
REGULATORY OVERVIEW

OVERVIEW OF LAWS AND REGULATIONS IN THE PRC

This section summarizes the principal PRC laws, rules and regulations relevant to our business.

Pharmaceutical Regulatory Authorities

The major regulatory authorities of pharmaceutical industry in the PRC include the NMPA (formerly known as the CFDA), the NHC (formerly known as the National Health and Family Planning Commission) and National Healthcare Security Administration (the “NHSA”). The NMPA carries on responsibilities for pharmaceutical supervision of CFDA, its predecessor, as the principal pharmaceutical regulatory authority in charge of the pharmaceutical registration and supervision, including non-clinical research, clinical trial, marketing approval, production and circulation. The NHC is the chief healthcare regulator of PRC, which is primarily responsible for drafting national healthcare policies, regulating public health, medical services and health contingency system, coordinating the implementation of healthcare reform and overseeing the operation of medical institutions and practice of medical personnel. The NHSA, a new authority established in May, 2018 in accordance with the Institutional Reform Program of the State Council, is responsible for drafting and implementing policies, plans and standards on medical insurance, maternity insurance and medical assistance; administering healthcare fund; formulating a uniform medical insurance catalogue and payment standards on drugs, medical consumables and healthcare services; formulating and administering the bidding and tendering policies for drugs and medical consumables.

Laws and Regulations Relating to Drugs

Drug Administration

The PRC Drug Administration Law (《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”) on September 20, 1984, and latest amended on August 26, 2019, as well as the Regulation for the Implementation of the PRC Drug Administration Law (《中華人民共和國藥品管理法實施條例》) (the “Regulation for the Implementation of the Drug Administration Law”) issued by the State Council on August 4, 2002, and latest amended on January 16, 2026 and will become effective on May 15, 2026, have together laid down the legal framework for the administration of drugs, including the research, development, manufacturing and business operation for new drugs, and administer the pharmaceutical manufacturing enterprises, pharmaceutical operating enterprises, and medicinal preparations of medical institutions, along with the development, research, production, distribution, packaging, pricing and advertisements of drugs.

Non-Clinical Research and Animal Testing

The State Administration for Market Regulation (the “SAMR”) requires preclinical data to support registration applications for imported and domestic drugs. According to the Provisions for Drug Registration (《藥品註冊管理辦法》), issued by the SAMR on January 22, 2020, and became effective on July 1, 2020, non-clinical drug safety evaluation studies shall comply with the Good Laboratory Practice for Non-clinical Laboratory Studies (《藥物非臨床研究質量管理規範》). The latest GLP has been implemented by the CFDA since September 1, 2017, to improve the quality of non-clinical research. The Measures for Administration of Certification of the Good Laboratory Practice for Non-clinical Laboratory Studies (《藥物非臨床研究質量管理規範認證管理辦法》) promulgated on January 19, 2023 and implemented since July 1, 2023 by the NMPA, sets out the requirements for institutions to apply for GLP certification to conduct non-clinical drug research. Pursuant to the Administrative Regulations on Experimental Animals (《實驗動物管理條例》) issued by the State Science and Technology Commission (the “SSTC”, now known as the Ministry of Science and Technology, the “MST”) on November 14, 1988, and latest amended on March 1, 2017 by the State Council, the Administrative Measures on Good Practice of Experimental Animals

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(《實驗動物質量管理辦法》) jointly issued by the SSTC and the State Bureau of Technical Supervision (now known as SAMR) on December 11, 1997, and the Administrative Measures on the Certificate for Experimental Animals (Trial) (《實驗動物許可證管理辦法(試行)》) issued by MST and other regulatory authorities on December 5, 2001 and implemented since January 1, 2002, using and breeding experimental animals shall be subject to certain rules, and performing experiments on animals requires a Certificate for Use of Experimental Animals. Any entity without such certification must engage a qualified third party to conduct such non-clinical studies regulated under relevant laws and regulations.

Approval of Clinical Trials

Pursuant to the Provisions for Drug Registration, an applicant that applies for a drug clinical trial after completion of the pharmaceutical, pharmacological and toxicological research, etc., which support the drug clinical trial, shall submit relevant research materials according to the requirements for application materials. The application materials shall be accepted if they are deemed acceptable upon formal examination. The CDE shall organize pharmaceutical, medical and other technicians to review the accepted application for the drug clinical trial. Furthermore, according to the Provisions for Drug Registration, conduct of drug clinical trial shall be subject to the examination and consent by the ethics review committee. On February 18, 2023, the NHC, the Ministry of Education, the MST and the State Administration of Traditional Chinese Medicine jointly issued the Notice on the Promulgation of the Measures for the Ethical Review of Life Science and Medical Research Involving Humans (《關於印發涉及人的生命科學和醫學研究倫理審查辦法的通知》), stipulates the work of ethical review of life science and medical research involving humans conducted by medical and health institutions, institutions of higher education and scientific research institutes in PRC. Pursuant to the aforementioned promulgation, secondary or higher medical institutions and municipal-level or higher health institutions, as well as institutions such as colleges, universities, and research institutes that carry out life sciences and medical research involving humans, are the main entities responsible for the management of ethical review work, such entities shall establish ethics review committees to conduct ethical reviews of life sciences and medical research involving humans. Under the guidance of the Department of Health Science, Technology and Education of the NHC, the Office of the Medical Ethics Expert Committee of the NHC and the Chinese Hospital Association, issued the Guidances to the Construction of the Ethics Review Committee of the Clinical Trials Involving Humans (《涉及人的臨床研究倫理審查委員會建設指南》), which specifies that all clinical trials shall be inspected and approved by the ethics review committee before conducting. According to the Specifications for the Administration of Registration and Information Disclosure of Drug Clinical Trials (Trial) (《藥物臨床試驗登記與信息公示管理規範(試行)》) issued by the CDE on July 1, 2020, the applicant shall register clinical trial information on the Registration Platform in accordance with certain specifications before conducting drug clinical trials, and shall continuously update it based on the progress of the clinical trial.

