling of hidden dangers, improve the risk prevention and resolution mechanism, and improve the level of work safety so as to ensure work safety.

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Enterprises that do not have the conditions for safe production shall not engage in production and business activities.

According to the Measures for the Supervision and Administration of “Three Simultaneities” Requirements for the Safety Facilities of Construction Projects (《建設項目安全設施“三同時”監督管理辦法》), which were promulgated by the former State Administration of Work Safety (now the Ministry of Emergency Management (the “MEM”)) on April 2, 2015 and became effective on May 1, 2015, the safety facilities of a construction project must be designed, constructed and put into operation simultaneously with the major construction works of the construction project.

Hazardous Chemicals

The Regulation on Safety Administration of Hazardous Chemicals (《危險化學品安全管理條例》, the “**Hazardous Chemicals Regulation**”) was promulgated by the State Council on January 26, 2002, became effective on March 15, 2002 and amended on March 2, 2011 and December 7, 2013, respectively. An entity using hazardous chemicals shall comply with the provisions of laws and administrative regulations and the requirements of national standards and industrial standards in terms of use conditions (including techniques), and shall, in accordance with the types and hazard characteristics of the used hazardous chemicals as well as the amount and mode of use, establish and perfect the safety administration regulations and safety operating rules for the use of hazardous chemicals so as to guarantee the safe use of hazardous chemicals.

The Regulation on the Administration of Precursor Chemicals (《易製毒化學品管理條例》) promulgated by the State Council on August 26, 2005, became effective on November 1, 2005 and last amended on September 18, 2018, stipulates the production, operation, purchase, transportation, import and export of precursor chemicals. The precursor chemicals are classified into three categories. Category I includes the major materials that can be used for producing drugs. Categories II and III include the chemical agents that can be used for producing drugs. An entity that applies for purchasing the precursor chemicals in Category I shall submit the following certificates to the competent administrative department for examination and approval and obtain the purchase license therefrom upon approval. An entity that is to purchase any chemical liable to producing drugs in Category II or III shall, prior to the purchase, shall file an information about the type and quantity in demand for record, with the public security organ of the local people’s government at the county level.

The Measures for the Administration of Public Security of Explosive Hazardous Chemicals (《易製爆危險化學品治安管理办法》) promulgated by the Ministry of Public Security on July 6, 2019 and came in to effect on August 10, 2019, stipulates that the selling and purchasing units of explosive hazardous chemicals shall report the variety, quantity and flow information of explosive hazardous chemicals sold and purchased to the local county- level public security organ for the record within five days after the sale and purchase.

Fire Prevention

According to the Fire Prevention Law of the PRC (《中華人民共和國消防法》) or the Fire Prevention Law, promulgated by the SCNPC on April 29, 1998, became effective on September 1, 1998 and last amended with effect from April 29, 2021, the design and construction of the fire control facilities for a construction work shall comply with the national fire control technical standards. The developer, designer, constructor and project supervisor of a construction project

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shall be responsible for the quality of the design and construction of such fire control facilities according to the relevant laws.

According to the Fire Prevention Law and the Interim Provisions on Design Inspection and Acceptance of Fire Protection of Construction Works (《建設工程消防設計審查驗收管理暫行規定》) or the interim Provisions on Fire Protection, (promulgated by the Ministry of Housing and Urban-Rural Development on April 1, 2020 and effective as of June 1, 2020, amended on August 21, 2023). The developer shall bear the primary responsibility for the fire protection design and construction quality of the construction project according to law.

Regulations on Labor

Labor

Pursuant to the Labor Law of the PRC (《中華人民共和國勞動法》) which was promulgated by the SCNPC on July 5, 1994, became effective on January 1, 1995, and last amended on December 29, 2018, the Labor Contract Law of the PRC (《中華人民共和國勞動合同法》) which was promulgated by the SCNPC on June 29, 2007, became effective on January 1, 2008 and subsequently amended on December 28, 2012 and the Implementing Regulations of the Labor Contract Law of the PRC (《中華人民共和國勞動合同法實施條例》) which was promulgated by the State Council on September 18, 2008, written labor contracts shall be needed to establish labor relationships between employers and employees. Wages cannot be lower than the local standards of minimum wages. Employers must establish and improve labor safety and hygiene systems, strictly implement national labor safety and hygiene regulations and standards, and educate workers about labor safety and hygiene. Employers must provide workers with labor safety and hygiene conditions and the necessary labor protective equipment in accordance with State regulations, and workers engaged in occupationally hazardous work should undergo regular health checks.

