
REGULATORY OVERVIEW

We are subject to a variety of PRC laws, rules and regulations affecting many aspects of our business. This section summarizes the major PRC regulatory authorities and PRC laws and regulations that we believe are relevant to our business and operations in the PRC.

PRINCIPAL REGULATORY AUTHORITIES

NMPA and Center for Drug Evaluation

The National Medical Products Administration (國家藥品監督管理局) (the “**NMPA**”) (formerly known as the China Food and Drug Administration (國家食品藥品監督管理總局) (the “**CFDA**”)) is the department in charge of the pharmaceutical industry of China. It is primarily responsible for supervision and management of safety of pharmaceuticals, medical devices and cosmetics, including drawing up the relevant laws and regulations; conducting standard management, registration management, quality management and post-market risk management for drugs, medical devices and cosmetics; and organizing and guiding the supervision and inspection of drugs, medical devices and cosmetics etc. The Center for Drug Evaluation of NMPA (國家藥品監督管理局藥品審評中心) (the “**CDE**”) is the technical evaluation unit for drug registration with NMPA. It is primarily responsible for conducting technical evaluation on the drugs application for registration and verifying the relevant drug registrations.

NHC

The National Health Commission (國家衛生健康委員會) (the “**NHC**”) (formerly known as the National Health and Family Planning Commission (國家衛生和計劃生育委員會)) (the “**NHC**”) is the primary national regulator for national public health and medical system. It is primarily responsible for drafting national health policies, supervising and regulating public health, healthcare services, and health emergency systems, coordinating the reform of the medical and health system, organizing the formulation of national drug policies and national essential medicine system, launching an early warning mechanism for the monitoring of the use and clinical comprehensive evaluation of medicine as well as the drug shortage, giving suggestions on the pricing policy of national essential medicine, and regulating the operation of medical institutions and practice of medical personnel.

NHSA

The National Healthcare Security Administration (國家醫療保障局) (the “**NHSA**”), a new authority established in May 2018, is directly under the State Council and responsible for the management of the healthcare security system. It is primarily responsible for drafting and implementing policies and standards on medical insurance, maternity insurance and medical assistance; supervising and administering the healthcare security funds; organizing the formulation of a uniform medical insurance catalogue and payment standards on drugs, medical disposables and healthcare services; and formulating and supervising the implementation of the bidding and tendering policies for drugs and medical disposables.

OVERVIEW OF LAWS AND REGULATIONS IN THE PRC

Laws and Regulations on New Drugs

Research and development of new drugs

The Drug Administration Law of the PRC (《中華人民共和國藥品管理法》) (the “**Drug Administration Law**”) promulgated by the Standing Committee of the National People’s Congress (the “**SCNPC**”) in September 1984, last amended on August 26, 2019 and became effective on December 1, 2019, and the Regulations for Implementation of the Drug Administration Law of the PRC (《中華人民共和國藥品管理法實施條例》) (the “**Implementation Regulations**”) promulgated by the State Council in August 2002 and last amended on January 16, 2026 and became

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effective on January 20, 2025 (the latest version was published on January 16, 2026 and will become effective on May 15, 2026), have laid down the legal framework for the establishment and maintenance of pharmaceutical manufacturing and trading enterprises, as well as for the administration of pharmaceutical products including the development and manufacturing of new drugs. The developer and clinical trial applicant of any new drug shall truthfully submit the new drug's manufacturing method, quality specifications, results of pharmacological and toxicological tests and the related data, documents and samples to the NMPA for approval before any clinical trial is conducted. The General Committee of China Communist Party and the General Office of the State Council jointly issued the Opinions on Deepening the Reform of Review and Approval System and Encouraging the Innovation of Drugs and Medical Devices (關於深化審評審批制度改革鼓勵藥品醫療器械創新的意見) (the “**Innovation Opinions**”) on October 2017.

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 Administrative Measures for Good Laboratory Practice for Non-Clinical 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 CFDA and became into effective on September 1, 2017. In April 2007, the CFDA issued the Administrative Measures for Certification of Good Laboratory Practice for Non-Clinical Laboratory Studies (《藥物非臨床研究質量管理規範認證管理辦法》), last amended on January 19, 2023 and taking effect on July 1, 2023, which set forth the requirements for an institution to apply for a Certification of Good Laboratory Practice to undertake non-clinical research on drugs.

Animal Testing

According to the Regulation on the Administration of Laboratory Animals (《實驗動物管理條例》) issued by the State Scientific and Technological Commission on November 14, 1988 and last amended by the State Council on March 1, 2017, the Administrative Measures on Quality Management of Experimental Animals (《實驗動物質量管理辦法》) jointly issued by the State Scientific and Technological Commission and the State Bureau of Quality and Technical Supervision on December 11, 1997 and the Administrative Measures on the Licenses for Experimental Animals (Interim) (《實驗動物許可證管理辦法(試行)》) issued by the Ministry of Science and Technology and other regulatory authorities on December 5, 2001 and effective from January 1, 2002, using, breeding, providing, transporting experimental animals shall be subject to some rules and requirements, and performing experimentation on animals requires a Certificate for Use of Experimental Animals.

Application for clinical trial

According to The Decision on Adjusting the Approval Procedures of the Administrative Approval Items for Certain 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, the decision on the approval of clinical trials of drugs shall be made by the CDE from May 1, 2017. According to the Provisions for Drug Registration (《藥品註冊管理辦法》) (the “**Circular 27**”), which was promulgated on January 22, 2020 and took effect on July 1, 2020, drug clinical trials shall be divided into Phase I clinical trial, Phase II clinical trial, Phase III clinical trial, Phase IV clinical trial, and bioequivalence trial. In accordance with Circular 27 and the Announcement on Adjustment of Review and Approval Process of Drug Clinical Study (《關於調整藥物臨床試驗審評審批程序的公告》) issued in July 2018, if a clinical trial applicant does not receive any negative or questioned 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. According to the Announcement on Matters Related to Optimizing the Review and Approval of Clinical Trials for Innovative Drugs (《關於優化創新藥臨床試驗審評審批有關事項的公告》) promulgated by the NMPA on September 12, 2025, the NMPA shall complete the review and approval process for qualifying innovative drug clinical trial applications within 30 working days.

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After obtaining the approval of the clinical trials 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 Announcement 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 in September 2013.

Conduct of clinical trial

Clinical trials must be conducted in accordance with the Good Clinical Practice (《藥物臨床試驗質量管理規範》) promulgated by NMPA and NHC on April 23, 2020 and effective on July 1, 2020, which stipulates the requirements for the procedures of conducting clinical trials, including preclinical trial preparation, trial protocols, protection of testees' rights and interests, duties of researchers, sponsors and monitors, as well as data management and statistical analysis.

According to the Announcement on Adjustment of Review and Approval Process of Drug Clinical Study (《關於調整藥物臨床試驗審評審批程序的公告》), where the application for clinical trial of a new drug has been approved, upon the completion of Phases I and II clinical trials and prior to Phase III clinical trial, the applicant shall submit the application for communication meetings to CDE to discuss with CDE the key technical questions including the design of Phase III clinical trial protocol. According to the Administrative Measures for Communication on the Research, Development and Technical Evaluation of Drugs (《藥物研發與技術審評溝通交流管理辦法》), revised by the NMPA on December 10, 2020, during the research and development periods and in the registration applications of, among others, the innovative new drugs, the applicants may propose to conduct communication meetings with the CDE.

