
REGULATORY OVERVIEW

PRINCIPAL REGULATORY LAWS AND REGULATIONS

Laws and Regulations in Relation to the Pharmaceutical Industry

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 “**Drug Administration Law**”) which was promulgated by the Standing Committee of the National People’s Congress (the “**SCNPC**”) on September 20, 1984, last amended on August 26, 2019 and became effective on December 1, 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.

Pursuant to 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》) (the “**Implementation Regulations**”), which was promulgated by the State Council on August 4, 2002, lastest amended on January 16, 2026 and took effect on March 15, 2026, respectively, clinical trials of drugs, the production of drugs and the import of drugs shall comply with the provisions of the Drug Administration Law and the Implementation Regulations, and shall be examined and approved by the pharmaceutical supervision and administration department of the State Council. The pharmaceutical supervisory and administrative department shall supervise and inspect the development, production, marketing and use of drugs according to law.

Non-Clinical Research

The non-clinical safety evaluation study for drugs for the purpose of applying for drug registration shall be conducted in accordance with the Good Laboratory Practice for Non-Clinical Laboratory Studies (《藥物非臨床研究質量管理規範》), which was promulgated in August 2003 and amended in July 2017 by the China Food and Drug Administration (國家食品藥品監督管理總局) (the “**CFDA**”). On April 16, 2007, the CFDA issued the Measures for Administration of Certification of the Good Laboratory Practice for Nonclinical Laboratory Studies (《藥物非臨床研究質量管理規範認證管理辦法》), last amended on January 19, 2023 and took effect on July 1, 2023, which set forth the requirements for an institution to apply for a Certification of Good Laboratory Practice (“**GLP**”) to undertake non-clinical research on drugs.

Application for Clinical Trial

According to the Administrative Measures for Drug Registration (《藥品註冊管理辦法》) (the “**Registration Measures**”) promulgated by the State Administration for Market Regulation (the “**SAMR**”) on January 22, 2020 and coming into effect on July 1, 2020, drug clinical trials are divided into phase 1 clinical trial, phase 2 clinical trial, phase 3 clinical trial, phase 4 clinical trial and bioequivalence test. Drug clinical trials shall be subject to review and approval by the Ethics Committee. A corresponding trial protocol shall be formulated for any approved drug clinical trial, and the trial may be carried out after review and approval by the Ethics Committee.

According to the Decision on Adjusting the Approval Procedures of Certain Administrative Approval Items for Drugs (《關於調整部分藥品行政審批事項審批程序的決定》) promulgated by the CFDA on March 17, 2017 and became effective on May 1, 2017, the decision on the approval of clinical trials of drugs shall be made by the Center for Drug Evaluation (國家藥品監督管理局藥品審評中心) (the “**CDE**”) from May 1, 2017. The CFDA issued the Announcement on Certain Policies Pertaining to the Review and Approval of Drug Registration (《關於藥品註冊審評審批若干政策的公告》) on November 11, 2015, according to which, the drug approval process was further simplified by implementing a one-time approval for INDs of new drugs, and eliminating declarations, reviews or approvals at different phases. In accordance with the Registration Measures and the Announcement on Adjusting Evaluation and Approval Procedures for Clinical Trials for Drugs (《關於調整藥物臨床試驗審評審批程序的公告》) issued on July 24, 2018, if a clinical trial applicant does not receive any

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negative or questioning opinions from the CDE within 60 days after the date when the trial application is accepted and the fees are paid, the applicant can proceed with the clinical trial in accordance with the trial protocol submitted to the CDE.

After obtaining the approval of clinical trial from the NMPA, the applicant must complete the clinical trial registration at the Drug Clinical Trial Information Platform for public disclosure in accordance with the Circular on Drug Clinical Trial Information Platform (《關於藥物臨床試驗信息平台的公告》), which came into effect on September 6, 2013.