Social Insurance and Housing Accumulation Fund

Under the Social Insurance Law of the PRC (《中華人民共和國社會保險法》) which was promulgated by the SCNPC on October 28, 2010, became effective on July 1, 2011 and amended on December 29, 2018, the Administrative Regulations on the Housing Provident Fund (《住房公積金管理條例》) which was promulgated by the State Council on April 3, 1999 with effect from the same date and amended on March 24, 2002 and March 24, 2019 respectively, employers are required to contribute, on behalf of their employees, to a number of social security funds, including funds for basic pension insurance, unemployment insurance, basic medical insurance, occupational injury insurance, maternity insurance and to housing provident funds. These payments are made to local administrative authorities and any employer who fails to contribute may be fined and ordered to make the deficit good within a stipulated time limit.

The General Office of the Central Committee of CPC and the General Office of the State Council jointly issued the Reform Program of the State Tax and Land Tax Collection and Management System (《國稅地稅徵管體制改革方案》) on July 20, 2018, which stipulates that from January 1, 2019, the tax department is responsible for the collection of social insurance premiums. According to the Circular on Doing the Work Relating to the Collection and Administration of Social Insurance Premiums in a Steady and Orderly Manner (《關於穩妥有序做好社會保險費管徵管有關工作的通知》) issued by the State Administration of Taxation on September 13, 2018, all local departments responsible for collecting social insurance are strictly prohibited from centrally clearing enterprises' historical arrears on their own. The Circular on

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the Implementation of Certain Measures to Further Support and Serve the Development of the Private Economy (《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 by the State Administration of Taxation on November 16, 2018 reiterated that tax agencies at all levels are not allowed to organize on their own to carry out centralized clearing of fees owed by contributors, including private enterprises, for previous years. The Circular on the Issuance of the Comprehensive Plan for Reducing Social Insurance Premium Rates (《關於印發降低社會保險費率綜合方案的通知》), issued by the General Office of the State Council on April 1, 2019, generally reduces the burden of social insurance payment on enterprises and re-emphasizes that local authorities shall not carry out centralized clearing of historical arrears of fees and charges owed by enterprises on their own.

Prevention and Control of Occupational Diseases

According to the Law of the PRC on the Prevention and Control of Occupational Diseases (《中華人民共和國職業病防治法》) which was promulgated on October 27, 2001, became effective as of May 1, 2002 and last amended on December 29, 2018, the prevention and control of occupational diseases shall follow the guideline of "focusing on prevention and combining prevention with control." An employer shall: (i) establish and improve the accountability system for prevention and treatment of occupational diseases, enhance management of, and raise the level in this field, and bear responsibility for the occupational disease hazards produced; (ii) contribute to occupational injury insurance; (iii) provide facilities for the effective prevention and protection of occupational diseases, and provide materials to employees for personal use against occupational diseases; (iv) provide alarm equipment, allocate on-spot emergency treatment materials, washing equipment, emergency safety exits and necessary safety zones for work places where acute occupational injuries are likely to take place due to poisonous and harmful elements therein; and (v) inform the employees of, and specify in the labor contracts with the employees the potential harm of, occupational disease as well as the consequences thereof, and the prevention and protection measures and treatment against occupational diseases when signing the labor contracts with employees.

According to the Law of the PRC on the Prevention and Control of Occupational Diseases, in the event that any newly built, expanded or renovated construction project, or technology renovation or introduction project (hereinafter the "**Construction Project**") may generate occupational disease hazards, the owner shall conduct the assessment of occupational disease hazards during the feasibility study stage. The occupational disease hazard pre-assessment report shall assess the Construction Project as to possible occupational disease hazard factors and their impact on the workplace and health of the workers and determine the type of the hazards and the measures for protection against occupational diseases. Pursuant to the Classified Management Catalog for the Risks of Occupational Disease Hazards at Construction Projects (《建設項目職業病危害風險分類管理目錄》) which was promulgated on March 12, 2021 with effect from the same date, the manufacturing of APIs of chemical drug falls within the "serious" category.