The Technical Guidance on Clinical Evaluation for Drug Marketing Authorisation Applications (《藥物上市申請臨床評價技術指導原則》), issued by the National Medical Products Administration on 23 March 2026, and the Technical Guidance on Clinical Evaluation for Drug Clinical Trial Applications (《藥物臨床試驗申請臨床評價技術指導原則》), issued on 25 March 2026, set out common principles to be followed across different therapeutic areas when addressing unmet clinical needs, and provide specific guidance on key technical considerations for clinical evaluation during drug clinical trial applications.

According to the Announcement on Matters Concerning the Review and Approval Procedures for Drug Registration (《關於優化藥品註冊審評審批有關事宜的公告》) jointly issued by the NMPA and the NHC on May 17, 2018, the CDE will prioritize the allocation of resources for review, inspection, examination and approval of registration applications that have been included in the scope of fast track clinical trial approval.

New drug registration

Pursuant to Circular 27, upon completion of clinical trials, determination of quality standards, completion of validation of commercial-scale production processes and completion of other related preparation works, the applicant may apply with the NMPA for the marketing authorization. The holders of any of the following drugs can apply for conditional approval of such drugs: (1) drugs which are used for the treatment of severe life-threatening diseases currently lacking effective treatment and the data of clinical trials can confirm their efficacy and forecast their clinical value; (2) drugs which are urgently needed for public health and the data of clinical trials can demonstrate their efficacy and forecast their clinical value; and (3) vaccines which are urgently needed to deal with major public health emergencies or other vaccines which the NHC deems to be urgently needed, the benefits of both of which are assessed to be outweigh the risk.

According to the Requirements for Registration Classification and Application Dossiers of Chemical Drugs (《化學藥品註冊分類及申報資料要求》) issued by the NMPA on June 29, 2020 with implementation of the Registration Classification of Chemical Drugs from July 1, 2020, the registration of chemical drugs is categorized into innovative drugs, improved new drugs, generic drugs, and chemical drugs marketed abroad only.

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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 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. 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.

Laws and Regulations on Gathering, Collection and Filing of Human Genetic Resources

Pursuant to the Service Guide for Administrative Licensing of Gathering, Collection, Deal, Export and Exit Approval of Human Genetic Resources of Human genetic resources (《人類遺傳資源採集、收集、買賣、出口、出境審批行政許可事項服務指南》) promulgated by the MOST on July 2, 2015 and the Notice on the Implementation of the Administrative License for the Gathering, Collection, Deal, Export and Exit of Human Genetic Resources (《關於實施人類遺傳資源採集、收集、買賣、出口、出境行政許可的通知》) promulgated by the MOST on August 24, 2015, the gathering and collection of human genetic resources through clinical trials by a foreign-invested sponsor shall be filed for record with the China Human Genetic Resources Management Office through an online system.

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 Implementation Rules for the Regulation of Human Genetic Resources Administration (《人類遺傳資源管理條例實施細則》), which was promulgated by 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.

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.

Laws and Regulations on the Manufacturing of Drugs

Drug Manufacturing Certificate

Pursuant to the Drug Administration Law and the Implementing Regulations, a drug manufacturer must obtain a Drug Manufacturing Certificate (藥品生產許可證) from the drug regulatory authority at provincial, autonomous regional or municipal level before it may start manufacturing drugs in the PRC. Each Drug Manufacturing Certificate is valid for a period of five years and the manufacturer is required to apply for renewal of the permit within six months prior to its expiration date.

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Contract manufacturing of drugs

Pursuant to the Administrative Regulations for the Contract Manufacturing of Drugs (《藥品委託生產監督管理規定》) (the “**Contract Manufacturing Regulations**”) issued by the CFDA in August 2014, only when a drug manufacturer temporarily lacks manufacturing conditions due to technology upgrade or is unable to ensure market supply due to insufficient manufacturing capabilities, can such drug manufacturer entrust the manufacturing of the drug to another domestic drug manufacturer. The Provisions for the Supervision and Administration of Drug Manufacturing (《藥品生產監督管理辦法》) promulgated by the State Administration for Market Regulation on January 22, 2020 and effective on July 1, 2020 further implements the drug marketing authorization holder system as stipulated in the Drug Administration Law.

Drug Operation License

According to the Drug Administration Law, the Measures for the Supervision and Administration of Drug Quality in Operation and Usage (《藥品經營和使用質量監督管理辦法》), which was issued by the SAMR on September 27, 2023 and came into effect on January 1, 2024, whoever engages in the wholesale or retail of drugs shall be subject to the approval of the drug regulatory authority, obtain a Drug Operation License in accordance with the law. The drug marketing authorization holders may sell the drugs for which they have obtained a drug registration certificate on their own or entrust a drug operating enterprise with the sale of such drugs.

Laws and Regulations on Drug Supply

Drug Purchases by Hospitals

According to the Opinion on the Guidance of the Reform of the Urban Medical and Health Care System (《關於城鎮醫藥衛生體制改革的指導意見》) promulgated and took into effect on February 16, 2000 and the Opinion on the Implementation of Classification Management of Urban Medical Institutions (《關於城鎮醫療機構分類管理的實施意見》) promulgated on July 18, 2000 and became effective from September 1, 2000, a medical institution must be defined as a profit-making or non-profit-making institution at the time when it is established. The PRC government does not establish any profit-making medical institutions, while non-government entities may establish profit-making medical institutions.

According to the Notice on the Trial Implementation of the Centralized Drug Procurement by Medical Institutions (《關於印發醫療機構藥品集中招標採購試點工作若干規定的通知》) promulgated and became effective on July 7, 2000, the Notice on the Further Standardizing of the Centralized Drug Procurement by Medical Institutions (《關於進一步做好醫療機構藥品集中招標採購工作的通知》) promulgated and became effective on July 23, 2001 and the Opinions concerning Further Regulating Centralized Drug Procurement by Medical Institutions (《進一步規範醫療機構藥品集中採購工作的意見》) promulgated and took into effect on January 17, 2009, any non-profit-making medical institutions established and/or controlled by any government at a county level or above must implement the Centralized Drug Procurement system in respect of purchase of any drugs which are contained in the Medicines List for National Basic Medical Insurance and are generally used for clinical purposes and purchased in relatively large amounts.

The Circular on the Good Practice of Centralized Drug Procurement by Medical Institutions with respect to Centralized Procurement of Drugs (《醫療機構藥品集中採購工作規範》) promulgated and was effective on July 7, 2010, provides stipulations in detail in respect of the catalog for centralized procurement and methods, procedures, evaluators, expert database construction and management of drugs, further regulating the centralized drug procurement and clarifying the code of conduct on the part of purchasing parties.

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According to the Pilot Program of the Centralized Procurement and Use of Drugs Organized by the State (《國家組織藥品集中採購和使用試點方案》) issued by the General Office of the State Council on January 1, 2019, eleven pilot cities including Beijing, Tianjin, Shanghai, Chongqing, Shenyang, Dalian, Xiamen, Guangzhou, Shenzhen, Chengdu and Xi'an, are selected to launch pilot programs of the centralized procurement and use of drugs under the organization of the State. According to the Implementation Opinions on Expanding the Regional Scope in the Pilot Program of Centralized Drug Procurement and Use Organized by the State (《關於國家組織藥品集中採購和使用試點擴大區域範圍的實施意見》) issued by the National Healthcare Security Administration and other departments on September 25, 2019, the regional scope in the pilot program of centralized procurement and use of drugs organized by the State is being expanded and the volume-based procurement model of the pilot program for conducting the centralized procurement and use of drugs organized by the State is being promoted throughout the country.