Conduct of Clinical Trial

According to the provisions of the Drug Administration Law, drug clinical trials shall be conducted in clinical trial institutions that meet corresponding conditions, and drug clinical trial institutions shall be subject to record-keeping management. The conduct of drug clinical trials shall comply with ethical principles, with a clinical trial protocol developed, and be subject to review and approval by the Ethics Committee. The Ethics Committee shall establish an ethics review system to ensure that the ethics review process is independent, objective, and fair, and supervise the standard conduct of drug clinical trials. Before a clinical trial is conducted, details such as the clinical trial objectives and risks shall be truthfully stated and explained to the trial subjects or their guardians, and an informed consent letter signed voluntarily by the trial subject or their guardian shall be obtained, and effective measures shall be taken to protect the lawful rights and interests of the trial subjects. Where safety issues or other risks are discovered during a drug clinical trial, the clinical trial sponsor shall promptly adjust the clinical trial protocol, suspend or terminate the clinical trial, and report to the drug regulatory departments under the State Council. If necessary, the drug regulatory departments under the State Council may order the sponsor to adjust the clinical trial protocol or suspend or end the clinical trial.

The Good Clinical Practice (《藥物臨床試驗質量管理規範》), which was revised by the National Medical Products Administration (國家藥品監督管理局) (the “NMPA”) and the National Health and Family Commission (國家衛生健康委員會) (the “NHC”) on April 23, 2020 and came into effect on July 1, 2020, specifies the quality standards for the whole process of drug clinical trials, including protocol design, organization, implementation, monitoring, auditing, recording, analysis, summarization and reporting.

International Multi-Center Clinical Trials

According to the International Multi-Center Clinical Trial Guidelines (Trial) (《國際多中心藥物臨床試驗指南(試行)》), which was issued by the CFDA on January 30, 2015 and became effective on March 1, 2015, the sponsor may conduct clinical trials simultaneously at multiple centers in multiple regions in accordance with the same clinical trial protocol, and may also conduct regional clinical trials simultaneously at multiple centers in different countries within a region in accordance with the same clinical trial protocol. If the applicants plan to use the data derived from international multi-center clinical trials for approval of drug registration in China, such international multi-center clinical trials shall comply with the provisions concerning clinical trials in the Registration Measures. When planning and implementing international multi-centre clinical trials in China, the sponsor shall comply with the Drug Administration Law, the Implementation Regulations, the Registration Measures and other related laws and regulations, implement the Good Clinical Practice in China, make reference to Good Clinical Practice (臨床試驗質量管理規範) provided by the International Council for Harmonisation of Technical Requirements for Pharmaceuticals for Human Use (人用藥品註冊技術要求國際協調會), and meet the legal and regulatory requirements of the corresponding countries.

The NMPA issued the Technical Guiding Principles for the Acceptance of Overseas Clinical Trial Data of Drugs (《接受藥品境外臨床試驗數據的技術指導原則》) on July 6, 2018, according to which, for drugs applied for registration within the PRC, overseas clinical trial data submitted by the applicant may be accepted as the information for clinical evaluation.

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Administration of Drug Registration

Pursuant to the Registration Measures, upon completion of clinical trials, determination of quality standards, completion of validation of commercial-scale production processes and completion of other related preparation work, the applicant may apply with the NMPA for the marketing authorization. The NMPA then determines whether to approve the application according to applicable laws and regulations.

Marketing Authorization Holder Mechanism

Pursuant to the Drug Administration Law, China implements the marketing authorization holder mechanism for management of the drug industry. The drug marketing authorization holder refers to an enterprise or a drug research and development institution that has obtained the drug registration certificate. The drug marketing authorization holder shall be responsible for non-clinical research, clinical trials, production and operation, post-marketing research, adverse reaction monitoring, reporting and processing of drugs in accordance with the provisions of the law.

The marketing authorization holders may manufacture drugs by themselves or entrust a pharmaceutical manufacturing enterprise to manufacture drugs. Likewise, they may sell drugs by themselves or entrust a pharmaceutical distribution enterprise to sell drugs. However, marketing authorization holders may not entrust a pharmaceutical manufacturing enterprise to produce blood products, narcotic drugs, psychotropic drugs, medical-use toxic drugs or pharmaceutical precursor chemicals, except as otherwise stipulated by the drug regulatory department under the State Council.

The drug marketing authorization holder shall establish a drug quality assurance system and be equipped with special personnel to take charge of quality management on drugs independently. The drug marketing authorization holder shall regularly review the quality management system of the drug manufacturer and the drug distributor, and supervise its continuous quality assurance and control capabilities.