Regulations on Self-Owned Real Properties

According to the PRC Civil Code, properties referred to in this law include real property and personal property. Establishment, modification, assignment and extinguishment of the property right of a real property shall be effective upon registration pursuant to law. The construction land use right may be established through assignment or allotment, etc. The holder of the construction land use right shall reasonably use the land and may not alter the use purpose.

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Regulations on Real Estate Leasing

According to the PRC Civil Code, a lease contract is a contract whereby the lessor delivers to the lessee the item for the latter's use or benefit therefrom, and the lessee pays the lease expense. The contents of a lease contract generally include terms such as the name, quantity and purpose of the leased property, lease term, rent, the time and method of payment and the maintenance of the leased property.

According to Administrative Measures on Leasing of Commodity Housing (《商品房屋租賃管理辦法》) promulgated by the Ministry of Housing and Urban-Rural Development of PRC on December 1, 2010 and effective from February 1, 2011, the lessor and the lessee shall complete property leasing registration and filing formalities within 30 days from execution of the property lease contract with the competent municipal or county level housing and construction authority where the leased property is located. Failure to comply with the above requirements may subject the relevant lessor and lessee to administrative penalties, including rectification order and fines.

Regulations on Intellectual Property

Patents

Pursuant to the Patent Law of the PRC (《中華人民共和國專利法》, the "**PRC Patent Law**"), promulgated by the SCNPC on March 12, 1984, became effective on April 1, 1985 and last amended on October 17, 2020 and effective from June 1, 2021, and the Implementation Rules of the PRC Patent Law (《中華人民共和國專利法實施細則》) last amended by the State Council on December 11, 2023, there are three types of patents in the PRC: invention patent, utility model patent and design patent. The protection period for an invention patent shall be 20 years, for a utility model patent shall be 10 years, and for a design patent shall be 15 years, all commencing from the date of filing of application. Any individual or entity that utilizes a patent or conducts any other activity in infringement of a patent without prior authorization of the patentee shall pay compensation to the patentee and is subject to administrative penalties and, if constituting a crime, shall be held criminally liable in accordance with the law. According to the PRC Patent Law, for the purpose of public health, the patent administrative department under the PRC State Council may grant mandatory licenses for patented drugs manufactured and exported to countries or regions which comply with the provisions of the relevant international treaties participated by the PRC.

Trademarks

According to the Trademark Law of the PRC (《中華人民共和國商標法》) which was promulgated by the SCNPC on August 23, 1982, became effective on March 1, 1983, last amended on April 23, 2019 and effective from November 1, 2019, the protection period for a registered trademark is 10 years from the date of registration and may be renewed for successive 10-year periods. 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; where renewal formalities are not completed within the stipulated period, a six-month grace period may be allowed. In the absence of renewal upon expiry, the registered trademark shall be canceled. Industrial and commercial administrative authorities have the right to investigate and deal with any behavior in infringement of the exclusive right to use registered trademarks in accordance with the law. In case of a suspected criminal offense, the case shall be promptly transferred to the judicial authorities in accordance with the law.

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Copyright

The SCNPC promulgated the Copyright Law of the PRC (《中華人民共和國著作權法》) in 1990 and last amended it in 2020. The Copyright Law of the PRC provides that Chinese citizens, legal persons, or other organizations shall, whether published or not, enjoy copyright in their works. Where a work is created according to the intention and under the supervision and responsibility of a legal entity or another organization, such legal entity or organization shall be the author of the work.

Domain Name

In accordance with the Administrative Measures for Internet Domain Names (《互聯網域名管理辦法》) promulgated by the Ministry of Industry and Information Technology (the "MIIT") on August 24, 2017 with effect from November 1, 2017, the corresponding permit shall be obtained pursuant to these Measures from the MIIT or the communication administrative bureau of the province, autonomous region or centrally-administered municipality for establishment of domain name root servers and domain name root server operating organizations, domain name registration management organizations and domain name registration service organizations. Domain name registration service organizations require applicants to provide true, accurate and complete registration information of the domain name holder, such as the identity information etc.