The Opinions of the General Office of the State Council on Promoting the Centralized Volume-based Procurement of Drugs in a Normalized and Institutionalized Manner (《國務院辦公廳關於推動藥品集中帶量採購工作常態化制度化開展的意見》), which was promulgated by the General Office of the State Council on January 22, 2021, set out the promotion of the normalization and institutionalization of the centralized procurement of drugs.

Drug Price Management

Pursuant to the Opinions on Promoting Drug Pricing Reform (《推進藥品價格改革的意見》), which was jointly promulgated by the authorities including the NDRC on May 4, 2015, from June 1, 2015, the original prices of the drugs formulated by the government will be canceled, except for narcotic drugs and Class I psychotropic drugs. The prices of narcotic drugs and Class I psychotropic drugs are still temporarily managed by the NDRC through the implementation of maximum factory prices and maximum retail prices. The drugs other than the narcotic drugs and Class I psychotropic drugs no longer adopted government-designated pricing.

The Several Opinions of the General Office of the State Council on Improving the Mechanism for the Formation of Drug Prices (《國務院辦公廳關於健全藥品價格形成機制的若干意見》), issued and implemented on March 30, 2026, has improved the market-driven mechanism for the formation of drug prices by refining pricing policies at key stages and strengthening the governance of drug pricing.

Two-invoice System

According to the Circular on Issuing the Implementing Opinions on Carrying out the Two-invoice System for Drug Procurement among Public Medical Institutions (Interim) (《印發《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)》的通知》) (the “Circular”), which was effective from December 26, 2016, the two-invoice system means one invoice between the pharmaceutical manufacturer and the pharmaceutical distributor, and one invoice between the pharmaceutical distributor and the hospital, and thereby only allows a single level of distributor for the sales of pharmaceutical products from the pharmaceutical manufacturer to the hospital. According to the Circular, the two-invoice system will be promoted in pilot provinces (autonomous regions and municipalities directly under the Central Government) involved in the comprehensive medical reform program and pilot cities for public hospital reform on a priority basis, while other regions are encouraged to implement such a system, so that such system can be promoted in full swing nationwide in 2018.

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Laws and Regulations in Relation to Anti-money Laundering, Anti-corruption and Anti-bribery

Laws and Regulations in Relation to Anti-money Laundering

According to the Anti-money Laundering Law of the People’s Republic of China (《中華人民共和國反洗錢法》) (the “**Anti-money Laundering Law**”) promulgated on November 8 2024 and effective from January 1 2025, financial institutions shall establish a sound internal control system for anti-money laundering in accordance with the provisions of the Anti-money Laundering Law. They shall also set up a special body or designate an internal body to take the lead to take charge of the anti-money laundering work. Entities and individuals in business relationships with financial institutions shall cooperate with the financial institution in conducting customer due diligence, including providing authentic and valid identity documents or other identity certificates, accurately and completely filling in identity information, and faithfully providing materials relating to transactions and funds. Where an entity or individual refuses to cooperate with the financial institution in taking reasonable measures for customer due diligence as required by the Anti-money Laundering Law, the financial institution may take money laundering risk management measures, such as limiting or refusing to handle business and terminating business relationship under the prescribed procedures, and submit a report on doubtful transactions in the light of the situation.

Laws and Regulations in Relation to Anti-corruption

According to the Criminal Law of the People’s Republic of China (《中華人民共和國刑法》), as last amended by the Standing Committee of the National People’s Congress on 29 December 2023, the crime of job appropriation means that staff members of companies, enterprises, or other organizations who, by virtue of their position, unlawfully appropriate property belonging to their organization for their own benefit shall, where the amount involved is substantial, be sentenced to fixed-term imprisonment of not more than three years or criminal detention, and shall also be fined. Where the amount involved is huge, they shall be sentenced to fixed-term imprisonment of not less than three years but not more than ten years, and shall also be fined. Where the amount involved is exceptionally huge, they shall be sentenced to fixed-term imprisonment of not less than ten years or life imprisonment, and shall also be fined.

Laws and Regulations in Relation to Anti-bribery

The Interpretation (II) on Several Issues Concerning the Application of Law in Handling Criminal Cases of Embezzlement and Bribery (《關於辦理貪污賄賂刑事案件適用法律若干問題的解釋(二)》) issued by the Supreme People’s Court and the Supreme People’s Procuratorate was released on April 10, 2026, and took effect on May 1, 2026, which primarily refines the criteria for determining corporate bribery and implicit bribery, standardizes sentencing guidelines for corruption in both public and private enterprises, improves rules regarding leniency for the return of ill-gotten gains and the full-chain recovery of assets involved in cases, unifies the judicial approach to adjudicating corruption and bribery cases, and cracks down rigorously on all forms of corruption.

According to the Anti-Unfair Competition Law of the People’s Republic of China (《中華人民共和國反不正當競爭法》), as amended on 27 June 2025 and implemented on 15 October 2025, promulgated by the Standing Committee of the National People’s Congress, operators shall not bribe the following entities or individuals by means of offering money or other benefits in order to seek out transactional opportunities or competitive advantages: (i) Staff members of the counterparty to the transaction; (ii) Entities or individuals entrusted by the counterparty to handle relevant affairs; and (iii) Entities or individuals who may influence transactions through their authority or influence. Pursuant to the Provisional Regulations on Prohibiting Commercial Bribery (《關於禁止商業賄賂行為的暫行規定》) issued by the former State Administration for Industry

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and Commerce on 15 November 1996, commercial bribery is defined as the offering of financial and material assets or other means by an operator to another organization or individual with the aim of influencing the sale or purchase of goods.

According to the Provisions on the Establishment of Adverse Records of Commercial Briberies in the Medicine Purchase and Sales Industry (《關於建立醫藥購銷領域商業賄賂不良記錄的規定》), which was promulgated by the National Health and Family Planning Commission (currently the NHC) and came into effect on March 1, 2014, an enterprise engaged in the manufacturing or distribution of medicines, medical devices or medical consumables (or its agent) that offers any items of value or other benefits to the staff of a medical institution may be listed in the Adverse Records of Commercial Bribery (“**Adverse Records**”) by the relevant government authorities. As a result, its products cannot be purchased by public medical institutions or medical and health institutions receiving financial subsidies within the relevant provinces, and the scores of its products in the centralized procurement processes conducted by public medical institutions or medical and health institutions receiving financial subsidies in other provinces will be reduced. Where the relevant enterprise (or its agent) is listed in Adverse Records twice within a five-year period, its products cannot be purchased by public medical institutions or medical and health institutions receiving financial subsidies across China for two years.

On April 28, 2026, the NMPA and six other departments jointly issued the Provisions for Medical Representatives (《醫藥代表管理辦法》), which took effect on August 1, 2026. These provisions regulate the academic promotion activities of medical representatives and further strengthen the management of medical representatives.

Regulations in relation to the Medical Insurance Program

Coverage of the national medical insurance program

The national medical insurance program was first adopted according to the Decision of the State Council on Establishing a Basic Medical Insurance System for Urban Employees (《國務院關於建立城鎮職工基本醫療保險制度的決定》) issued by the State Council on December 14, 1998, under which all employers in urban cities are required to enroll their employees in the basic medical insurance program and the insurance premium is jointly contributed by the employers and employees. On July 10, 2007, the State Council issued the Guiding Opinions of the State Council about the Pilot Urban Resident Basic Medical Insurance (《國務院關於開展城鎮居民基本醫療保險試點的指導意見》), further enlarged the coverage of the basic medical insurance program. In addition, on January 3, 2016, the Opinions of the State Council on Consolidating the Basic Medical Insurance Systems of Urban and Rural Residents (《國務院關於整合城鄉居民基本醫療保險制度的意見》) issued by the State Council required the integration of the urban resident basic medical insurance and the new rural cooperative medical care system and the establishment of a unified basic medical insurance system.