Gathering, Collection and Filing of Human Genetic Resources

The Biosecurity Law of the PRC (《中華人民共和國生物安全法》) (the “**Biosecurity Law**”), which was promulgated by SCNPC on October 17, 2020 and last amended on April 26, 2024, establishes a comprehensive legislative framework for the pre-existing regulations in such areas as epidemic control of infectious diseases for humans, animals and plants, research, development, and application of biology technology, biosecurity management of pathogenic microbial laboratories, security management of human genetic resources and biological resources, countermeasures for microbial resistance, and prevention of bioterrorism and defending threats of biological weapons.

Pursuant to the Regulations on the Management of Human Genetic Resources of the PRC (《中華人民共和國人類遺傳資源管理條例》), last amended by the State Council on March 10, 2024 and came into effect on May 1, 2024, the State supports the rational use of human genetic resources for scientific research, development of the biomedical industry, improvement of diagnosis and treatment technology, improvement of China’s ability to guarantee biosafety and improvement of the level of people’s health. The Implementing Rules of the Regulation on the Administration of Human Genetic Resources (《人類遺傳資源管理條例實施細則》), which was promulgated by the Ministry of Science and Technology (the “**MOST**”) on May 26, 2023 and became effective on July 1, 2023, further provides specific requirements on the collection, preservation, utilization and external provision of China’s human genetic resources.

Drug Distribution and Two-Invoice System

According to the Implementing Opinions on Promoting the “Two-Invoice System” for Drug Procurement By Public Medical Institutions (For Trial Implementation) (《關於在公立醫療機構藥品採購中推行「兩票制」的實施意見(試行)》), which was issued on December 26, 2016, the Two-Invoice System is a system under which invoices are issued by drug manufacturers to drug distributors on a once-off basis while invoices are issued by drug distributors to medical institutions on a once-off

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basis. Wholly-owned or holding commerce companies (there shall be only one commerce company throughout the country) and domestic general agents of overseas drugs (there shall be only one domestic general agent throughout the country) that are established by drug manufacturers or group enterprises integrating scientific research, manufacture, and trade to sell the drugs of these enterprise (groups) can be regarded as manufacturers. Within an enterprise that is a drug circulation group, the allocation of drugs between the group and wholly-owned (holding) subsidiaries or between wholly-owned (holding) subsidiaries should not be regarded as invoicing, but invoicing is allowed once at most.

According to the Several Opinions of the General Office of the State Council on Further Reform and Improvement in Policies of Drug Production, Circulation and Use (《國務院辦公廳關於進一步改革完善藥品生產流通使用政策的若干意見》), which was issued on January 24, 2017, on a priority basis, the Two-Invoice System would be promoted in pilot provinces (autonomous regions and municipalities directly under the Central Government) and pilot cities for public hospital reform, with the goal of having it implemented nationwide by 2018. Pharmaceutical companies must comply with the Two-Invoice System in order to engage in procurement processes with public hospitals.

Laws and Regulations on the Manufacturing of Drugs

Drug Manufacturing License

Pursuant to the Drug Administration Law and the Implementation Regulations, drug manufacturing activities are subject to the approval of drug regulatory departments of local people’s governments of provinces, autonomous regions or municipalities directly under the central government and a drug manufacturing license shall be obtained. No drugs shall be manufactured without a drug manufacturing license. The drug manufacturing license shall indicate the period of validity and the scope of manufacturing. The license shall have a validity period of five years. If it is necessary to renew the license after the expiration thereof, the license-holding enterprise shall, within six months before the license expires, apply for a new license in accordance with the provisions of the drug regulatory departments under the State Council.

Good Manufacturing Practice

The drug manufacturer must conduct the manufacturing process in accordance with the Good Manufacturing Practice for Drugs (《藥品生產質量管理規範》) issued by the MOH on January 17, 2011, which sets forth a set of detailed standard guidelines governing the manufacture of drugs including institution and staff qualifications, production premises and facilities, equipment, hygiene conditions, production management, quality controls, product operation, raw material management, maintenance of sales records and management of customer complaints and adverse event reports.