Phases of Clinical Trials and Communication with the CDE

Pursuant to the Drug Administration Law, drug clinical trials shall be carried out in a clinical trial institution with corresponding conditions. The conditions that clinical trial institutions should satisfy shall mainly comply with the relevant requirements of the Administrative Regulations for Drug Clinical Trial Institutions (《藥物臨床試驗機構管理規定》), which came into effect on December 1, 2019. Such drug clinical trial institutions shall be subject to filing administration. The NMPA is responsible for setting up a filing management information platform for drug clinical trial institutions for registration, filing and operation management of drug clinical trial institutions, as well as the entry, sharing and disclosure of information on supervision and inspection of the drug regulatory authority and competent healthcare authority. According to the Provisions for Drug Registration, based on the drug's characteristics and the purpose of research, clinical trials of drugs consist of Phase I, II, III and IV clinical trials, as well as the bioequivalence trials, contents of which include clinical pharmacology research, exploratory clinical trials, confirmatory clinical trials and post-marketing research. Clinical trials shall be conducted in accordance with the provisions of the

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PRC GCP. Pursuant to the Administrative Measures for Communication on Drug Development and Technical Reviews (《藥物研發與技術審評溝通交流管理辦法》) revised by the CDE on April 1, 2026, during the research and development, and application for registration stages of innovative drugs, the applicant may propose communication sessions with the CDE.

International Multi-Center Clinical Trial

Pursuant to the International Multi-Center Clinical Trial Guidelines (Trial) (《國際多中心藥物臨床試驗指南(試行)》) issued by the CFDA on January 30, 2015 and effective from March 1, 2015, applicants may simultaneously conduct clinical trials in different centers of multiple regions using the same clinical trial protocol, or conduct regional clinical trials simultaneously in multiple centers in different countries within a certain region using the same protocol. 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, to guide work related to the acceptance of overseas clinical trial data as clinical evaluation reference by the applicant applying for the registration of drugs in the PRC.

Registration and Application of New Drugs

According to the Provisions for Drug Registration, the drug registration administration shall be categorized into traditional Chinese drugs, chemical drugs and biological products; among them, the registration of chemical drugs shall be categorized into innovative chemical drugs, improved new chemical drugs, generic chemical drugs, etc.. Pursuant to the Reform Plan for Registration Category of Chemical Medicine (《化學藥品註冊分類改革工作方案》) issued by the CFDA on March 4, 2016, new registration of chemical drugs are divided into 5 categories. According to the Registration Classification of Chemical Drugs and the Reporting Information Requirements (《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 such requirements 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. According to the Provisions for Drug Registration, the applicant may submit an application for permission of the drugs registration for marketing (NDA) upon determining quality standards after completion of researches on pharmacy, pharmacology, toxicology, and clinical trials of drugs that support the registration of drugs for marketing and completing the commercial-scale production process verification and preparations for receiving on-site inspections. The NDA shall be evaluated by the NMPA in accordance with applicable laws and regulations.

Accelerated Approval for Clinical Trial and New Drug Registration

The Opinions of the State Council on the Reform of Evaluation and Approval System for Drugs and Medical Devices (《國務院關於改革藥品醫療器械審評審批制度的意見》) issued by the State Council on August 9, 2015, specified the tasks of enhancing the standards of approval for, among others, drug registration, accelerating the evaluation and approval process for innovative drugs, and improving the approval for clinical trials of drugs. The Announcement on Several Policies on Drug Registration Review and Approval (《關於藥品註冊審評審批若干政策的公告》) issued by the CFDA on November 11, 2015, provided fast-track clinical trial approvals and drug registration pathways for certain new drug applications such as innovative new drugs treating malignant tumors (cancers), severe infectious diseases and rare diseases. On October 8, 2017, the General Office of the Central Committee of the Communist Party of China and the General Office of the State Council jointly issued the Opinions on Deepening the Reform of the Evaluation and Approval System and Encouraging 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》), aiming to simplify the clinical trial procedures and shorten the time. For new drugs and medical devices urgently needed in clinical practice and drugs and medical devices used for the treatment of rare diseases, the evaluation and approval procedures for marketing shall be accelerated. Furthermore, according to the Announcement on Matters Concerning the Optimization of Drug Registration Review and Approval (《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 drug

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approval process shall be further streamlined and expedited. On July 24, 2018, the Announcement of the National Medical Products Administration on Adjusting the Review and Approval Procedures for Drug Clinical Trials (《國家藥品監督管理局關於調整藥物臨床試驗審評審批程序的公告》) issued by the NMPA further making adjustments to matters relating to the review and approval of drug clinical trials. Pursuant to the provisions of the Procedures for the Evaluation of Breakthrough Therapeutic Drugs (Trial) (《突破性治療藥物審評工作程序(試行)》) issued by the NMPA on July 7, 2020, during the clinical drug trials, the applicant is allowed to apply for the breakthrough therapeutic drug procedure during Phase I and Phase II clinical trials and normally no later than the commencement of Phase III clinical trials for the innovative or improved drugs etc., which are used for the prevention and treatment of diseases that seriously endanger life or seriously affect quality of life and there is no effective means of prevention and treatment or there is sufficient evidence to show a significant clinical advantage over existing treatment approach.