Regulations on Taxation

PRC Enterprise Income Tax

The PRC Enterprise Income Tax, or EIT, is calculated based on the taxable income determined under the Enterprise Income Tax Law of the PRC (《中華人民共和國企業所得稅法》, the "PRC EIT Law"), which was promulgated on March 16, 2007, became effective on January 1, 2008 and last amended on December 29, 2018. The PRC EIT Law generally imposes a uniform enterprise income tax rate of 25% on all resident enterprises in China, including foreign-invested enterprises. The PRC EIT Law and its implementation rules permit the enterprises qualified as "High and New Technologies Enterprises", or HNTEs, to enjoy a reduced 15% enterprise income tax rate.

PRC Value Added Tax

On March 23, 2016, Ministry of Finance of PRC (the "MOF") and the State Administration of Taxation (the "SAT") jointly issued the Circular on the Pilot Program for Overall Implementation of the Collection of Value Added Tax Instead of Business Tax (《關於全面推開營業稅改徵增值稅試點的通知》) (the "Circular 36"), which took effect on May 1, 2016 and was last amended with effect from April 1, 2019 following the enactment of the Announcement 39 (as defined below). According to Circular 36, all of the companies operating in construction, real estate, finance, modern service or other sectors which were required to pay business tax are required to pay Value-added Tax, or VAT, in lieu of business tax. A VAT rate of 6% applies to revenue generated from the provision of certain services.

On March 20, 2019, the MOF, the SAT and the General Administration of Customs of the PRC issued the Announcement on Policies for Deepening the VAT Reform (《關於深化增值稅改革有關政策的公告》) (the "Announcement 39"), which came into effect on April 1, 2019, to further slash VAT rates. According to Announcement 39, (i) the 16% or 10% VAT rate previously imposed on sales and imports by general VAT taxpayers is reduced to 13% or 9% respectively;

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(ii) the 10% VAT deduction rate previously allowed for the procured agricultural products is reduced to 9%; (iii) for the agricultural products procured for production or commissioned processing with a 13% VAT rate, the amount of input VAT shall be calculated at the 10% VAT deduction rate; and (iv) the 16% or 10% export VAT refund rate previously granted to the exportation of goods or labor services is reduced to 13% or 9%, respectively.

Regulations on Import and Export

Promulgated by The General Administration of Customs of the PRC on November 19, 2021 and effective January 1, 2022, Administrative Provisions of the Customs of the People’s Republic of China on Record-filing of Customs Declaration Entities (《中華人民共和國海關報關單位備案管理規定》) stipulates that consignors or consignees of imported or exported goods or customs declaration enterprises that apply for record-filing shall obtain market entity qualifications; in the case of consignors or consignees of imported or exported goods applying for record-filing, they shall also complete the record-filing formalities for foreign trade dealers. If the record-filing materials are complete and meet the record-filing requirements for a customs declaration entity upon review, Customs shall approve the record-filing within three business days. The record-filing information shall be made public via the Import and Export Credit Information Publicity Platform of the Customs of China.

Regulations on Enterprise Investment Projects

According to Regulations on the Administration of Approval and Record-Filing of Enterprise Investment Projects (《企業投資項目核准和備案管理條例》) which were promulgated by the PRC State Council on November 30, 2016 and became effective from February 1, 2017, pre-approval is required for projects that have national security concern or relate to major productivity distribution, strategic resource development and major public interests, and projects other than the aforesaid ones are subject to administration by way of filing. The Notice of the PRC State Council on Issuing the Catalogue of Investment Projects Approved by the Government (2016 Version) (《國務院關於發佈政府核准的投資項目目錄(2016年本)的通知》) issued by the PRC State Council and taking effect from December 12, 2016 set out projects required for pre-approval.

Regulations on Foreign Investment and Outbound Investment

Foreign Investment

The Company Law of the PRC (《中華人民共和國公司法》, the “**PRC Company Law**”), promulgated by the SCNPC on December 29, 1993 (effective as from July 1, 1994) and last amended on December 29, 2023 and effective from July 1, 2024, provides general regulations for companies’ incorporation and operation in the PRC including the foreign-invested companies. Unless otherwise provided in the Foreign Investment Law of the PRC (《中華人民共和國外商投資法》, the “**PRC Foreign Investment Law**”), the provisions in the PRC Company Law shall prevail.

