

REGULATORY OVERVIEW

OVERVIEW OF LAWS AND REGULATIONS IN THE PRC

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

Regulatory Authorities

The regulatory authorities of the drug industry in the PRC include: the National Medical Products Administration of the PRC (中華人民共和國國家藥品監督管理局) (the “NMPA”), 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) and the National Healthcare Security Administration (國家醫療保障局) (the “NHSA”).

The NMPA is an authority under the State Administration for Market Regulation of the PRC (中華人民共和國國家市場監督管理總局) (the “SAMR”) and is primarily responsible for supervising and managing drugs, medical devices and cosmetics. The NHC is primarily responsible for drafting and implementing national health policies, and supervising and regulating public health, healthcare services, and health emergency systems. The NHSA 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, and pricing of drugs, medical disposables and healthcare services.

Laws and Regulations in Relation to New Drugs

Administration of Drug Registration

The Measures for the Administration of Drug Registration (《藥品註冊管理辦法》) effective from July 1, 2020, govern the development, registration, supervision and management activities carried out in the territory of the PRC for marketing of drugs. These measures provide that a drug registration applicant files an application and other supplementary applications for clinical trials of drugs, approval for drug marketing, and re-registration, among others, according to the relevant requirements, and that the medical products administrative department examines the safety, effectiveness, and quality based on the laws and regulations, and the existing scientific cognitions, to decide whether to approve the applications. A drug registration certificate shall be valid for five years.

Non-clinical Research

The non-clinical safety assessment of drugs for marketing approval shall be conducted in accordance with the Good Laboratory Practices for Non-clinical Laboratory Studies (《藥物非臨床研究質量管理規範》) promulgated by the State Food and Drug Administration (國家食品藥品監督管理局) (the “SFDA”, predecessor of the CFDA) as last amended in July 2017 and effective from September 1, 2017.

Application for Clinical Trial

After completing the preclinical studies, the applicant must obtain approval for clinical trials of drugs from the NMPA before the conduction of clinical trials. According to the Decision on Adjusting the Approval Procedures of Certain Administrative Approval Items for Drugs (《關於調整部分藥品行政審批事項審批程序的決定》) effective from May 2017, the decision on the approval of clinical trials of drugs can be made by the Center for Drug Evaluation of NMPA (國家藥品監督管理局藥品審評中心) (the “CDE”). Pursuant to the Drug Administration Law of the PRC (《中華人民共和國藥品管理法》) (the “Drug Administration Law”) in 2019, the dossier on a new drug R&D shall be truthfully submitted to the CDE for approval before clinical drug trial is conducted. The CDE shall decide whether to approve the clinical trial application and notify the decision to the clinical trial applicant within sixty (60) business days from the date of accepting the clinical trial application. If the CDE fails to do so, the clinical trial application shall be deemed as approval, and if the bioequivalence test is conducted, it is required to report it to the CDE for filing.

Conduct of Clinical Trial

After obtaining clinical trial approval, the applicant shall choose qualified institutions to conduct clinical trials. Pursuant to the Administrative Regulations for Drug Clinical Trial Institutions (《藥物臨床試驗機構管理規定》), drug development activities and clinical trials of drugs (including bioequivalence test conducted after filing) approved by the NMPA within the territory of the PRC shall be conducted in the drug clinical trial institutions.

REGULATORY OVERVIEW

A drug clinical trial to be carried out shall be examined and approved by the ethics committee. A sponsor approved to carry out a drug clinical trial shall, before carrying out subsequent drug clinical trial by stages, develop corresponding plan for drug clinical trials, carry out drug clinical trial upon examination and with consent of the ethics committee, and submit a corresponding plan for drug clinical trial and supporting materials on the website of the CDE.

In compliance with the Measures for the Administration of Drug Registration, clinical trials are divided into Phase I, Phase II, Phase III and Phase IV and bioequivalence trial. According to 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》), if a new drug clinical trial has been approved to be carried out, after the completion of Phase I and Phase II clinical trials and before the implementation of Phase III clinical trials, the applicant shall submit an application for a communication meeting to the CDE to discuss with the CDE on key technical issues including the Phase III clinical trial design. According to the Measures for the Administration of Drug Registration and the Measures for the Administration of Communication and Exchange in Drug Development and Technology Review (《藥物研發與技術審評溝通交流管理辦法》) latest amended by the CDE on December 10, 2020, the applicant can also apply for communication on key technical issues at different stages of clinical R&D.