On September 9, 2025, the Announcement of the NMPA on Matters Related to Optimizing the Review and Approval of Clinical Trials for Innovative Drugs (《國家藥監局關於優化創新藥臨床試驗審評審批有關事項的公告》) further supporting clinical value-oriented innovative drug research and development, improving the quality and efficiency of clinical development, and therefore including clinical trial applications for traditional Chinese medicine, chemical drug, and biological product category 1 innovative drugs that meet certain requirements and can submit application materials as required into a fast-track process for review and approval within 30 working days after acceptance.

Marketing Authorization Holder System

Pursuant to Drug Administration Law, the drug marketing authorization holder system has been implemented for drug management in the PRC. The drug marketing authorization holder refers to an enterprise or a drug research and development institution that has obtained the drug registration certificate, which is responsible for the safety, efficacy and controlled quality of medicine during the whole process of drug development, production, operation and utilization processes in accordance with laws. The marketing authorization holders shall be liable for non-clinical study, clinical trial, manufacturing and business operation, post-market launch study, monitoring, reporting and handling of adverse reactions of the pharmaceuticals. The legal representative and the key person-in-charge of a drug marketing authorization holder shall be fully responsible for the quality of drugs. The drug marketing authorization holders may produce drugs by themselves or entrust drug manufacturers with the production of such drugs; they may sell drugs with a drug registration permit on their own or through entrusting qualified drug operating enterprises. Blood products, anesthetics, psychotropic drugs, toxic drugs for medical use and pharmaceutical precursor chemicals are in principle not allowed to be produced through entrustment. The drug marketing authorization holders shall establish a pharmaceutical quality assurance system, equipped with specialized staff solely responsible for the management of drug quality; the drug marketing authorization holders shall regularly review the quality management system of the drug manufacturer and the drug distributor, and supervise their continuous quality assurance and control capabilities. The drug marketing authorization holders, drug manufacturers, drug distributors and medical institutions shall establish and implement a drug traceability system, provide traceability information in accordance with regulations and ensure that drugs are traceable.

Filing for Gathering and Collection of Human Genetic Resources

Pursuant to the Service Guide for Administrative Licensing of Gathering, Collection, Deal, Export and Exit Approval 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 MST on July 2, 2015, the sampling, collection or research activities of human genetic resources by a foreign-invested sponsor fall within the scope of international cooperation, and the cooperating organization of China shall apply for approval of the China Human Genetic Resources Management Office through the online system. Furthermore, the MST promulgated the Notice on Updating the Service Guide, Filing, and Scope and Procedures for Prior Reporting of Administrative Licensing Matters for Human Genetic

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Resources (《關於更新人類遺傳資源行政許可事項服務指南、備案以及事先報告範圍和程序的通知》) on July 14, 2023, enhancing the service quality of human genetic administrative approvals and facilitating applicants’ understanding of application requirements. According to the HGR Regulation, as promulgated by the State Council on May 28, 2019, revised on March 10, 2024, and became effective on May 1, 2024, in order to obtain marketing authorization for relevant drugs and medical devices in China, no approval is required in international clinical trial cooperation using China’s human genetic resources at clinical institutions without export of human genetic resources materials. On May 26, 2023, the MST issued the Implementing Rules of the HGR Regulation (《人類遺傳資源管理條例實施細則》), which became effective from July 1, 2023, further specifying the requirements for the collection, preservation, use, and outbound offering of the human genetic resources in the PRC. On October 17, 2020, the SCNPC promulgated the Biosecurity Law which became effective on April 15, 2021 and was revised on April 26, 2024, establishing a comprehensive legislative framework on the current regulations in the areas including epidemic control of human, animal and plant infectious diseases, security of biotechnology research, development and application, biosafety management of pathogenic microbiology laboratories, security management of human genetic resources and biological resources, countermeasures against microbial resistance and prevention of bioterrorism and threat of biological weapons.

Drug Manufacturing License

According to the Drug Administration Law and its implementation, when engaging in pharmaceutical manufacturing activities, an enterprise must obtain a Drug Manufacturing License granted by the drug regulatory authority of the people’s government of the province, autonomous region, or municipality directly under the central government at the place where the enterprise is located. No medicinal products shall be manufactured without a Drug Manufacturing License. The Drug Manufacturing License shall be valid for five years. Where continued drug manufacturing is required upon expiration of the validity period, a certificate holder shall, six months prior to the expiration, apply for renewal of the Drug Manufacturing License in accordance with the regulations of the drug regulatory department under the State Council.

GMP

The GMP for Drugs (《藥品生產質量管理規範》) was first promulgated on March 17, 1988, subsequently revised on December 28, 1992, by the Ministry of Health (the “MOH”). After the establishment of the NMPA, the GMP for Drugs was amended on June 18, 1999 and became effective on August 1, 1999. The GMP for Drugs, which was amended by the MOH on January 17, 2011 and became effective on March 1, 2011, stipulates the basic standards for pharmaceutical production. On August 2, 2011, the CFDA issued the Circular on Printing and Distributing the Administrative Measures for the Certification of GMP for Drugs (《關於印發藥品生產質量管理規範認證管理辦法的通知》), which provided that newly established drug manufacturers, or existing drug manufacturers that wish to expand manufacturing scope or build new workshops shall apply for the GMP certification in accordance with the Regulation for the Implementation of the Drug Administration Law. On December 30, 2015, the CFDA issued the Notice on Effectively Implementing the GMP for Drugs (《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 those drug manufacturers that failed to obtain the GMP certificates shall not be granted the drug manufacturing license. On November 29, 2019, the NMPA issued the Announcement on Matters relating to the Implementation of the Drug Administration Law (《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》), which confirmed that the GMP certification would be canceled from December 1, 2019, and no application for GMP certification would be accepted and no GMP certificate would be granted. However, according to the Drug Administrative Law, drug manufacturers shall still comply with the GMP, establish and improve the GMP system, and ensure the whole drug production process is consistently in compliance with statutory requirements. The Administrative Measures for Drug Inspection (Trial) (《藥品檢查管理辦法(試行)》) was issued by the NMPA on May 24, 2021, and revised on July 19, 2023, and the Administrative Measures for the Certification of GMP was repealed accordingly. The Administrative Measures for Drug Inspection (Trial) provided that onsite inspections shall be

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conducted pursuant to the GMP on a drug manufacturer applying for the Drug Manufacturing License for the first time, while for the drug manufacturers applying for the renewal of Drug Manufacturing License, the review shall be conducted based on the risk management principles, in combination with the drug manufacturers’ compliance with the laws and regulations of drug administration, and the operation of the GMP and quality management system, and inspections on the drug manufacturers’ conformity to the GMP may be conducted where necessary.