Foreign investors in the PRC are subject to certain restrictions regarding the types of industries they can invest in. The Special Administrative Measures for the Access of Foreign Investment (2024) (the “**Negative List**”) (《外商投資准入特別管理措施負面清單》(2024年版)) was promulgated by the MOFCOM and the NDRC on September 6, 2024 and came into effect on November 1, 2024. The Negative List set out the restrictive measures in a unified manner, such as the requirements on shareholding percentages and management, for the access of foreign

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investments, and the industries that are prohibited for foreign investment. The Negative List covers 11 industries, and any field not falling in the Negative List shall be administered under the principle of equal treatment to domestic and foreign investment.

Outbound Investment

According to the Measures for the Administration of Overseas Investment of Enterprises (《企業境外投資管理辦法》), which was promulgated by the NDRC on December 26, 2017 and became effective on March 1, 2018, to make outbound investment, any investor shall go through the formalities to have a proposed overseas investment project approved or filed on the record, report relevant information, and cooperate with supervision and inspection. Projects that involve any sensitive country or region or any sensitive industry need to be approved by the NDRC, while other overseas investment projects are subject to filing administration. The NDRC promulgated the List of Sensitive Sectors for Outbound Investment (2018) (《境外投資敏感行業目錄》(2018年版)) on January 31, 2018 and effective as from March 1, 2018 to list the current sensitive industries in detail.

According to the Administrative Measures for Outbound Investment (《境外投資管理辦法》), which was promulgated by the MOFCOM on March 16, 2009, became effective on May 1, 2009 and amended on September 6, 2014, outbound investment refers to the activities of possessing non-financial enterprises or acquiring the ownership of, the control over, the operation and management right of, and other rights of and interests in, the existing non-financial enterprises outbound through consolidation, merger and acquisition, or otherwise conducted by enterprises that are established in the PRC in accordance with the law. The MOFCOM and the provincial departments in charge of commerce shall conduct archive filing and verification management according to different circumstances of outbound investment of an enterprise. Where the outbound investment carried out by an enterprise involves sensitive countries and regions and sensitive industries, verification management shall be implemented. Archive filing management shall be implemented for other circumstances of outbound investment of an enterprise.

Pursuant to the Provisions on the Foreign Exchange Administration of Overseas Investment of Domestic Institutions (《境內機構境外直接投資外匯管理規定》) promulgated by the State Administration of Foreign Exchange (國家外匯管理局, the "SAFE") on July 13, 2009, which became effective on August 1, 2009 and the Notice of the SAFE on Further Simplifying and Improving the Foreign Exchange Management Policies for Direct Investment (《關於進一步簡化和改進直接投資外匯管理政策的通知》) promulgated by the SAFE on February 13, 2015, upon obtaining approval for overseas investment, a PRC enterprise shall apply for foreign exchange registration for its overseas direct investments with the banks in the place where it's registered.

Regulations on Foreign Exchange and Dividend Distribution

Foreign Exchange Control

The PRC Regulations for the Foreign Exchange Administration (《中華人民共和國外匯管理條例》), which were promulgated by the State Council on January 29, 1996, became effective on April 1, 1996 and amended on January 14, 1997 and August 5, 2008, established the regulatory framework of the administration on foreign currency exchange in China.

According to the Circular on Optimizing Administration of Foreign Exchange to Support the Development of Foreign-related Business (《關於優化外匯管理支持涉外業務發展的通知》)

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issued by the SAFE on April 10, 2020, eligible enterprises are allowed to make domestic payments by using their funds received by way of capital contribution, foreign debts and overseas listing, with no need to provide the evidentiary materials concerning authenticity of such payment to banks in advance, provided that their capital use shall be authentic and compliant, and conform with the prevailing administrative regulations on the use of income under capital accounts. The concerned bank shall conduct ex-post spot check and the local branches of the SAFE shall strengthen monitoring analysis and interim and ex-post regulation in accordance with the relevant requirements.

Dividend Distribution

According to the PRC Company Law, companies shall contribute 10% of the profits into their statutory capital reserve (法定公積金) upon distribution of their post-tax profits of the current year until the aggregate sum of the statutory capital reserve is more than 50% of its registered capital. Where the statutory capital reserve of a company is insufficient to cover its losses in the previous year, the company shall offset such losses using its profits of the current year before making contribution to the statutory capital reserve. Upon contribution to the statutory capital reserve with its post-tax profits, a company may make further contribution to the capital reserve with its post-tax profits upon a resolution made by the shareholders' meeting.