Good Clinical Practices (GCP)

To improve the quality of clinical trials, the NMPA and NHC promulgated the Good Clinical Practices for Drug Trials (《藥物臨床試驗質量管理規範》) in 2020 and latest amended in May, 2026 which will come into effect on September 1, 2026, which stipulates the criteria for the entire procedure of the clinical trial including trial preparation and the necessary conditions, protection of testees’ rights and interests, trial protocols, duties of researchers, duties of sponsors, duties of monitors, trial record and report, data management and statistical analysis, administration of drug products for trial, guarantee for quality, polycentric trials, with reference to the internationally recognized principles. Clinical trials should also follow GCP and protocols approved by the ethics committee of each research center.

Regulations on International Multi-Center Clinical Trials and Acceptance of Overseas Clinical Trial Data

According to the Notice on Issuing the International Multi-Center Clinical Trial Guidelines (Trial) (《關於發佈國際多中心藥物臨床試驗指南(試行)的通告》), promulgated by the CFDA and effective from 2015, clinical trial applicants may simultaneously perform clinical trials in different centers using the same clinical trial protocol. Where the applicants plan to use the data derived from the international multi-center clinical trials for approval of a drug registration in the PRC, it shall involve at least two countries, including China, and shall satisfy the requirements for clinical trials set forth in the Multi-Center Clinical Trial Guidelines and other related laws and regulations.

New Drug Application

Pursuant to the Measures for the Administration of Drug Registration, after completing the pharmaceutical research, pharmacological and toxicological research, drug clinical trial, and other research supporting the marketing registration of a drug, determining the quality standards, completing the verification of commercial large-scale production process, and making sound preparation for the acceptance of drug registration inspection and examination, an applicant shall file an application for drug marketing authorization, and submit relevant research materials in accordance with the requirements of the application materials. After the formal examination of the application materials, an application that satisfies the requirements shall be accepted.

The CDE shall evaluate the accepted applications for drug marketing authorization and decide to approve the marketing application or not. If the application is approved, a drug registration certificate shall be issued and shall specify the drug approval number, holder, manufacturer and other information.

After an application for drug registration is accepted, the CDE shall conduct preliminary examination within forty (40) business days of acceptance, notify the Center for Food and Drug Inspection of NMPA (the “**Center for Inspection**”) of organizing inspection and provide the relevant materials required for inspection, where production site inspection for drug registration is required, and concurrently notify the local applicant and the medical products administrative department. In principle, the Center for Inspection shall complete the inspection work forty (40) business days prior to the expiry of the time limit for inspection, and report the inspection information, inspection results and other relevant materials to the CDE.

REGULATORY OVERVIEW

Normally, the review period for an application for drug marketing authorization shall be 200 business days. The review period for the procedures for prioritized review and approval shall be one hundred and thirty (130) business days, and the review period for the procedures for prioritized review and approval for clinically urgently needed overseas-marketed drug for a rare disease shall be seventy (70) business days.

Regulations of Biosimilars

In February 2015, the CFDA promulgated the Technical Guidelines for the Research, Development and Evaluation of Biosimilars (《生物類似藥研發與評價技術指導原則》) (the "**Biosimilars Guidelines**"), which outline the regulatory framework for biosimilars in China and provide the basic principles for the evaluation and management of biosimilars. The Biosimilars Guidelines set forth the definition of biosimilars and reference drugs, the requirements in relation to the selection of reference drugs, the basic principles for technical review, the criteria for comparability and the conditions under which extrapolations of indications would be permissible.

According to the Biosimilar Guidelines, biosimilars shall refer to therapeutic biological products that are similar to approved and registered reference drugs in terms of quality, safety and efficacy. The R&D and marketing of biosimilars need to comply with the relevant regulations of the Drug Administration Law and the Measures for the Administration of Drug Registration. After completion of preclinical studies, the applicant is required to apply for a clinical trial, and once approved complete the clinical trial in accordance with the clinical trial protocol. The applicant shall submit the new drug application after completion of the clinical trials and relevant preparations.

Marketing Authorization Holder System

Pursuant to the Drug Administration Law and the Measures for the Administration of Drug Registration, the state implements the drug marketing authorization holder system for drug management. After obtaining a drug registration certificate, an applicant shall be the drug marketing authorization holder. During the validity period, a holder of a drug registration certificate shall continue to ensure the safety, effectiveness and quality of the marketed drug, and apply for re-registration of the drug six months prior to the expiry of the validity period.