Entrusted Manufacturing of Drugs

Pursuant to the Measures on the Supervision and Administration of the Manufacture of Drugs (《藥品生產監督管理辦法》), promulgated by the SAMR on December 11, 2002, with latest amendments on January 22, 2020 effective from July 1, 2020, the drug marketing authorization holders may entrust qualified drug manufacturing enterprises with drug production, provided that they shall evaluate the entrusted party’s quality assurance capabilities and risk management capabilities. They shall also sign the quality agreement and the entrustment agreement with the entrusted party in accordance with the requirements of the guidelines for entrusted drug production promulgated by the NMPA and supervise the fulfillment of the obligations agreed by the entrusted party in the agreement; the entrusted party shall not recommission the production of the drugs it agreed to be entrusted to another third party.

Drug Distribution Management

On September 27, 2023, the Measures for the Supervision and Administration of Drug Circulation was repealed upon the formal implementation of 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》) was issued by the SAMR and took into effect on January 1, 2024, which clarifies the operation management of drugs.

Drug Technology Transfer

The Administrative Regulations for Technology Transfer Registration of Drugs (《藥品技術轉讓註冊管理規定》) issued by the former CFDA and being effective on August 19, 2009 standardizes the registration process of drug technology transfer and stipulated the application, evaluation, examination, approval and supervision of registration for drug technology transfer. The application for drug technology transfer shall be submitted to the provincial drug regulatory authority, and the ultimate approval decision shall be made by the NMPA based on the comprehensive opinions of the center for drug evaluation. A letter of approval and a drug approval number for the supplementary application shall be issued for eligible applications.

Other Relevant Regulations in the PRC Pharmaceutical Industry

Coverage of the NMIP

The NMIP was first adopted according to the Decision of the State Council on the Establishment of the Urban Employee Basic Medical Insurance Program (《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. 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 on Integrating the Basic Medical Insurance Systems for 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. Furthermore, on July 26, 2024, the Guiding Opinions on Improving the Long-term Mechanism for Basic Medical Insurance Participation (《關於健全基本醫療保險參保長效機制的指導意見》) issued by the General Office of the State Council provides directives on implementing citizens’

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rights and obligations to participate in basic medical insurance in accordance with the law, and on standardizing and unifying the management services for insurance participation. Pursuant to Interim Measures for the Administration of Drug Use in Basic Medical Insurance (《基本醫療保險用藥管理暫行辦法》) issued by the NHSA on July 30, 2020, and became effective on September 1, 2020, the scope of medical insurance coverage for pharmaceutical products needs to be managed through the formulation of the Medical Insurance Catalogue (《基本醫療保險藥品目錄》), the cost of drugs falls under which shall be paid by the Basic Medical Insurance Fund in accordance with regulations in the PRC. The administrative department of medical insurance under the State Council established and improved the dynamic adjustment mechanism so that the Medical Insurance Catalogue shall be adjusted once a year in principle.

National Essential Drug List

According to the Circular on the Printing and Distribution of the Administrative Measures for the National Essential Drug List (《關於印發國家基本藥物目錄管理辦法的通知》) issued on February 13, 2015, the Opinions of the General Office of the State Council on Improving the National Essential Drugs System (《國務院辦公廳關於完善國家基本藥物制度的意見》) issued on September 13, 2018 and the National Essential Drug List (2018 version) (《國家基本藥物目錄(2018年版)》) (the “National Essential Drug List”) issued by the NHC on September 30, 2018, basic healthcare institutions funded by the government, shall store up and use drugs listed in the National Essential Drug List. The drugs listed in the National Essential Drug List shall be purchased by centralized tender process and shall be subject to the price control by the NDRC. The National Drug Catalog for 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》), which promulgated by the NHSA and the Ministry of Human Resources and Social Security on December 5, 2025, sets forth the payment standard for pharmaceutical products under such insurances.

Centralized Procurement of Drugs

According to the Certain Regulations on the Trial Implementation of Centralized Tender Procurement of Drug by Medical Institutions (《醫療機構藥品集中招標採購試點工作若干規定》) jointly issued by authorities including the MOH on July 7, 2000, non-profit medical institutions run by the people’s governments at county level and above are required to implement centralized tender procurement of drugs. 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. All public medical institutions shall participate in the centralized procurement of drugs, with reference to the requirements of the management of designated social medical institutions and designated pharmacies in accordance with the management of designated agreements for medical insurance.

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 Guiding Opinions on Effectively Conducting Current Drug Pricing Reform (《關於做好當前藥品價格管理工作的意見》), which was promulgated by the NHSA on November 26, 2019, required the continuous improvement of the market-oriented drug pricing mechanism and the establishment of a sound, regularized drug pricing supervision system.