Medical Insurance Catalogue

According to the Interim Measures for the Administration of Drugs Covered by Basic Medical Insurance (《基本醫療保險用藥管理暫行辦法》) or the NRDL Administrative Measures, which promulgated by the NHSA, on July 30, 2020 and took effect on September 1, 2020, the scope of drugs covered by the basic medical insurance shall be administered through a reimbursement drug list.

The Medicines List for National Basic Medical Insurance, Maternity Insurance and Work-Related Injury Insurance (《國家基本醫療保險、生育保險和工傷保險藥品目錄》), or the National Reimbursement Drug List (the “**NRDL**”), which was promulgated by the NHSA and the Ministry of Human Resources and Social Security on December 7, 2025, sets forth the payment standard for pharmaceutical products under the basic medical insurance, maternity insurance funds and work-related injury insurance.

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According to the NRDL Administrative Measures, a Provincial Reimbursement Drug List (“**PRDL**”) must be made by the provincial healthcare security authorities. Patients purchasing List A drugs can directly obtain reimbursement under the basic medical insurance program. Patients purchasing List B drugs shall pay a certain percentage of the purchase price first and then obtain reimbursement under the basic medical insurance program.

National Essential Medicines List

On August 18, 2009, the MOH and eight other ministries and commissions in the PRC issued the Provisional Measures on the Administration of the National Essential Medicines List (Interim) (《國家基本藥物目錄管理辦法(暫行)》), which was amended to the Provisional Measures on the Administration of the National Essential Medicines List (《國家基本藥物目錄管理辦法》) on February 13, 2015, and the Guidelines on the Implementation of the National Essential Medicines List System (《關於建立國家基本藥物制度的實施意見》), which aims to promote essential medicines sold to consumers at fair prices in the PRC and ensure that the general public in the PRC has equal access to the drugs contained in the National Essential Medicines List. The NHC promulgated the National Essential Medicines List (2026) (《國家基本藥物目錄(2026年版)》) (the “**National Essential Medicines List**”) on June 23, 2026 which will take effect on September 1, 2026, replacing the National Essential Medicines List (2018) (《國家基本藥物目錄(2018年版)》). According to these regulations, basic healthcare institutions funded by the government shall store up and use drugs listed in the National Essential Medicines List. The drugs listed in the National Essential Medicines List shall be purchased by the National Volume-Based Procurement and shall be subject to the price control by the NHSA. Remedial drugs in the National Essential Medicines List are all listed in the Medical Insurance Catalogue and the entire amount of the purchase price of such drugs is entitled to reimbursement.

Laws and Regulations on Intellectual Property

In terms of international conventions, the PRC has entered into (including but not limited to) the Agreement on Trade-Related Aspects of Intellectual Property Rights (《與貿易有關的知識財產權協定》), the Paris Convention for the Protection of Industrial Property (《保護工業產權巴黎公約》), the Madrid Agreement Concerning the International Registration of Marks (《商標國際註冊馬德里協定》) and the Patent Cooperation Treaty (《專利合作條約》).

Patent

Patents in the PRC are mainly protected by the Patent Law of the PRC (《中華人民共和國專利法》), which was promulgated by the SCNPC on March 12, 1984, last amended on October 17, 2020 and became effective on June 1, 2021, and the Implementation Rules of the Patent Law of the PRC (《中華人民共和國專利法實施細則》), which were promulgated by the State Council on June 15, 2001, last amended on December 11, 2023 and became effective on January 20, 2024. The Patent Law of the PRC and its Implementation Rules provide for three types of patents, “invention”, “utility model” and “design.” The duration of a patent right for “invention” is 20 years, the duration of a patent right for “utility model” is 10 years, and the duration of a patent right for “design” is 15 years, from the date of application.

Trade Secret

According to the Anti-Unfair Competition Law of the PRC (《中華人民共和國反不正當競爭法》), promulgated by the SCNPC in September 1993 and subsequently amended on November 4, 2017, April 23, 2019, June 27, 2025 and which will become effective on October 15, 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.

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Trademark

Pursuant to the Trademark Law of the PRC (《中華人民共和國商標法》) promulgated by the SCNPC on August 23, 1982, which was last amended on June 26, 2026 and will become effective on January 1, 2027, the period of validity for a registered trademark is 10 years, commencing from the date of registration.

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 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.

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 Information Industry on August 24, 2017 and came into effect on November 1, 2017, the Ministry of Industry and Information Technology is responsible for supervision and administration of domain name services in the PRC.

Laws and Regulations on Labor Protection and Social Insurance

General Labor Contracts Rules

According to the Labor Law of the PRC (《中華人民共和國勞動法》), which was promulgated by the SCNPC in July 1994 and last amended and came into effect in December 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.

Labor, Social Insurance and Housing Provident Funds

According to the Social Insurance Law of PRC (《中華人民共和國社會保險法》), which was promulgated by the SCNPC in October 2010 and last amended and came into effect in December 2018, and the Interim Regulation on the Collection and Payment of Social Insurance Premiums (《社會保險費徵繳暫行條例》), which was promulgated by the State Council in January 1999 and last amended in March 2019, and the Regulations on Management of Housing Provident Fund (《住房公積金管理條例》), which was promulgated by the State Council in April 1999 and last amended in March 2019, 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 and maternity insurance and to housing provident funds. Any employer who fails to make the required contributions may be fined and ordered to compensate the deficit within a stipulated time limit.

According to the Interpretation (II) of the Supreme People’s Court on Issues Concerning the Application of Law in the Trial of Labor Dispute Cases (《最高人民法院關於審理勞動爭議案件適用法律問題的解釋(二)》), which was promulgated by the Supreme People’s Court in July 2025 and came into effect in September 2025, an employer and an employee conclude an agreement, or an employee promises to an employer, that there is no need to pay social insurance premiums, such agreement or promise shall be determined invalid; where an employer fails to pay social insurance premiums in accordance with the law, and the relevant employee requests to terminate the labor

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contract and requests for the employer to pay economic compensation, the people’s court shall support such requests in accordance with the law. Where an employer, after making up the social insurance contributions in accordance with the law under the circumstances stipulated in the preceding paragraph, requests the employee to return the social insurance compensation already paid, the people’s court shall support such request in accordance with the law.

Prevention and Control of Occupational Diseases

The Prevention and Control of Occupational Diseases Law of the PRC (《中華人民共和國職業病防治法》) (the “**Prevention and Control of Occupational Diseases Law**”), which was promulgated by the SCNPC on October 27, 2001 and latest amended on December 29, 2018 (the “Prevention and Control of Occupational Diseases Law”), is the basic law for the prevention and control of occupational diseases. According to the Prevention and Control of Occupational Diseases Law, the budget for facilities for the prevention and control of occupational diseases of a construction project shall be included in the budget of the project and those facilities shall be designed, constructed and put into operation simultaneously with the main body of the project.

Laws and Regulations on Leasing

On December 1, 2010, the Ministry of Housing and Urban-Rural Development promulgated the Administrative Measures on Leasing of Commodity Housing (《商品房屋租賃管理辦法》), which became effective on February 1, 2011. According to such measures, the lessor and the lessee are required to complete property leasing registration and filing formalities within 30 days from execution of the property lease contract with the development authorities or real estate authorities of the municipality or county where the leased property is located. If a company fails to do as aforesaid, it may be ordered to rectify within a stipulated period, and if such company fails to rectify, a fine ranging from RMB1,000 to RMB10,000 may be imposed on each lease agreement.