The drug marketing authorization holder shall proactively carry out post-marketing research on drugs, further confirm the safety, effectiveness and quality of drugs, and strengthen the continuous management of marketed drugs. Where a drug registration certificate and its annex require the marketing authorization holder to carry out relevant research work after the drug is marketed, the marketing authorization holder shall complete the research within the prescribed time limit and file a supplementary application, undergo recordation formalities or report as required. After a drug is approved for marketing, the marketing authorization holder shall continue to conduct research on drug safety and effectiveness, undergo recordation formalities in a timely manner or file a supplementary application for revising the instructions according to the relevant data, and continuously update and improve the instructions and labels. According to the duties, the medical products administrative department may require the marketing authorization holder to revise the instructions and labels based on the monitoring of adverse drug reactions and the post-marketing reevaluation results of the drug.

Transfer of Drug Marketing Authorization

Pursuant to the Drug Administration Law, subject to the approval by the drug administrative department of the State Council, a drug marketing authorization holder may transfer its marketing authorization. The transferee shall possess the capability of quality management, risk prevention and control and liability compensation to ensure the safety, efficacy and quality of the drug, and perform the obligations of the drug marketing authorization holder. Pursuant to the Administrative Measures for Drug Post-marketing Changes (for Trial Implementation) (《藥品上市後變更管理辦法(試行)》), drug post-marketing changes shall not have any adverse impact on the safety, effectiveness and quality of drugs.

REGULATORY OVERVIEW

Laws and Regulations in Relation to Drug Manufacturing

Drug Manufacturing Permit

Pursuant to the Drug Administration Law, the state adopts an industry entry permit system for drug manufacturers. The conduct of drug manufacturing activities shall be approved and granted with a Drug Manufacturing License (《藥品生產許可證》) by the drug regulatory authority of the people’s government at provincial, autonomous regional or municipal level. The Drug Manufacturing License shall indicate the validity period and the scope of production, and shall be reviewed for renewing upon expiration.

Good Manufacturing Practices

Pursuant to the Drug Administration Law, and the Announcement on the Relevant Issues Concerning the Implementation of the Drug Administration Law of the PRC (《關於貫徹實施〈中華人民共和國藥品管理法〉有關事項的公告》) in 2019, when engaging in drug manufacturing activities, a manufacturer shall comply with the GMP and establish a sound GMP management system, to ensure that the entire process of drug manufacturing maintain to meet the statutory requirements, and meet the GMP requirements enacted by the drug regulatory authority under the State Council in accordance with the law. The legal representative of and principal person in charge of a drug manufacturer are fully responsible for the drug manufacturing activities of the enterprise.

The Good Manufacturing Practices (《藥品生產質量管理規範》), promulgated by the Ministry of Health of the PRC (now known as the NHC) in March 1988, newly amended in January 2011 and came into effect on March 1, 2011, provided guidance for the quality management, organization and staffing, production premises and facilities, equipment, material and products, recognition and inspection, documentation maintenance, manufacture management, quality control and quality assurance, contractual manufacture and contractual inspection for the products, product delivery and recalls of a manufacturer in a systematical manner.

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》) 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, could such drug manufacturer entrust the manufacturing of the drug to another domestic drug manufacturer. Such contract manufacturing arrangements shall be approved by the provincial branch of the NMPA.

The Administrative Measures on Supervision of Drug Manufacturing (《藥品生產監督管理辦法》) in 2020 further stipulates that drug marketing authorization holders entrusting others to manufacture drugs shall enter into outsourcing agreements and quality agreements with qualified drug manufacturing enterprises and submit the relevant agreements together with the actual manufacturing site application materials to the competent drug administrative authority in order to apply for the Drug Manufacturing Certificate.

NMPA further issued the Announcement on Strengthening the Supervision and Administration of Entrusted Production by Drug Listing License Holders (《國家藥監局關於加強藥品上市許可持有人委託生產監督管理工作的公告》) in October, 2023 and the Announcement on Strengthening the Supervision and Management of Entrusted Production of Drugs (《國家藥監局關於加強藥品受託生產監督管理工作的公告》) in December 2025 regarding the supervision and administration of contract manufacturing of drugs.

Laws and Regulations on Drug Supply

Drug Supply Permit

According to the Drug Administration Law and the Measures for the Supervision and Administration of Drug Supply and Usage (《藥品經營和使用質量監督管理辦法》) took into effect on January 1, 2024, the operation of drug business, including drug wholesale and drug retail, is prohibited without a Drug Supply Permit. A Drug Supply Permit is valid for five years. Each holder of the Drug Supply Permit must apply for an extension of its permit six months to two months prior to expiration.