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Two-invoice System

Pursuant to the 2016 Key Tasks for Deepening the Reform of the Pharmaceutical and Healthcare System (《深化醫藥衛生體制改革2016年重點工作任務》) issued by the General Office of the State Council on April 21, 2016, in order to optimize the order of purchasing and selling pharmaceutical products and reduce circulation steps, the implementation of the “two-invoice system” shall be constructed throughout the pilot provinces for comprehensive healthcare reform and actively encouraged in the public hospitals of the pilot cities therefor. According to the Opinions on the Implementation of the “Two Invoice System” in 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)》) issued by Deepen Medical and Healthcare System Reform Leading Group Office of the State Council on December 26, 2016, the “Two Invoice System” refers to the system that requires one invoice to be issued from pharmaceutical manufacturers to pharmaceutical distributors and the other invoice to be issued from pharmaceutical distributors to medical institutions. The allocation of drugs between a pharmaceutical distribution group enterprise and its wholly-owned (holding) subsidiaries or among its wholly-owned (holding) subsidiaries may not be regarded as a process for which an invoice should be issued, but one invoice is allowed to be issued at most. According to the Notice on Issuing the Key Tasks for the Second Half of 2023 in Deepening the Medical and Health System Reform (《關於印發深化醫藥衛生體制改革2023年下半年重點工作任務的通知》), which was jointly issued by the NHC, NDRC, the Ministry of Finance and the Ministry of Human Resources and Social Security on July 21, 2023, measures related to the “Two-invoice System” shall be further researched and improved during the procedure of deepening the medical and health system reform.

Other Significant PRC Regulations Affecting Our Business Activities in the PRC

Laws and Regulations relating to PRC Company Law and Foreign Investment

The establishment, operation and management of enterprises in the PRC are governed by the PRC Company Law, which was promulgated by the SCNPC on December 29, 1993 and became effective on July 1, 1994. It was latest amended on December 29, 2023. Pursuant to the PRC Company Law, companies are classified into two categories, namely limited liability companies and limited companies by shares. The PRC Company Law shall also apply to foreign-invested limited liability companies and companies limited by shares. According to the PRC Company Law, the provisions otherwise prescribed by the laws on foreign investment shall prevail. On March 15, 2019, the National People’s Congress (the “NPC”) issued the Foreign Investment Law of the PRC (《中華人民共和國外商投資法》) (the “Foreign Investment Law”), which came into effect on January 1, 2020. Since then, the Foreign Investment Law has become the basic law regulating foreign-invested enterprises wholly or partially invested by foreign investors. The PRC implements a pre-access national treatment plus exceptions list management system for foreign investment, which means that foreign investors and their investments are given treatment no less favorable than that accorded to domestic investors and their investments at the stage of investment access; while the “exceptions list” refers to special administrative measures for access of foreign investment in specific fields as stipulated by the PRC. The national treatment shall be granted to foreign investments outside of the exceptions list.

Laws and Regulations on Outbound Investment

Pursuant to the Administrative Measures on Outbound Investments (《境外投資管理辦法》) issued by the MOC on March 16, 2009, and amended on September 6, 2014, and the Administrative Measures for the Outbound Investments of 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. Non-sensitive projects directly conducted by domestic enterprise in China, involving direct contribution of assets or rights and interests or provision of financing or security, shall be subject to filing. On May 5, 2026, the State Council published the Regulation on Outbound Investment (《國務院關於對外投資的規定》), which took effect from July 1, 2026. The Regulation on Outbound Investment implements the whole-process supervision by category/tier, and incorporates approval, filing, information reporting, business operation standardization, security review and other requirements into a unified regulatory framework.

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Laws and Regulations relating to Foreign Exchange

The principal law governing foreign currency exchange in the PRC is the Foreign Exchange Administration Regulations of the PRC (《中華人民共和國外匯管理條例》) (the “Foreign Exchange Administration Regulations”). The Foreign Exchange Administration Regulations were enacted by the State Council on January 29, 1996 and implemented on April 1, 1996. On January 14, 1997 and August 5, 2008, the State Council amended the Foreign Exchange Administration Regulations. According to the Foreign Exchange Administration Regulations, international payments in foreign currencies and transfer of foreign currencies under current items shall not be restricted. Foreign currency transactions under the capital account are still subject to limitations and require approvals from, or registration with, the SAFE or its local counterpart and other relevant PRC governmental authorities. 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 and implemented 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 Foreign Exchange Administration at the place of its establishment. The Circular of SAFE on Reforming and Regulating Policies on the Control over Foreign Exchange Settlement of Capital Accounts (《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 was promulgated on June 9, 2016, and revised on December 4, 2023, by the SAFE, stipulates that the foreign exchange proceeds under the capital account of and the Renminbi funds obtained from foreign exchange settlement by a domestic institution may be used for expenditures under the current account within its business scope or the expenditures under the capital account permitted by the laws and regulations. On December 24, 2025, the PBOC and the SAFE jointly issued the Notice on Issues Concerning the Fund Management for Overseas Listings of Domestic Enterprises (《中國人民銀行國家外匯管理局關於境內企業境外上市資金管理有關問題的通知》), which took effect on April 1, 2026, to further facilitate domestic enterprises in efficiently raising funds in overseas financial markets. According to the aforementioned Notice, the proceeds from overseas listings, such as funds raised and income from share reductions or transfers, may be repatriated in either foreign currency or Renminbi, and the listing entities participating in the Full Circulation of H shares shall distribute dividends to domestic shareholders domestically in Renminbi. Additionally, the Notice specifies that funds raised from overseas listings and repatriated in foreign currency may be independently converted and used, and listing entities may autonomously choose their approaches to managing exchange rate risks within China. Upon the formal implementation of such Notice, the Notice of the SAFE 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 was repealed.