According to the Civil Code of the PRC (《中華人民共和國民法典》), if the relevant parties fail to complete property leasing registration and filing formalities in accordance with the laws and regulations, the validity of the lease is not affected.

Laws and Regulations on Environmental Protection, Health and Safety

Environment Protection

The Environmental Protection Law of the PRC (《中華人民共和國環境保護法》) (the “**Environmental Protection Law**”), which was promulgated by the SCNPC on December 26, 1989 and last amended on October 24, 2023, came into effect on January 1, 2024, outlines the authorities and duties of various environmental protection regulatory agencies. The Ministry of Ecology and Environment is authorized to issue national standards for environmental quality and emissions, and to monitor the environmental protection scheme of the PRC.

Environmental Impact Appraisal

According to the Regulations on Environmental Protection Management for Construction Projects (《建設項目環境保護管理條例》), which was promulgated by the State Council on November 29, 1998, amended on July 16, 2017 and became effective on October 1, 2017, depending on the impact of the construction project on the environment, a construction employer shall submit an environmental impact report or an environmental impact statement, or file a registration form. According to the Environmental Impact Appraisal Law of PRC (《中華人民共和國環境影響評價法》) (the “**Environmental Impact Appraisal Law**”), which was promulgated by the SCNPC on October 28, 2002, amended on July 2, 2016 and December 29, 2018, for any construction projects that have an impact on the environment, an entity is required to produce either a report, or a statement, or a registration form of such environmental impacts depending on the seriousness of the effect that may be exerted on the environment.

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Completion and Acceptance

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

Fire Prevention

According to the Fire Control Law of the PRC (《中華人民共和國消防法》), promulgated by the SCNPC on April 29, 1998 and last amended with effect from April 29, 2021, design and construction of the fire control facilities for a construction work shall comply with the national fire control technical standards. The developer, designer, constructors and project supervisor of a construction project shall be responsible for the quality of the design and construction of the fire control facilities for the construction work according to the relevant laws.

Management of Pollutant Discharge

Pursuant to the Catalogue of Classified Management of Discharge Permits for Stationary Pollution Sources (2019 Version) (《固定污染源排污許可分類管理名錄(2019年版)》) issued by the Ministry of Ecology and Environment of the PRC and became effective on December 20, 2019, the State implements the primary management, simplified management and registration management of pollutant discharge permits based on the pollutant production, emission amount and the extent of environmental impact of the pollutant discharge entities.

Pursuant to the Regulations on the Administration of Pollutant Discharge Permits (《排污許可管理條例》) promulgated by the State Council on January 24, 2021 and became effective on March 1, 2021, based on the quantity of pollutants generated and discharged, their impacts on the environment and other factors, categorical administration of the pollutant discharge permit system is implemented to regulate pollutant-discharging entities. The entities that generate and discharge relatively small quantities of pollutants and have a relatively small impact on the environment shall fill in the pollutant discharge registration form (排污登記表) and are no longer required to obtain a pollutant discharge permit (排污許可證).

Laws and Regulations on Foreign Investment

Company Law of the PRC

The Company Law of the PRC (《中華人民共和國公司法》) (the “**Company Law**”) which was promulgated by the Standing Committee of the NPC on December 29, 1993, came into effect on July 1, 1994, revised on December 25, 1999, August 28, 2004, October 27, 2005 and December 28, 2013, October 26, 2018, December 29, 2023 respectively and the latest revision of which was implemented on July 1, 2024, governs the establishment, operation and management of companies in the PRC, including foreign-invested companies. Unless foreign investment laws provide otherwise, foreign-invested companies shall abide by the Company Law of the PRC.

Foreign Investment

The Regulations of the State Council on Foreign Investment (《國務院關於對外投資的規定》) were promulgated on May 5, 2026, and took effect on July 1, 2026. The Regulations balance development and security, establishing a unified framework to regulate all types of foreign investment by domestic enterprises, organisations and individual residents. They also standardise

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approval and filing procedures, as well as security review processes; implement penetrative supervision; and clarify that the Regulations apply mutatis mutandis to investments in Hong Kong, Macao and Taiwan. The Regulations also include measures to combat discrimination and counteract violations.

Foreign investment in the PRC is subject to the Catalogue of Industries for Encouraged Foreign Investment (2022 Version) (《鼓勵外商投資產業目錄(2022年版)》) (the “**Catalogue**”), amended on October 26, 2022 and effective since January 1, 2023 and the Special Administrative Measures for Foreign Investment Access (Negative List) (2024 Version) (《外商投資准入特別管理措施(負面清單)(2024年版)》) (the “**Negative List**”), promulgated on September 6, 2024 and effective since November 1, 2024, both of which issued by the National Development and Reform Commission (國家發展和改革委員會) (the “**NDRC**”) and the Ministry of Commerce of the PRC (中華人民共和國商務部) (the “**MOFCOM**”). The Catalogue and the Negative List lay out the basic framework for foreign investment in China, classifying businesses into three categories with regard to foreign investment: “encouraged,” “restricted,” and “prohibited.” Industries not listed in the Catalogue or the Negative List are generally deemed as falling into a fourth category, “permitted,” unless specifically restricted by other PRC laws and regulations. The Foreign Investment Law of the PRC (《中華人民共和國外商投資法》) (the “**FIL**”), promulgated by the National People’s Congress (全國人民代表大會) (the “**NPC**”) on March 15, 2019, effective since January 1, 2020, and the Implementation Regulations for the Foreign Investment Law of the PRC (《中華人民共和國外商投資法實施條例》) (the “**Implementation Regulations for FIL**”), promulgated by the State Council on December 26, 2019, effective since January 1, 2020, are the principal existing law and regulation governing foreign investment in the PRC. The FIL and the Implementation Regulations for FIL are enacted to further expand opening-up, actively promote foreign investment, protect legitimate rights and interests in foreign investment, and standardize foreign investment management.

On December 30, 2019, the Ministry of Commerce and the SAMR, jointly promulgated the Measures for Reporting Foreign Investment Information (《外商投資信息報告辦法》), which became effective on January 1, 2020. On December 19, 2020, the NDRC and the MOFCOM jointly promulgated the Measures on the Security Review of Foreign Investment (《外商投資安全審查辦法》), effective on January 18, 2021, setting forth provisions concerning the security review mechanism on foreign investment, including the types of investments subject to review, review scopes and procedures, among others.

Laws and Regulations on Overseas Investment

Pursuant to the Measures for the Administration of Overseas Investment (《境外投資管理辦法》) issued by the MOFCOM on March 16, 2009, and amended on September 6, 2014, and the Administrative Measures for Overseas Investment by Enterprises (《企業境外投資管理辦法》) issued by the NDRC on December 26, 2017, and effective from March 1, 2018, if an enterprise in the PRC intends to make outbound investments, it shall be subject to approval or filing for the project, report relevant information, and cooperate in the supervisory inspections.

Laws and Regulations on Foreign Exchange and Taxation

Foreign Exchange

On January 29, 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 became effective on April 1, 1996 and was amended on January 14, 1997 and August 5, 2008. 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.