Prior to December 1, 2019, pursuant to the Certification Measures for Good Manufacturing Practice for Drugs (《藥品生產質量管理規範認證管理辦法》) issued by the CFDA in August 2011, when establishing a pharmaceutical manufacturer or a new factory or expanding the production scope, the drug manufacturer is required to submit an application for a good manufacturing practice certificate (the “**GMP certificate**”) with the drug regulatory authority. If the Good Manufacturing Practices (the “**GMP**”) are satisfied, a GMP certificate will be issued. On December 30, 2015, the CFDA issued the Notice on Matters concerning the Implementation of Good Manufacturing Practice (《關於切實做好實施藥品生產質量管理規範有關工作的通知》), which provided that drug manufacturers failing to obtain the GMP certificates would not be issued with the drug manufacturing license.

Pursuant to the Circular on the Relevant Issues Concerning the Implementation of the Drug Administration Law of the 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》), promulgated by the NMPA on November 29, 2019, and the Drug Administration Law, since December 1, 2019, the GMP and Good Supply Practice (the “**GSP**”) certifications have been

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canceled, applications for GMP and GSP certifications are no longer accepted, and GMP and GSP certificates are no longer issued. The legal representative of and principal person in charge of a drug manufacturer are fully responsible for the drug manufacturing activities of the enterprise.

The Administrative Measures for the Inspection of Pharmaceuticals (Trial) (《藥品檢查管理辦法(試行)》) was promulgated by the NMPA on May 24, 2021 and amended on July 19, 2023, and the Certification Measures for Good Manufacturing Practice for Drugs was repealed simultaneously. The Administrative Measures for the Inspection of Pharmaceuticals (Trial) stipulated that if a drug manufacturer applies for a drug manufacturing license for the first time, it will be subject to on-site inspection under relevant contents of the GMP. If a drug manufacturer applies for re-issuance of drug manufacturing license, relevant authorities shall conduct examination pursuant to risk management principle, taking into account the enterprise's compliance with pharmaceutical administration laws and regulations, operation status of GMP and quality system, and may conduct GMP compliance inspection where necessary.

Entrusted Manufacturing of Drugs

Pursuant to the Drug Administration Law and the Administrative Regulations for the Contract Manufacturing of Drugs (《藥品委托生產監督管理規定》) promulgated by the former CFDA on August 14, 2014 and taking effect on October 1, 2014, in the event a drug manufacturer that has obtained a drug marketing license is temporarily unqualified for manufacturing as a result of technology upgrade or is under capacity and is therefore unable to ensure market supply, it can entrust the manufacturing of that drug to another drug manufacturer. The NMPA shall be responsible for guiding, supervising and inspecting the review, approval, supervision and administration of the contract manufacturing of drugs nationwide. The local branches of NMPA of all provinces, autonomous regions and municipalities directly under the central government shall be responsible for the review, approval, supervision and administration of contract manufacturing of drugs.

The Administrative Measures for Supervision of Drug Production (《藥品生產監督管理辦法》) (the “**Revised Administrative Measures for Drug Production**”) promulgated by the SAMR on January 22, 2020 and became effective on July 1, 2020, further implementing the marketing authorization holder system for drugs as required by the Drug Administration Law. A drug marketing authorization holder who entrusts others to produce pharmaceutical preparations shall sign an entrustment agreement and a quality agreement with a qualified drug manufacturer, and apply for the drug production license by submitting the relevant agreements together with the application materials of the actual production site to the regulatory departments of drugs. Announcement of the NMPA on Strengthening the Supervision and Administration of Entrusted Production of Drug Marketing Authorization Holders (《國家藥監局關於加強藥品上市許可持有人委托生產監督管理工作的公告》), issued by the NMPA on October 17, 2023 and became effective on October 17, 2023, further implemented the main responsibility for the quality and safety of drug production entrusted by the drug marketing authorization holders, and ensured the quality and safety of the drug safety production cycle.

Drug Operation Permit

According to the Drug Administration Law, a drug operation permit shall be obtained for drug wholesale activities upon approval by the drug regulatory departments of the local people's governments of the provinces, autonomous regions or municipalities directly under the central government, and a drug operation permit shall be obtained for drug retailing activities upon approval by the drug regulatory departments of the local people's governments above the county level. The Measures for the Quality Supervision and Administration of the Operation and Use of Medical Products (《藥品經營和使用質量監督管理辦法》) promulgated by the SAMR on September 27, 2023 came into effect on January 1, 2024. The Measures for the Quality Supervision and Administration of the Operation and Use of Medical Products stipulates the conditions, procedures, changes and supervision and administration of the drug operation permit.