Dividend Withholding Tax

According to the Notice of the SAT on Issues Related to Withholding and Paying Corporate Income Tax by China Resident Enterprises to Overseas H-share Non-resident Enterprise Shareholders (《國家稅務總局關於中國居民企業向境外H股非居民企業股東派發股息代扣代繳企業所得稅有關問題的通知》) issued and implemented by the SAT on November 6, 2008, when China Resident Enterprises distribute dividends to overseas H-share non-resident enterprise shareholders in 2008 and beyond, they will uniformly withhold and pay corporate income tax at the rate of 10%.

Pursuant to the Arrangement between the Mainland of China and the Hong Kong Special Administrative Region for the Avoidance of Double Taxation and the Prevention of Fiscal Evasion with respect to Taxes on Income (《內地和香港特別行政區關於對所得避免雙重徵稅和防止偷漏稅的安排》) (the “**Arrangement for Avoidance of Dual Taxation**”), if a Hong Kong enterprise directly holds at least 25% of the equities in a Chinese resident enterprise and meets certain conditions (including): (i) the Hong Kong enterprise must directly hold specified percentages of the shares and voting rights of the Chinese resident enterprise; and (ii) the Hong Kong enterprise must directly hold such specified percentages within 12 months prior to receiving the dividend, then, the income tax rate for the income tax withheld by the Chinese resident enterprise on the dividend distributed to the Hong Kong enterprise can be reduced from the standard tax rate of 10% to 5%.

According to the Circular on Relevant Issues relating to the Implementation of Dividend Clauses in Tax Treaty Agreements (《關於執行稅收協定股息條款有關問題的通知》) issued by the SAT on February 20, 2009, if the relevant Chinese tax authority determines a certain company benefits mainly from the reduced income tax rate under the tax-driven structure or arrangement as the case may be, it can adjust the preferential tax treatment. Also, if the operating activity of an applicant doesn't constitute the substantive operating activity, it may not be identified as the “beneficial owner”, and finally, the applicant will have no right to enjoy the reduced income tax rate of 5% said above according to the Arrangement for Avoidance of Dual Taxation, according to the Notice on Issues relating to “Beneficial Owners” in Tax Conventions

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(《關於稅收協定中“受益所有人”有關問題的公告》) issued by the State Administration of Taxation on February 3, 2018 and put in effect since April 1, 2018.

Laws and Regulations on Overseas Securities Offering and Listing by Domestic Enterprises

On February 17, 2023, the China Securities Regulatory Commission (the “CSRC”) released the Trial Administrative Measures for 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 “**Trial Measures**”) with effect from March 31, 2023. The Trial Measures comprehensively improve and reform the existing regulatory regime for overseas offering and listing of PRC domestic companies’ securities and regulate both direct and indirect overseas offering and listing of PRC domestic companies’ securities by adopting a filing-based regulatory regime. According to the Trial Measures, 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 within three (3) working days after submitting the listing application documents to the overseas supervisory authorities and report relevant information.

H-share Full Circulation

“Full circulation” means the conversion of domestic unlisted shares of an H-share listed company, including unlisted domestic shares held by domestic shareholders prior to overseas listing, unlisted domestic shares additionally issued after overseas listing, and unlisted shares held by foreign shareholders, into shares that may be listed and traded on the Stock Exchange of Hong Kong.

On August 10, 2023, the CSRC issued the Guidelines for the “Full Circulation” Program for Domestic Unlisted Shares of H-share Listed Companies (revised in 2023) (《H股公司境內未上市股份申請“全流通”業務指引(2023修訂)》) (the “**Guidelines for the Full Circulation**”). According to H-Guidelines for the Full Circulation, on the premise of complying with relevant laws and regulations of state-owned assets management, foreign investment and industry supervision, domestic unlisted shareholders can independently negotiate to determine the number and proportion of shares to be circulated and entrust H-share companies to file with the CSRC. Shareholders of unlisted shares in China shall handle the share re-registration business in accordance with the relevant business rules of China Securities Depository and Clearing Co., Ltd. (the “CSDC”), handle the procedures of share registration and listing in accordance with the relevant provisions of the Hong Kong market, and disclose information in compliance with laws and regulations. H-share companies shall submit relevant reports to the CSRC within 15 days after the shares involved in the application are settled in China and registered.