REGULATORY OVERVIEW

Good Supply Practice

The Good Supply Practice for Pharmaceutical Products (《藥品經營質量管理規範》) (the "GSP Rules") was recently amended and came into effect on July 13, 2016. The GSP Rules set forth the basic standards in management of drug supply and apply to enterprises engaged in drug supply in the PRC, which require drug suppliers to implement strict controls on its supply of pharmaceutical products, including standards regarding staff qualifications, premises, warehouses, inspection equipment and facilities, management and quality control.

Other Laws and Regulations in Relation to Pharmaceutical Industry

Basic Medical Insurance Policy

Pursuant to the Decision on the Establishment of the Urban Employee Basic Medical Insurance Program (《關於建立城鎮職工基本醫療保險制度的決定》) promulgated by the State Council on December 14, 1998 and the Tentative Measures for the Administration of the Scope of Medical Insurance Coverage for Pharmaceutical Products for Urban Employee (《城鎮職工基本醫療保險用藥範圍管理暫行辦法》) promulgated by the NDRC, the SFDA and other authorities, came into effect on May 12, 1999, all employers in cities and towns, including enterprises (state-owned enterprises, collective enterprises, foreign-invested enterprises, private enterprises, etc.), institutions, public institutions, social organizations, private non-enterprise units and their employees are required to participate in basic medical insurance. Pursuant to the Opinions of the State Council on the Integration of the Basic Medical Insurance System 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》) promulgated by the State Council on January 3, 2016, a unified basic medical insurance system for urban and rural residents was established, including the existing urban residents' medical insurance and all the insured personnel of New Rural Cooperative Medical System, covering all urban and rural residents except those who should be covered by the employee's basic medical insurance.

National Reimbursement Drug List of China

The National Reimbursement Drug List for Basic Medical Insurance, Work Injury Insurance and Maternity Insurance (《國家基本醫療保險、工傷保險和生育保險藥品目錄》) (the "NRDL") sets out the standards for payment of medicines by the basic medical insurance, work injury insurance and maternity insurance funds. The NHSA and other governmental organizations have the authority to determine the drugs to be included in the NRDL. Drugs listed in the NRDL are divided into two parts: Class A and Class B. Class A drugs are widely used for clinical treatment, with favorable efficacy and lower prices than their counterparts, while Class B drugs are used for clinical treatment, with favorable efficacy and slightly higher prices than Class A drugs.

On July 30, 2020, the NHSA issued the Provisional Measures for the Administration of Medicines for Basic Medical Insurance (《基本醫療保險用藥管理暫行辦法》) (the "Measures for the Administration of the NRDL"), which came into effect on September 1, 2020. The Measures for the Administration of the NRDL provides guidance on the inclusion and adjustment of the NRDL and the payment, management and supervision of basic medical insurance. According to the Measures for the Administration of the NRDL, a dynamic adjustment mechanism shall be established for the NRDL, which shall be adjusted annually in principle. According to the Opinions of the NHSA and the Ministry of Finance on Establishing a List-Based System for Healthcare Security Benefits (《國家醫保局、財政部關於建立醫療保障待遇清單制度的意見》), which came into effect in January 2021, all provinces shall implement the NRDL in a strict manner, and shall not have the discretion to formulate the catalog or increase the drugs in any form, or adjust the scope of limited payment unless explicitly stipulated. On December 5, 2025, the NHSA and the Ministry of Human Resources and Social Security of the PRC released the latest NRDL (effective from January 1, 2026), which has been expanded to cover a total of 3,253 drugs. Inclusion in the NRDL will generally result in increased sales volume and lower drug prices (which are determined on a case-by-case basis and negotiated based on factors such as the initial drug price).

National Essential Drug List

Pursuant to the Opinions of the General Office of the State Council on Improving the National Essential Drug System (《國務院辦公廳關於完善國家基本藥物制度的意見》) issued on 13 September 2018 and the Circular on the Printing and Issuance of the Measures for the Administration of the National Essential Drug List (《關於印發國家基本藥物目錄管理辦法的通知》) newly issued and promulgated on 27 January 2026, primary healthcare institutions operated by the government (mainly including county hospitals, county hospitals of traditional Chinese medicine, township health centers and community outpatient clinics) shall be equipped with and use the drugs listed in the National Essential Drug List. Drugs in the National Essential Drug List must be procured through a centralized bidding process and are subject to price control by the NDRC. Therapeutic drugs in the National Essential Drug List are included in the medical insurance catalogue and the full cost of purchasing such drugs is reimbursed.