Distribution of Dividends

Pursuant to the provisions of the PRC Company Law, when distributing each year’s profits after taxation, the company shall set aside 10% of its profits for the company’s statutory common reserve fund until the fund has reached more than 50% of the company’s registered capital. When the company’s statutory common reserve fund is not sufficient to make up for the company’s losses for the previous years, the current year’s profits shall first be used to make good the losses before any allocation is set aside for the statutory common reserve fund. After the company has made allocations to the statutory common reserve fund from its profits after taxation, it may, upon the resolution at a shareholders’ general meeting, make further allocations from its profits after taxation to the discretionary common reserve fund. After the company has made good its losses and made allocations to its common reserve fund, the remaining profits after taxation shall be distributed to the shareholders. According to the Notice on Matters Concerning the Deepening of Foreign Exchange Management Reforms for Cross-Border Investment and Financing (《關於深化跨境投融資外匯管理改革有關事宜的通知》) issued by the SAFE, for foreign-invested enterprises, legally generated profits in foreign currency and the reinvestment within the PRC of foreign exchange profits lawfully obtained by foreign investors may be transferred into the capital account of the invested enterprise or the capital project settlement account of the equity transferor. The use of funds shall be handled in accordance with the relevant account management requirements.

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Laws and Regulations Related to Intellectual Property Rights

Patents

Pursuant to PRC Patent Law (《中華人民共和國專利法》) promulgated by the SCNPC on March 12, 1984, and latest amended on October 17, 2020, and became effective from June 1, 2021, and the Implementation Rules of the PRC Patent Law (《中華人民共和國專利法實施細則》) promulgated by the State Council on June 15, 2001, with the latest amendments on December 11, 2023, effective from January 20, 2024, the patents in the PRC refer to invention, utility model and design. The Patent Office under the State Intellectual Property Office is responsible for receiving, examining, and approving patent applications. A patent is valid for a twenty-year term for an invention, a ten-year term for a utility model, or a fifteen-year term for a design, commencing from their respective application dates. According to the PRC Patent Law, for the purpose of public health, the Patent Administration Department under the State Council may grant a compulsory license to manufacture a drug which has been granted a patent right and to export it to the countries or regions specified in related international conventions in which the PRC is a contracting member. According to the provisions of the PRC Patent Law and the Implementation Rules of the PRC Patent Law, for the purpose of compensating for the time taken to examine and approve a new drug to be marketed, the patent administrative department under the State Council shall grant compensation to the validity period of patent rights for the invention patents of new drugs approved to be marketed in the PRC upon request of the patentee. The compensation period shall not exceed five years, and the total validity period of patent rights after a new drug is approved to be marketed shall not exceed fourteen years.

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, and amended on February 22, 1993, October 27, 2001 and August 30, 2013, respectively, and last amended on April 23, 2019 with the latest amendment effective on November 1, 2019 and the Implementation Regulations of the Trademark Law of the PRC (《中華人民共和國商標法實施條例》) promulgated by the State Council on August 3, 2002 which became effective on September 15, 2002 and was revised on April 29, 2014 and the latest amendment became effective on May 1, 2014, the period of validity for a registered trademark is 10 years, commencing from the date of registration. Upon expiry of the period of validity, the registrant shall go through the formalities for renewal within 12 months prior to the date of expiry as required if the registrant needs to continue to use the trademark. Where the registrant fails to do so, a grace period of six months may be granted. The period of validity for each renewal of registration is 10 years, commencing from the day immediately after the expiry of the preceding period of validity for the trademark. In the absence of renewal upon expiry, the registered trademark shall be canceled.

Copyright

Copyright is protected by the Copyright Law of the PRC (《中華人民共和國著作權法》) promulgated by the SCNPC on September 7, 1990 and last amended on November 11, 2020 with the latest amendment 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》) issued by the State Council on August 2, 2002 and last amended on January 30, 2013 with the latest amendment effective on March 1, 2013, which provided provisions on the classification of works and the obtaining and protection of copyright and the related rights.

Domain Names

Domain names are protected by the Administrative Measures of Internet Domain Names (《互聯網域名管理辦法》) issued by the Ministry of Industry and Information Technology (the “MIIT”) on August 24, 2017 and effective from November 1, 2017 and the Implementing Rules on Registration of China Country Code Top-level Domain Names (《國家頂級域名註冊實施細則》)

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issued by China Internet Network Information Center on June 18, 2019. The MIIT is the regulatory body responsible for the administration of PRC internet domain names. The China Internet Network Information Center is responsible for the administration of registration of China country code top-level domain names. Domain name registrations are processed by the domain name registration service agencies established pursuant to the relevant provisions.

Trade Secrets

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 on September 2, 1993 and amended on November 4, 2017, April 23, 2019 and June 27, 2025, respectively, and the Provisions of the Supreme People’s Court on Several Issues Concerning the Application of Law in the Trial of Civil Cases Involving Trade Secret Infringement (《最高人民法院關於審理侵犯商業秘密民事案件適用法律若干問題的規定》) issued by the Supreme People’s Court on September 10, 2020 and effective from September 12, 2020, together with the Regulations on the Protection of Trade Secret (《商業秘密保護規定》) issued by the SAMR on February 24, 2026, which shall be effective from June 1, 2026, the term “trade secrets” refers to commercial information such as technical information and business information that is not known to the public, has commercial value, and for which the rights holder has taken corresponding confidentiality measures.

Regulations relating to EIT and VAT

EIT

Pursuant to the EIT Law promulgated by the SCNPC on March 16, 2007, which became effective from January 1, 2008, and last amended on December 29, 2018, enterprises shall be classified into resident enterprises and non-resident enterprises. The income tax rate of resident enterprises is 25%, while the income tax rate of non-resident enterprises is 20%. According to the EIT Law and the Implementation Regulations for the EIT Law (《中華人民共和國企業所得稅法實施條例》) issued by the State Council on December 6, 2007, which became effective from January 1, 2008, and last amended on April 23, 2019, enterprise income tax shall be payable by a resident enterprise for the income derived from or accruing in or outside the PRC.