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Laws and Regulations on Labor, Social Insurance and Housing Provident Funds

According to the Labor Law of the PRC (《中華人民共和國勞動法》), which came into effect 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 in June 2007 and amended in December 2012 and came into effect in July 2013, and the Implementing Regulations of the Labor Contracts 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 and came into effect in September 2008, labor contracts in written form shall be executed to establish labor relationships between employers and employees. The employers must establish a system for labor safety and sanitation, strictly comply with national rules and standards, provide education regarding labor safety and sanitation to their employees, provide employees with labor safety and sanitation conditions and necessary protection materials in compliance with national rules, and carry out regular health examinations for employees engaged in work involving occupational hazards.

According to the Social Insurance Law of the People’s Republic of China (《中華人民共和國社會保險法》), which was revised on December 29, 2018, the Regulations on Management of Housing Provision Funds (《住房公積金管理條例》), which was revised by the State Council and took effect on March 24, 2019, employers and employees shall pay housing, pension insurance, Medical Insurance, unemployment insurance, maternity insurance, and other social insurances according to the statutory payment basis and proportions.

Laws and Regulations on Intellectual Properties

Trademark

The Trademark Law of the People’s Republic of China (《中華人民共和國商標法》) amended by the SCNPC on April 23, 2019 and taking effect on November 1, 2019, and the Regulations for the Implementation of the Trademark Law of the People’s Republic of China (《中華人民共和國商標法實施條例》) amended on April 29, 2014 and taking effect on May 1, 2014 provide for the registration application, examination and approval, renewal, alteration, transfer, use and invalidation of trademarks, and protect the exclusive right of a trademark registrant to the relevant trademark. According to the above laws and regulations, the validity period of a registered trademark shall be ten years from the date the registration is approved. Any trademark registrant may, by signing a trademark license contract, authorize other persons to use his/her registered trademark.

Patent

Under the Patent Law of the PRC (《中華人民共和國專利法》) (the “**Patent Law**”), a patentable invention or utility model must meet three conditions: novelty, inventiveness and practical applicability. Patents cannot be granted for scientific discoveries, rules and methods for intellectual activities, methods used to diagnose or treat diseases, animal and plant breeds, nuclear transformation methods and substances obtained through methods of nuclear transformation, or designs that are used principally to identify the pattern, color, or a combination thereof, on printed materials. The Patent Law was amended on October 17, 2020, effective as of June 1, 2021, pursuant to which an invention patent is valid for 20 years, a utility model is valid for 10 years, and a design patent is valid for 15 years, starting from the application date.

Trade Secret

According to the PRC Anti-Unfair Competition Law (《中華人民共和國反不正當競爭法》), promulgated by the SCNPC in September 1993, most recently amended on June 27, 2025, the term “trade secrets” refers to technical and business information that is unknown to the public, has utility, may create business interests or profits for its legal owners or holders, and is maintained as a secret by its legal owners or holders. Under the PRC Anti-Unfair Competition Law, businesses are prohibited from infringing others’ trade secrets by: (1) acquiring a trade secret from the right holder by theft, bribery, fraud, coercion, electronic intrusion, or any other means; (2) disclosing, using, or

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allowing another person to use a trade secret acquired from the right holder by any means as specified in item (1) above; (3) disclosing, using, or allowing another person to use a trade secret in its possession, in violation of its confidentiality obligation or the requirements of the right holder for keeping the trade secret confidential; (4) abetting a person, or tempting another person into or inducing another person to use the trade secret of the right holder in violation of his or her non-disclosure obligation of the requirements of the right holder for keeping the trade secret confidential.

Pursuant to the provisions of the Criminal Law of the PRC (《中華人民共和國刑法》), which was amended by the SCNPC on December 29, 2023 and came into effect on March 1, 2024, for obtaining business secrets from a business secret owner or the user authorized by a business secret owner (“obligee”) by stealing, bribery, fraud, coercion, electronic intrusion or other illegitimate means; disclosing, using, or allowing others to use the business secrets obtained from the obligee by means mentioned in the preceding paragraph; in violation of the confidentiality obligation or against the obligee’s requirements for keeping business secrets, disclosing, using, or allowing another person to use the business secrets he has, whoever commits any of the above-mentioned acts of infringing on business secrets and the consequences are serious shall be sentenced to fixed-term imprisonment of not more than three years and shall also, or shall only, be fined; if the consequences are especially serious, he shall be sentenced to fixed-term imprisonment of not less than three years but not more than ten years and shall also be fined.