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On November 19, 2012, the SAFE issued the Circular of Further Improving and Adjusting Foreign Exchange Administration Policies on Foreign Direct Investment (《國家外匯管理局關於進一步改進和調整直接投資外匯管理政策的通知》) (the “**SAFE Circular 59**”), which came into effect on December 17, 2012 and was revised on May 4, 2015, October 10, 2018 and partially abolished on December 30, 2019. The SAFE Circular 59 aims to simplify the foreign exchange procedure and promote the facilitation of investment and trade. Later, the SAFE promulgated the Circular on Further Simplifying and Improving Foreign Exchange Administration Policies in Respect of 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》) on February 13, 2015, which was partially abolished on December 30, 2019 and prescribed that the bank instead of SAFE can directly handle the foreign exchange registration and approval under foreign direct investment while SAFE and its branches indirectly supervise the foreign exchange registration and approval under foreign direct investment through the bank.

On May 10, 2013, the SAFE issued the Administrative Provisions on Foreign Exchange in Domestic Direct Investment by Foreign Investors (《外國投資者境內直接投資外匯管理規定》) (the “**SAFE Circular 21**”), which became effective on May 13, 2013, amended on October 10, 2018 and partially abolished on December 30, 2019. The SAFE Circular 21 specifies that the administration by SAFE or its local branches over direct investment by foreign investors in the PRC must be conducted by way of registration and banks must process foreign exchange business relating to the direct investment in the PRC based on the registration information provided by SAFE and its branches.

According to the Notice of the State Administration of Foreign Exchange on Issues Concerning the Foreign Exchange Administration of Overseas Listing (《國家外匯管理局關於境外上市外匯管理有關問題的通知》) issued by the SAFE on December 26, 2014, a domestic company shall, within 15 business days from the date of the end of its overseas listing issuance, register the overseas listing with the local branch office of the State Administration of Foreign Exchange at the place of its establishment; the proceeds from an overseas listing of a domestic company may be remitted to the domestic account or deposited in an overseas account, but the use of the proceeds shall be consistent with the content of the document and other disclosure documents.

On June 9, 2016, SAFE issued the Notice of the State Administration of Foreign Exchange on Reforming and Standardizing the Foreign Exchange Settlement Management Policy of Capital Account (《國家外匯管理局關於改革和規範資本項目結匯管理政策的通知》) (the “**SAFE Circular 16**”), which came into effect on the same day and was partially amended according to Notice of the State Administration of Foreign Exchange on Further Deepening Reforming to Facilitate Cross-border Trade and Investment (《國家外匯管理局關於進一步深化改革促進跨境貿易投資便利化的通知》) promulgated by the SAFE on December 4, 2023. The SAFE Circular 16 provides that discretionary foreign exchange settlement applies to foreign exchange capital, foreign debt offering proceeds and remitted foreign listing proceeds, and the corresponding RMB capital converted from foreign exchange may be used to extend loans to related parties or repay inter-company loans (including advances by third parties).

On October 23, 2019, SAFE promulgated the Notice on Further Facilitating Cross-Board Trade and Investment (《國家外匯管理局關於進一步促進跨境貿易投資便利化的通知》), which became effective on the same date (except for Article 8.2, which became effective on January 1, 2020) and was partially amended according to Notice of the State Administration of Foreign Exchange on Further Deepening Reforming to Facilitate Cross-border Trade and Investment (《國家外匯管理局關於進一步深化改革促進跨境貿易投資便利化的通知》) promulgated by the SAFE on December 4, 2023.

On September 15, 2025, SAFE promulgated the Notice of the State Administration of Foreign Exchange on Matters Concerning Deepening the Reform of Foreign Exchange Administration for Cross-Border Investment and Financing (《國家外匯管理局關於深化跨境投融資外匯管理改革有關事宜的通知》).

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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, came into effect on January 1, 2008 and was amended on February 24, 2017 and 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, came into force on January 1, 2008 and were 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 is obtained outside the PRC but has an actual connection with the set-up institutions or sites.

Value-Added Tax (the “VAT”)

Pursuant to the Provisional Regulations of the PRC on Value-added Tax (《中華人民共和國增值稅暫行條例》) amended in November 2017, and the Detailed Rules for the Implementation of the Interim Regulations of the PRC on Value-Added Taxes (《中華人民共和國增值稅暫行條例實施細則》) amended in October 2011, all entities or individuals engaged in the sale of goods, provision of processing, repair and maintenance services, or importation of goods within China shall be value-added tax taxpayers and subject to value-added tax in accordance with relevant laws and regulations. Through the value-added tax reform in China, value-added tax rates have undergone multiple adjustments and value-added tax are regulated by the Value-Added Tax Law of the PRC (《中華人民共和國增值稅法》), which was implemented in January 2026.

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》), which came into effect on February 15, 2022.

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.

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According to the Measures for Standard Contract for Outbound Transfer of Personal Information (《個人信息出境標準合同辦法》) issued by the CAC on February 22, 2023 and effective from June 1, 2023, to provide personal information to an overseas recipient through the conclusion of the standard contract, a personal information processor shall meet all of the following circumstances: (i) it is not a CIIO; (ii) it has processed the personal information of less than one million individuals; (iii) it has cumulatively provided the personal information of less than 100,000 individuals to overseas recipients since January 1 of the previous year; and (iv) it has cumulatively provided the sensitive personal information of less than 10,000 individuals since January 1 of the previous year.

According to the Provisions on Promoting and Regulating Cross-border Data Flows (《促進和規範數據跨境流動規定》), which was promulgated by the CAC on March 22, 2024 and came into effect on the same day, if the data have not been informed or publicly announced as important data by relevant departments or regions, data handlers are not required to declare security assessment for cross-border provision of the data as important data.

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. 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.

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, 2016 and effective on June 1, 2017, 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

Securities Law of the PRC

The Securities Law of the People’s Republic of China (《中華人民共和國證券法》) (the “**Securities Law**”) took effect on July 1, 1999 and was revised on August 28, 2004, October 27, 2005, June 29, 2013, August 31, 2014 and December 28, 2019, respectively. The latest revised Securities Law came into effect on March 1, 2020. The Securities Law comprehensively regulates activities in the PRC securities market. Article 224 of the Securities Law provides that domestic enterprises shall comply with the relevant provisions of the State Council to list their shares outside the PRC. Currently, the issuance and trading of foreign issued shares (including H shares) are mainly governed by the rules and regulations promulgated by the State Council and the CSRC.

Overseas Listing

On February 17, 2023, the CSRC promulgated the Trial Administrative Measures of Overseas Securities Offering and Listing by Domestic Companies (《境內企業境外發行證券和上市管理試行辦法》) (the “**Overseas Listing Trial Measures**”), and relevant supporting guidelines, which came into effect on March 31, 2023. Any domestic company that is deemed to conduct overseas offering and listing activities shall file with the CSRC in accordance with the Overseas Listing Trial Measures. The Overseas Listing Trial Measures provide that the overseas securities offering and listing will be considered a direct overseas offering by a PRC domestic company if the issuer is a company limited by shares registered and established in mainland China. Pursuant to the Overseas Listing Trial Measures, an issuer shall file with the CSRC within three business days after its application for initial public offering is submitted to competent overseas securities regulators.

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Confidentiality and Archives Administration

On February 24, 2023, the CSRC, the MOF, the National Administration of State Secrets Protection and the National Archives Administration jointly released the revised Provisions on Strengthening the Confidentiality and Archives Administration of Overseas Securities Offering and Listing by Domestic Companies (《關於加強境內企業境外發行證券和上市相關保密和檔案管理工作的規定》) (the “**Archives Administration Provisions**”), which came into effect on March 31, 2023. According to the Archives Administration Provisions, the domestic companies shall establish and implement a solid confidentiality and archives administration system and take necessary measures to fulfill the confidentiality and archives administration obligations, and shall not divulge state secrets or work secrets of state organs, or harm the interests of the state or the public in the overseas securities offering and listing activities of such domestic companies.