VAT

According to the VAT Law of the PRC (《中華人民共和國增值稅法》), which was promulgated by the SCNPC on December 25, 2024, became effective on January 1, 2026 and the Regulations for the Implementation of the Value-added Tax Law of the People’s Republic of China (《中華人民共和國增值稅法實施條例》) issued on December 25, 2025 and implemented on January 1, 2026, entities and individuals (including individual businesses) that sell goods, services, intangible assets, immovable property, or import goods within the territory of the PRC are VAT taxpayers and shall pay VAT in accordance with this Law.

Laws and Regulations Relating to Product Quality

The Product Quality Law of the PRC (《中華人民共和國產品質量法》) promulgated on February 22, 1993 by the SCNPC and latest amended on December 29, 2018, is the main law regulating the supervision and management of quality of products in China. According to the Product Quality Law of the PRC, producers shall be responsible for the quality of the products they produce, and sellers shall take measures to maintain the quality of the products they sell. Pursuant to the Civil Code of the PRC (《中華人民共和國民法典》) promulgated by the NPC on May 28, 2020 and coming into effective on January 1, 2021, where a patient suffers damage due to defects in drugs, he/she may seek compensation from the drug marketing authorization holder, producer or also from the medical institution. Where the patient seeks compensation from the medical institution, the medical institution, after it has made the compensation, shall have the right to recover the compensation from the liable drug marketing authorization holder or the producer.

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Laws and Regulations Relating to Safety Production

Pursuant to the Safety Production Law of the PRC (《中華人民共和國安全生產法》) promulgated by the SCNPC on June 29, 2002 and latest amended on June 10, 2021, production and operation units shall abide by the Safety Production Law of the PRC and other laws and regulations related to production safety, strengthen production safety management, and establish a sound production safety responsibility system and formulate a set of production safety rules and regulations for all employees; increase the efforts to guarantee the input of funds, supplies, technology and personnel to production safety, improve production safety conditions, and strengthen standardization and informatization of production safety; construct a “dual-prevention” mechanism consisting of graded management and control of safety risks and examination and control of potential risks, improve the risk prevention and resolution mechanism, enhance production safety levels and ensure production safety.

Precursor Chemicals and Explosive Precursor Hazardous Chemicals

Pursuant 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, which became effective on November 1, 2005 and was latest amended on September 18, 2018, the State regulates the production, operation, purchase, transport, import and export of precursor chemicals. Unit intending to purchase Category II and III precursor chemicals shall file with the public security authorities of the local people’s government at the county level for the types and quantities of precursor chemicals required before making the purchase. Pursuant to Measures for Public Security Administration of Explosive Precursor Hazardous Chemicals (《易製爆危險化學品治安管理办法》) promulgated by the Ministry of Public Security on July 6, 2019 and effective from August 10, 2019, unit intending to purchase explosive precursor hazardous chemicals shall file with the public security authorities at the county level where it operates within five days after the purchase, through the explosive hazardous chemicals information system, about the information of the variety, quantity and flow of the explosive precursor hazardous chemicals it purchased.

Labor, Social Insurance and Housing Fund

The Labor Law of the PRC (《中華人民共和國勞動法》) promulgated by the SCNPC on July 5, 1994 and last amended on December 29, 2018 and the Labor Contract Law of the PRC (《中華人民共和國勞動合同法》) promulgated on June 29, 2007, effective from January 1, 2008, and last amended on December 28, 2012 and effective on July 1, 2013 stipulate the relationship between the employers and the employees, and specifies the terms and conditions of the labor contracts. Pursuant to the Social Insurance Law of the PRC (《中華人民共和國社會保險法》) promulgated by the SCNPC on October 28, 2010, effective from July 1, 2011, and last amended on December 29, 2018, the Provisional Regulations for the Collection and Payment of Social Insurance Premiums (《社會保險費徵繳暫行條例》) issued by the State Council on January 22, 1999 and last amended on March 24, 2019, and the Regulations on the Administration of Housing Provident Fund (《住房公積金管理條例》) issued by the State Council on April 3, 1994, and amended on March 24, 2002 and March 24, 2019, respectively, employers are required to pay social insurance premiums such as basic pension insurance, unemployment insurance, basic medical insurance, work-related injury insurance and maternity insurance for their employees, and contribute to housing provident funds. On July 31, 2025, the Supreme People’s Court issued the Interpretation (II) of the Supreme People’s Court on Several 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)》) (“Interpretation (II)”), which came into effect on September 1, 2025. According to Interpretation (II), participation in social insurance is a statutory obligation for both employers and employees, and any unilateral commitment or bilateral agreement to not participate in social insurance is invalid.

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Regulations Relating to Information Security and Data Privacy

On June 10, 2021, the SCNPC promulgated the Data Security Law of the PRC (《中華人民共和國數據安全法》), with effect on September 1, 2021, which establishes a classified and tiered system for data protection. On July 7, 2022, the Cyberspace Administration of the PRC promulgated the Measures for the Security Assessment of Outbound Data Transfer (《數據出境安全評估辦法》), which came into effect on September 1, 2022, according to which under certain circumstances, a data processor who shall process outbound data transfer shall report to the national cyberspace department through the local cyberspace department at the provincial level for security assessment of outbound data transfer. On February 22, 2023, the Cyberspace Administration of China promulgated the Measures for Standard Contract for Outbound Transfer of Personal Information (《個人信息出境標準合同辦法》), with effect from June 1, 2023. Accordingly, the personal information processor who provides personal information to any overseas recipient through standard contract shall not be a critical information infrastructure operator, or handle personal information of less than one million individuals, etc. On October 14, 2025, the Cyberspace Administration of China and the SAMR promulgated the Measures for Outbound Certification of Personal Information (《個人信息出境認證辦法》), which came into effect on January 1, 2026. Pursuant to the Measures, personal information processor who provides personal information to any overseas recipient through personal information outbound certification shall not be a critical information infrastructure operator or handle personal information of over 100 thousand but no more than 1 million individuals since January 1 of the current year.