Copyright

Copyright in the PRC is primarily protected by the Copyright Law of the PRC (《中華人民共和國著作權法》), which was promulgated by the SCNPC on September 7, 1990, last amended on November 11, 2020 and became effective on June 1, 2021, and the Implementation Regulations of the Copyright Law of PRC (《中華人民共和國著作權法實施條例》), which was promulgated by the State Council on August 2, 2002 and last amended on January 30, 2013. These laws and regulations provide provisions on the classification of works and the obtaining and protection of copyright.

Domain Names

In accordance with the Measures for the Administration of Internet Domain Names (《互聯網域名管理辦法》) which was issued by the Ministry of Industry and Information Technology Industry on August 24, 2017, domain name registration services shall, in principle, be subject to the principle of “first apply, first register”. A domain name registrar shall, in the process of providing domain name registration services, ask the applicant for which the registration is made to provide authentic, accurate and complete identity information on the holder of the domain name and other domain name registration related information.

Laws and Regulations on Environmental Protection

Environment Protection

The Ecological and Environmental Code of the PRC (《中華人民共和國生態環境法典》), which was promulgated by the NPC on March 12, 2026 and came into effect on August 15, 2026, establishes the principal legal framework for ecological and environmental protection in the PRC. The Ministry of Ecology and Environment is authorized to issue national standards for environmental quality and emissions, and to monitor the environmental protection scheme of the PRC. Meanwhile, local environmental protection authorities may formulate local standards which are more rigorous than the national standards, in which case, the concerned enterprises must comply with both national and local standards.

Environmental Impact Appraisal

According to The Ecological and Environmental Code of the PRC, the Management Regulations for the Environmental Protection of Construction Projects (《建設項目環境保護管理條例》) amended by the State Council on July 16, 2017 and coming into effect on October 1, 2017 and

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the Interim Measures for Acceptance Inspections for Environmental Protection Purposes over Completed Construction Projects (《建設項目竣工環境保護驗收暫行辦法》) promulgated by the former Ministry of Environmental Protection on November 20, 2017 and taking effect on the same day, enterprises planning construction projects shall provide environmental impact reports, environmental impact statements and environmental impact registration forms related to such projects.

Laws and Regulations on Hazardous Chemicals

The Hazardous Chemicals Safety Law of the PRC (《中華人民共和國危險化學品安全法》), which was promulgated on December 27, 2025 and came into effect on May 1, 2026, regulates the production, storage, use, business operation and transportation of 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 and newly revised on December 7, 2013. The Hazardous Chemicals Regulation provides regulatory requirements on the safe production, storage, use, operation and transportation of hazardous chemicals.

According to 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, effective on November 1, 2005, and Lastest amended on Spetember 18, 2018, the State regulates the production, operation, purchase, transportation, import and export of precursor chemicals.

Laws and Regulations on Foreign Investment

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

The Catalogue of Industries Encouraging Foreign Investment (2025 Version) (《鼓勵外商投資產業目錄(2025年版)》) issued by the National Development and Reform Commission (“**NDRC**”) and the Ministry of Commerce of the PRC (“**MOFCOM**”) on December 15, 2025 (effective on February 1, 2026), and the Special Administrative Measures for Foreign Investment Entry (Negative List) (2024 Version) (《外商投資准入特別管理措施(負面清單)(2024年版)》) issued by the NDRC and the MOFCOM on September 6, 2024 (the “**Negative List**”), which became effective on November 1, 2024) together constitute the catalogue of industries encouraging foreign investment and the special administrative measures for foreign investment access to industries restricted or prohibited for foreign investment, of which the Negative List has uniformly listed the special administrative measures in respect of foreign investment access, such as shareholding requirements and senior management requirements. Fields outside the Negative List are managed in accordance with the principle of consistency between domestic and foreign investments. Domestic enterprises engaging in businesses in the areas of investment prohibited by the Negative List that issue shares abroad and list them for trading shall be subject to the examination and consent of the relevant competent state authorities. Foreign investors shall not participate in the operation and management of the enterprise, and the proportion of their shareholding shall be implemented with reference to the relevant provisions on the management of domestic securities investment by foreign investors. Our principal business is the research, development and manufacturing of pharmaceutical products,

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which does not fall within the prohibited or restricted sectors under the Negative List, and shall therefore be administered in accordance with the principle of equal treatment for domestic and foreign investment.