In terms of providing accounting archives or copies thereof to any other entities or persons (such as securities companies, securities services providers and overseas regulators), the Archives Administration Provisions stipulate that relevant governmental procedures should be complied with. Any violation of the above regulations may subject the domestic companies to regulatory penalties under the Law of the PRC on Guarding State Secrets (《中華人民共和國保守國家秘密法》) and the Archives Law of the PRC (《中華人民共和國檔案法》) and even criminal liabilities to the extent applicable.

OVERVIEW OF LAWS AND REGULATIONS IN THE U.S.

In the U.S., the FDA regulates drugs and biologics. The Federal Food, Drug, and Cosmetic Act, the Public Health Service Act and other federal and state statutes and regulations, govern, among other things, the research, development, testing, manufacture, storage, recordkeeping, approval, labeling, promotion and marketing, distribution, post-approval monitoring and reporting, sampling, and import and export of biopharmaceutical drugs.

Approval Process

The FDA must approve any new drug or biologic before a manufacturer can market it in the U.S.. If a company does not comply with applicable U.S. requirements, it may be subject to a variety of administrative or judicial sanctions, such as FDA refuse to approve pending applications, warning or untitled letters, clinical holds, drug recalls, drug seizures, total or partial suspension of production or distribution, injunctions, fines, civil penalties, and criminal prosecution. The procedures a company must undertake prior to marketing a drug or biologic include: completion of pre-clinical research studies according to international council for harmonization of technical requirements for pharmaceuticals for human use (“**ICH Guidelines**”). Key animal safety assessment studies should be performed in accordance with the FDA’s good laboratory practice (“**GLP**”) regulations; completion of drug substance, drug product and manufacturing process studies according to ICH guidelines as well as production of clinical products under current good manufacturing practices (“**cGMP**”); submission to the FDA of an investigational new drug (“**IND**”) application for human clinical studies, which must be cleared by FDA before human clinical studies start. The sponsor should submit the development safety update report (“**DSUR**”) annually while the IND is open; approval of the study by an independent institutional review board (“**IRB**”) or ethics committee representing each clinical site before each clinical study starts; performance of adequate and well-quality controlled human clinical studies to establish the safety and efficacy of the drug for each indication to the FDA’s satisfaction; maintain communication with the FDA at key stages of product development, seek opinions and guidance from the FDA; submission of a NDA or BLA to the FDA, including payment of a significant user fee; technical review of the application by the FDA, including potentially an external advisory committee; satisfactory completion of FDA inspection of clinical sites, sponsors and the manufacturing facility or facilities to assess compliance with GCP and cGMP requirements; and FDA review and approval of the NDA or BLA.

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It generally takes companies many years to satisfy the FDA approval requirements, but this varies substantially based upon the type, complexity, and novelty of the product or disease. Pre-clinical studies include laboratory evaluation of a product’s chemistry, formulation, and toxicity, as well as animal studies to assess the characteristics and potential safety and activity of the drug or biologic. The conduct of the pre-clinical studies should comply with federal regulations and requirements, and the key safety pre-clinical studies should be conducted in GLP laboratories. The company submits the IND application to the FDA, including pre-clinical study reports, CMC research documents, proposed clinical study protocol, along with other information. Long term pre-clinical studies, such as animal studies of reproductive toxicity and carcinogenicity, may continue after submitting the initial IND. The FDA usually takes 30 days for technical review after the IND application submission and issues a letter of study may proceed if no objection. After that, the clinical studies can be initiated in humans. The FDA may, within the 30-day time period, raise concerns or questions on the proposed clinical protocol and place the study on clinical hold. In such a case, the outstanding concerns must be resolved before clinical study initiation.

Clinical Studies

Clinical studies involve administering the investigational drug or biologic to healthy volunteers or patients under the supervision of a qualified investigator. The company must conduct clinical studies: (i) in compliance with federal regulations; (ii) in compliance with GCP, an international standard meant to protect the rights and health of patients and to define the roles of clinical study sponsors, administrators, and monitors; as well as (iii) under protocols detailing the objectives of the trial, the safety monitoring parameters, and the effectiveness criteria.

The company must submit each protocol involving patients and subsequent protocol amendments to the FDA as part of the IND application. The FDA may order the temporary or permanent discontinuation of a clinical study at any time, or impose other sanctions, if it believes that the sponsor is not conducting the clinical study in accordance with FDA requirements or presents an unacceptable risk to the clinical study patients. The sponsor must also submit the study protocol and informed consent information for patients in clinical studies to an IRB for approval. An IRB may halt the clinical study, either temporarily or permanently, for failure to comply with the IRB’s requirements, or may impose other conditions.

A pivotal study is a clinical study that adequately meets regulatory agency requirements to evaluate a drug’s efficacy and safety to justify the approval of the drug. Generally, pivotal studies are Phase III studies, but the FDA may accept results from Phase II studies if the study design provides a well-controlled and reliable assessment of clinical benefit, particularly in situations in which there is an unmet medical need and the results are sufficiently robust.

The FDA, the IRB, or the clinical study sponsor may suspend or terminate a clinical study at any time on various grounds, including a finding that the research subjects are being exposed to an unacceptable health risk. Additionally, an independent group of qualified experts organized by the clinical study sponsor, known as a data and safety monitoring board, may oversee some clinical studies. This group provides authorization for whether or not a study may move forward at designated check points based on access to certain data from the study.

Submission of NDA or BLA and the FDA’s Decision

After the required clinical studies are completed, the sponsor can prepare and submit the NDA or BLA to the FDA. The company can launch the drug or biologic in the U.S. only after the NDA or BLA is approved. The NDA or BLA must include all relevant data from pertinent pre-clinical and clinical studies, including negative or inconclusive results as well as positive findings. In addition, the application must include detailed information regarding the product’s CMC development, and proposed labeling, among other relevant materials. Data can come from company-sponsored clinical

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studies, or from a number of alternative sources. To support marketing authorization, the data submitted must be sufficient in quality and quantity to establish the safety and effectiveness of the investigational drug to meet FDA’s requirements.

The cost of NDA or BLA preparation and submission is substantial. The submission of most NDAs and BLAs are additionally subject to a substantial application user fee, and the manufacturer and/or sponsor under an approved NDA or BLA are also subject to annual program user fees. The FDA typically increases these fees annually. Orphan drug designation entitles a party to financial incentives such as opportunities for grant funding towards clinical study costs, tax advantages, and user-fee waivers.

The FDA has 60 days from its receipt of an NDA or BLA to determine whether the application can be accepted based on the agency’s threshold determination that the application is sufficiently complete to permit substantive review. Once the FDA accepts the filing, the FDA begins an in-depth review. The FDA has agreed to certain performance goals in the review of NDAs and BLAs. Under the Prescription Drug User Fee Act (“**PDUFA**”), the FDA has a goal of responding to standard review applications within ten months after the 60-day filing review period, but this timeframe is often extended. The FDA reviews most applications for priority review drugs and biologics within six to eight months. Priority review can be applied to products that the FDA determines offer major advances in treatment, or provide a treatment where no adequate therapy exists.