Regulations Relating to Overseas Listing

According to the Trial Measures released by the CSRC on February 17, 2023 and come into effect on March 31, 2023, domestic enterprise in the PRC that directly issues securities outside the PRC shall file with the CSRC in accordance with the Trial Measures. For the overseas initial public offering or listing, issuers shall file with the CSRC within three working days after the submission of its application for listing in overseas region. If the filing materials are complete and comply with regulations, the CSRC will complete the filing within 20 working days from the date of receipt of the filing materials and will announce the filing information through its website publicly.

Confidentiality and Archives Administration Concerning Overseas Listing

Pursuant to the Provisions on Strengthening Confidentiality and Archives Administration Concerning Overseas Securities Offerings and Listings 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》), which was jointly announced by numerous departments including CSRC on February 24, 2023 and came into effect since March 31, 2023, during the overseas issuance and listing activities of domestic enterprises, such enterprises and securities companies, securities service institutions which provide corresponding services shall strictly comply with the relevant laws and regulations of PRC and the requirements of these Provisions, they shall not leak any national secrets and work secrets of national authorities, and shall not jeopardize the national and public interests.

Regulations Relating to “Full Circulation” of H Shares

According to the Trial Measures, if a domestic enterprise is directly listed overseas, when its shareholders of its domestic unlisted shares apply to convert their domestic unlisted shares held to overseas listed shares and to be circulated in overseas exchanges, it shall comply with the relevant regulations of CSRC and entrust the domestic enterprises to file with the CSRC. According to the Guidelines for the “Full Circulation” Program for Domestic Unlisted Shares of H-share Listed Companies (《H股公司境內未上市股份申請“全流通”業務指引》) announced by the CSRC on November 14, 2019 and amended on August 10, 2023, shareholders of domestic unlisted shares may, determine the amount and proportion of shares whose circulation is applied for on their own through consultation, and entrust H-share companies with undergoing the filing formalities with the CSRC. Domestic companies with limited liability which have not been listed in any exchanges, may

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file with the “full circulation” of its H-shares with the CSRC along with its overseas initial public offering. H-share companies shall submit relevant status report to the CSRC within 15 days after the shares involved in the application are transferred to the CSDC. On December 31, 2019, the CSDC and Shenzhen Stock Exchange jointly announced the Measures for Implementation of H-share “Full Circulation” Business (《H股“全流通”業務實施細則》), which are applicable to businesses of cross-border share transfer registration, maintenance of deposit and holding details, transaction entrustment and instruction transmission and other related operations in relation to the H-share “full circulation business”. On September 20, 2024, the Shenzhen Branch of CSDC issued the Guidelines to the Program for “Full Circulation” of H-shares of Shenzhen Branch of China Securities Depository and Clearing Corporation Limited (《中國證券登記結算有限責任公司深圳分公司H股“全流通”業務指南》), which was amended by the Shenzhen Branch of CSDC on June 27, 2025 and became effective from June 30, 2025, are applicable to the business preparation, cross-border share transfer registration and overseas centralized custody, the initial maintenance of details of domestic shareholding and other related operations. On the same day, China Securities Depository and Clearing (Hong Kong) Company Limited issued the H-Share Full Circulation Business Guide of China Securities Depository and Clearing (Hong Kong) Limited (《中國證券登記結算(香港)有限公司H股“全流通”業務指南》), which is applicable to businesses such as share custody and depository, agent service, arrangement for settlement and delivery, and risk management measures.

OTHER RELEVANT LAWS AND REGULATIONS

Outbound Investment Rule by the U.S. Department of the Treasury

On August 9, 2023, the U.S. President issued Executive Order No. 14105, directing the Secretary of the Treasury to establish a program to prohibit or require notification of certain types of outbound investments by U.S. persons into certain entities located in or subject to the jurisdiction of countries of concern (including China, Hong Kong and Macau) that are engaged in activities in certain sectors (currently including semiconductors and microelectronics, quantum information technologies or artificial intelligence). On January 2, 2025, the Provisions Pertaining to U.S. Investments in Certain National Security Technologies and Products in Countries of Concern became effective (the “Outbound Investment Rule”). Under the Outbound Investment Rules, U.S. persons are subject to notification requirements or prohibitions if they engage in “covered transactions” involving “covered foreign persons”.

A “covered foreign person” generally refers to a person of a country of concern that engages in a “covered activity”, or certain persons with specified board, voting, equity or contractual rights in such person and meeting the applicable revenue, net income, capital expenditure or operating expense thresholds. “Covered activity” encompasses activities falling within the definitions of “prohibited transactions” and “notifiable transactions” and includes research, development, or manufacturing involving “covered national security technologies and products”, which are sensitive technologies and products in the semiconductors and microelectronics, quantum information technologies, and AI sectors that have military, intelligence, surveillance, or cyber-enabled capabilities. Generally, activities and technologies deemed to present the most acute national security concerns are prohibited, while other designated activities are subject to notification requirements.

A “covered transaction” generally includes specified direct or indirect transactions by a U.S. person involving a covered foreign person or expected to result in a person of a country of concern engaging in a “covered activity”, including acquisitions of equity or contingent equity interests, certain loans or similar debt financing arrangements, certain asset transactions, joint ventures and certain limited partner or equivalent investments in non-U.S. pooled investment funds, where the relevant requirements under the Outbound Investment Rules are met.