The foreign investment information reporting shall be subject to the Foreign Investment Information Reporting Method (《外商投資信息報告辦法》) jointly developed by the MOFCOM and the SAMR, which came into effect on January 1, 2020. According to the Foreign Investment Information Reporting Method, foreign investors who directly or indirectly carry out investment activities in China shall submit investment information to the competent commercial department through the enterprise registration system and the National Enterprise Credit Information Publicity System, and the reporting methods include initial reports, change reports, cancellation reports, and annual reports.

Laws and Regulations on Foreign Exchange and Taxation

Foreign Exchange

On 29 January 1996, the State Council promulgated the Administrative Regulations on Foreign Exchange of the PRC (《中華人民共和國外匯管理條例》), which came into effect on 1 April 1996 and was amended on 14 January 1997 and 5 August 2008. Foreign exchange payments under current account items shall, pursuant to the administrative provisions of the foreign exchange control department of the State Council on payments of foreign currencies and purchase of foreign currencies, be made using self-owned foreign currency or foreign currency purchased from financial institutions engaging in conversion and sale of foreign currencies by presenting the valid document. Domestic entities and domestic individuals making overseas direct investments or engaging in issuance and trading of overseas securities and derivatives shall process registration formalities pursuant to the provisions of the foreign exchange control department of the State Council.

According to the Notice on Issues Concerning the Management of Funds for Domestic Enterprises’ Overseas Listing (《關於境內企業境外上市資金管理有關問題的通知》) issued by the People’s Bank of China and the State Administration of Foreign Exchange on December 24, 2025, when a domestic enterprise conducts overseas listing, it should apply for the registration of overseas listing at a bank within the provincial or plan-single-listed city region where it is registered, either on the first trading day of the overseas listing or within 30 working days after the completion of the over-allotment option.

Taxation

Enterprise Income Tax

The Enterprise Income Tax Law of the PRC (《中華人民共和國企業所得稅法》) (the “**EIT Law**”), promulgated by the NPC on March 16, 2007 and lastest amended on December 29, 2018, as well as the Implementation Rules of the EIT Law (《中華人民共和國企業所得稅法實施條例》) (the “**Implementation Rules**”), promulgated by the State Council on December 6, 2007 and last amended on December 6, 2024, are the principal law and regulation governing enterprise income tax in the PRC. According to the EIT Law and its Implementation Rules, enterprises are classified into resident enterprises and non-resident enterprises. A uniform income tax rate of 25% applies to all resident enterprises and non-resident enterprises that have set up institutions or sites in the PRC to the extent that such incomes are derived from their set-up institutions or sites in the PRC, or such income are obtained outside the PRC but have an actual connection with the set-up institutions or sites. Non-resident enterprises that have not set up institutions or sites in the PRC, or have set up institutions or sites but the incomes obtained by the said enterprises have no actual connection with the set-up institutions or sites, shall pay enterprise income tax at the rate of 10% in relation to their income sources from the PRC.

REGULATORY OVERVIEW

Value-Added Tax

The major PRC law and regulation governing value-added tax are the Value-Added Tax Law of the PRC (《中華人民共和國增值稅法》) issued on December 25, 2024 by the SCNPC, came into effect on January 1, 2026. Any entities and individuals sell goods, services, intangible assets, or immovables, or import goods within the territory of the PRC are taxpayers of VAT and shall pay the VAT in accordance with the law and regulation. Depending on the taxable acts of the general taxpayers, the applicable VAT rates are 13%, 9%, 6% and 0%, respectively.

Laws and Regulations on Information Security and Data Privacy

Data Security and Data Export

The SCNPC promulgated the Data Security Law of the PRC (《中華人民共和國數據安全法》) on June 10, 2021, which became effective from September 1, 2021, for the establishment of a data classification and grading protection system to conduct classified and hierarchical protection of data.