The FDA may also refer applications for novel products that present difficult questions of safety or efficacy to an advisory committee. This is typically a panel that includes clinicians and other experts that will review, evaluate, and recommend whether the FDA should approve the application. The FDA is not bound by the recommendation of an advisory committee, but it generally follows such recommendations. Before approving an NDA or BLA, the FDA typically inspects one or more clinical sites to ensure compliance with GCP, and inspects the GMP status of the drug production and manufacturing facilities or equipment. The FDA will not approve the drug or biologic unless compliance with cGMPs is satisfactory and the application contains data demonstrating that the drug is safe and effective for the proposed indication, and in the case of biologics, safe pure and potent for the proposed clinical indication.

After the FDA evaluates the NDA or BLA and the manufacturing facilities, it issues either an approval letter or a complete response letter. A complete response letter indicates that the FDA has completed its review of the application, and the agency has determined that it will not approve the application in its present form. A complete response letter generally outlines the deficiencies in the submission and may require substantial additional clinical data and/or other significant, expensive, and time-consuming requirements related to clinical studies, pre-clinical studies and/or manufacturing. The FDA has committed to reviewing resubmissions of the NDA addressing such deficiencies in two or six months, depending on the type of information included. Even if such data is submitted, the FDA may ultimately decide that the application does not satisfy the criteria for approval. Also, the government may establish additional requirements, including those resulting from new legislation, or the FDA’s policies may be changed, which could delay or prevent regulatory approval of new products under development.

An approval letter authorizes commercial marketing of the drug with specific prescribing information for specific indications. The FDA may require a risk evaluation and mitigation strategy (“**REMS**”) to help ensure that the benefits of the drug or biologic outweigh the potential risks. REMS can include medication guides, communication plans for healthcare professionals, special training or certification for prescribing or dispensing, dispensing only under certain circumstances, special monitoring, and the use of patient registries. The requirement for REMS can materially affect the potential market and profitability of the product. Moreover, the FDA may condition approval on substantial post-approval study and surveillance to monitor the product’s safety or efficacy. Once granted, the FDA may withdraw approvals if the sponsor fails to comply with regulatory standards or identifies problems.

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Changes to conditions established in an approved application, including changes in indications, labeling, or manufacturing processes or facilities, can require submission and FDA approval of a new application or supplement before a company can implement the change. A supplement for a new indication typically requires clinical data similar to that in the original application, and the FDA uses the same procedures and actions in reviewing supplements as it does in reviewing NDAs and BLAs.

Post-approval Requirements

The FDA regulates products that are manufactured or distributed pursuant to FDA approvals and has specific requirements pertaining to recordkeeping, periodic reporting, sampling and distribution, advertising and promotion and reporting of adverse experience.

Manufacturers are subject to periodic or unannounced inspections by the FDA and relevant state agencies to ensure compliance with cGMP requirements. There are stringent regulatory controls governing modifications to the manufacturing process, and depending on the nature and impact of the change, prior FDA approval may be required before implementation. FDA regulations also require investigation and correction of any deviations from cGMP standards, and impose reporting and documentation requirements upon a company and any third-party manufacturers that it may use. Accordingly, manufacturers must continue to expend time, money and effort in the area of production and quality control to maintain compliance with cGMPs and other aspects of regulatory compliance.

The FDA may withdraw approval if a company does not comply with regulatory requirements and maintain standards or if problems occur after the product reaches the market. If a company or the FDA discovers previously unknown problems with a product, including adverse events of unanticipated severity or frequency, issues with manufacturing processes, or the company’s failure to comply with regulatory requirements, the FDA may revise the approved labeling to add new safety information; impose post-marketing studies or other clinical studies to assess new safety risks; or impose distribution or other restrictions under a REMS program. Other potential consequences may include: (i) restrictions on the marketing or manufacturing of the product, complete withdrawal from the market or recalls; (ii) fines, warning letters or holds on post-approval clinical studies; (iii) refusal to approve pending applications or supplements, or suspending or revoking approvals; (iv) product seizure or detention, or refusal to permit the import or export of products; or (v) injunctions or the imposition of civil or criminal penalties.

The FDA strictly regulates marketing, labeling, advertising, and promotion of drugs and biologics. Products may be promoted only for the approved indications and in accordance with the provisions of the approved label. The FDA and other agencies actively enforce the laws and regulations prohibiting the promotion of off-label uses. Violation of any of these laws and regulations could result in significant administrative, civil and criminal liability.

Orphan Drug Designation

The FDA may grant orphan drug designation to drugs intended to treat a rare disease or condition that affects fewer than 200,000 individuals in the U.S., or if it affects more than 200,000 individuals in the U.S., there is no reasonable expectation that the cost of developing and making the drug for this type of disease or condition will be recovered from sales in the U.S. Orphan drug designation entitles a party to financial incentives such as opportunities for grant funding towards clinical study costs, tax advantages, and user-fee waivers. In addition, if a drug receives FDA approval for the indication for which it has orphan drug designation, the drug may be entitled to orphan drug exclusivity, which means the FDA may not approve any other application to market the same drug for the same indication for a period of seven years, except in limited circumstances, such as a showing of clinical superiority over the drug with orphan exclusivity.

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Healthcare Reform

The United States and some foreign jurisdictions are considering or have enacted a number of reform proposals to change the healthcare system. There is significant interest in promoting changes in healthcare systems with the stated goals of containing healthcare costs, improving quality or expanding access.

In addition, there has been heightened governmental scrutiny in the United States of pharmaceutical pricing practices in light of the rising cost of prescription drugs and biologics. Such scrutiny has resulted in several presidential executive orders, Congressional inquiries and proposed and enacted federal and state legislation designed to, among other things, bring more transparency to product pricing, review the relationship between pricing and manufacturer patient programs, and reform government program reimbursement methodologies for products. For example, on July 4, 2025, the One Big Beautiful Bill Act (the “**OBBBA**”), was signed into law, which narrowed access to ACA marketplace exchange enrollment and declined to extend the ACA enhanced advanced premium tax credits that expired at the end of 2025, which, among other provisions in the law, are anticipated to reduce the number of Americans with health insurance. The OBBBA also is expected to reduce Medicaid spending and enrollment by implementing work requirements for some beneficiaries, capping state-directed payments, reducing federal funding, and limiting provider taxes used to fund the program. Congress is considering proposed legislation intended to further reduce healthcare costs with alternatives to replace the expired ACA subsidies. The IRA includes a provision requiring the Secretary of the United States Department of Health and Human Services (“**HHS**”) to negotiate prices with drug companies for a small number of single-source brand-name drugs that have been on the market for at least 7 years or biologics that have been on the market for at least 11 years that are covered under Medicare (the “**Medicare Drug Price Negotiation Program**”). The number of drugs subject to price negotiation will be 10 Part D drugs for 2026, another 15 Part D drugs for 2027, another 15 Part D and Part B drugs for 2028, and another 20 Part D and Part B drugs for 2029 and later years. These drugs will be selected from among the 50 drugs with the highest total Medicare Part D spending and the 50 drugs with the highest total Medicare Part B spending. The law establishes an upper limit for the negotiated price for a given drug or biologic, and specifies factors the Secretary of HHS is required to consider when negotiating these upper pricing limits. The IRA also imposes rebates under Medicare Part B and Medicare Part D that penalize manufactures for price increases that outpace inflation. Further, on December 7, 2023, an initiative to control the price of prescription drugs through the use of march-in rights under the Bayh-Dole Act was announced. At the state level, legislatures have increasingly passed legislation and implemented regulations designed to control pharmaceutical product pricing, including price or patient reimbursement constraints, discounts, restrictions on certain product access and marketing cost disclosure and transparency measures, and, in some cases, designed to encourage importation from other countries and bulk purchasing.