On December 28, 2021, the Cyberspace Administration of China (the “CAC”) and other twelve PRC regulatory authorities jointly revised and promulgated the Measures for Cybersecurity Review (《網絡安全審查辦法》) (the “**Cyber Review Measures**”), which came into effect on February 15, 2022. The Cyber Review Measures stipulate that, among others, (i) when the purchase of network products and services by a critical information infrastructures operator (the “**CIIO**”) (關鍵信息基礎設施運營者) or the data processing activities conducted by a network platform operator (網絡平台運營者) affect or may affect national security, a cybersecurity review shall be conducted pursuant to the Cyber Review Measures; (ii) an application for cybersecurity review shall be made by an issuer who is a network platform operator holding personal information of more than one million users before such issuer applies to list its securities abroad; and (iii) the relevant PRC governmental authorities may initiate cybersecurity review if such governmental authorities determine that the issuer’s network products or services, or data processing activities affect or may affect national security.

According to the Measures on Security Assessment of Cross-border Data Transfer (《數據出境安全評估辦法》) issued by the CAC on July 7, 2022 and effective on September 1, 2022, a data processor that provides data overseas under any of the following circumstances shall apply to the national cyberspace administration for the security assessment of the outbound data transfer through local provincial cyberspace administration: (i) a data processor provides important data abroad; (ii) the CIIO or the data processor that has processed the personal information of more than 1 million people provides personal information abroad; (iii) the data processor that has provided the personal information of over 100,000 people or the sensitive personal information of over 10,000 people cumulatively since January 1 of the previous year provides personal information abroad.; and (iv) any other circumstance where an application for the security assessment of outbound data transfer is required by the national cyberspace administration.

Personal Information Protection

According to the Civil Code of the PRC (《中華人民共和國民法典》), personal information of natural persons is protected by law. If any organization or individual needs to obtain other people’s personal information, they should obtain it in accordance with the law, ensure the security of the information, and must not illegally collect, use, process, or transmit other people’s personal information or illegally buy, sell, provide, or disclose the information. The Personal Information Protection Law of the PRC (《中華人民共和國個人信息保護法》) promulgated by the SCNPC on August 20, 2021 and implemented on November 1, 2021 further emphasizes the obligations and responsibilities of processors for the protection of personal information, and requests higher level of protective measures on the processing of sensitive personal information.

REGULATORY OVERVIEW

According to the Cybersecurity Law of the PRC (《中華人民共和國網絡安全法》) promulgated by the SCNPC on November 7, most recently amended on October 28, 2025, network operators must follow the principles of legality, legitimacy and necessity when collecting and using personal information, publicly disclose the rules for collection and use, clearly state the purpose, method and scope of collecting and using information, and obtain the consent of the person whose data is being collected.

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

CSRC Filing Requirements for Overseas Offering and Listing

On February 17, 2023, the China Securities Regulatory Commission (the “CSRC”) issued the Trial Measures for the Administration of Overseas Securities Offering and Listing by Domestic Enterprises (《境內企業境外發行證券和上市管理試行辦法》) (the “**Trial Measures for Administration**”) and the 5 ancillary guidelines, which have come into effect since March 31, 2023. The Trial Measures for Administration comprehensively improve and reform the current regulatory system for overseas offering and listing of securities by domestic enterprises, and regulate the direct and indirect offering and listing of securities overseas by domestic enterprises through the adoption of a regulatory system based on filing.

Overseas Listing Confidentiality and Archives Administration

On February 24, 2023, the CSRC and other relevant government authorities promulgated the Provisions on Strengthening Confidentiality and Archives Administration for Overseas Securities Offering and Listing by Domestic Enterprises (《關於加強境內企業境外發行證券和上市相關保密和檔案管理工作的規定》) (the “**Confidentiality Provisions**”), which became effective from March 31, 2023. Pursuant to Confidentiality Provisions, a domestic enterprise must obtain approval from the competent departments with the authority to examine and approve, in accordance with the laws, and file a record with the administrative department for the same level, when providing or publicly disclosing, or providing or public disclosing through its overseas listed entities, documents and information involving secrets of the State and work secrets of the organizations of the State to relevant securities companies, securities service institutions, overseas regulatory authorities, and other entities and individuals.