REGULATORY OVERVIEW

Drug Price

Pursuant to the Drug Administration Law, for drug products with market-regulated prices in accordance with the law, the drug marketing authorization holder, the drug manufacturer, the drug distributor and medical institution shall determine the price pursuant to the principles of fairness, reasonableness, integrity and trustworthiness as well as quality for value in order to supply drug users with reasonably priced drug products; and shall comply with the requirements relating to drug price administration promulgated by the State Council's pricing authorities, determine and clearly mark the retail prices of drug products. Pursuant to the Notice on Issuing Opinions on Promoting Drug Price Reform (《關於印發<推進藥品價格改革意見>的通知》) jointly promulgated by NDRC, NHC, the Ministry of Human Resources and Social Security, Ministry of Industry and Information Technology (the "MIIT"), the Ministry of Finance, the Ministry of Commerce of the PRC (the "MOFCOM") and the CFDA on May 4, 2015 and came into effect on June 1, 2015, from June 1, 2015, except for narcotic drugs and first-class psychotropic drugs, the price of drugs set by the government will be canceled.

Drug Purchases by Hospitals

According to the Guiding Opinions concerning the Urban Medical and Health System Reform (《關於城鎮醫藥衛生體制改革的指導意見》) promulgated and came into effect on February 21, 2000, and the Opinions 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 came into effect on September 1, 2000, a medical institution must be defined as a for-profit or not-for-profit institution at the time of its establishment. A not-for-profit medical institution refers to a medical institution established for the purpose of public interest services, which maintains and develops the institution with its income, while a for-profit medical institution is established by investors for the purpose of investment return.

According to the Notice on the Trial Implementation of the Centralized Tender with Respect to Drug Purchases 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 came into effect on July 7, 2000, the Notice on the Further Standardizing of the Centralized Tender with respect to Drug Purchases 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 came into effect on August 8, 2001 and the Opinions concerning Further Regulating Drug Purchases by Medical Institutions through Centralized Tendering (《關於進一步規範醫療機構藥品集中採購工作的意見》) promulgated and came into effect on January 17, 2009, any not-for-profit medical institutions established and/or controlled by any government at the county level or above must use a centralized tender system for the procurement of drugs which are listed in the Catalog of Drugs for National Basic Medical Insurance (《國家基本醫療保險藥品目錄》) and are generally for clinical use and bulk purchase.

The Good Practice of 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 came into effect on July 7, 2010, provides detailed provisions on the catalog and procurement methods of centralized procurement of drugs, the procedures of centralized procurement of drugs, the evaluation methods of centralized procurement of drugs, and the construction and management of the expert pools, further regulates the centralized procurement of drugs and clarifies the code of conduct of the parties involved in centralized procurement of drugs.

According to the Guidance Opinion of the General Office of the State Council on the Improvement of the Drug Centralized Procurement Work of Public Hospitals (《國務院辦公廳關於完善公立醫院藥品集中採購工作的指導意見》) promulgated and came into effect on February 9, 2015, the centralized procurement work of public hospitals will be improved through the purchase of drugs by classification. All drugs used by public hospitals (with the exception of traditional Chinese medicine decoction pieces) should be procured through a provincial centralized pharmaceutical procurement platform. The provincial drug procurement agency should work out a summary of the procurement plans and budget submitted by hospitals and compile reasonably a drug procurement catalog of the hospitals within its own administration region, listing by classification the drugs to be procured through bids, negotiations, direct purchases by hospitals or to be manufactured by appointed pharmaceutical manufacturers.

Drug Distribution and Two-Invoice System

According to the Implementing Opinions on Promoting the "Two-Invoice System" for Drug Procurement By Public Medical Institutions (For Trial Implementation) (《關於在公立醫療機構藥品採購中推行「兩票制」的實施意見(試行)》) which was issued on December 26, 2016, the Two-Invoice System is a system under which invoices are issued by drug manufacturers to drug distributors on a once-off basis while invoices are issued by drug distributors to medical institutions on a once-off basis. Wholly-owned or holding commerce companies (there shall be only one commerce company throughout the country) and domestic general agents of overseas drugs (there

REGULATORY OVERVIEW

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

According to the Notice on Promulgation of the Key Points for the Special Campaign to Rectify the Misconduct in the Medicine Purchase and Sales Field and Medical Services in 2018 (《關於印發<2018年糾正醫藥購銷領域和醫療服務中不正之風專項治理工作要點>的通知》), which was issued on August 15, 2018, the Two-Invoice System shall be fully implemented for drug purchase and sale among public medical institutions. Pharmaceutical companies must comply with the Two-Invoice System in order to engage in procurement processes with public hospitals.

Advertising of Pharmaceutical Products

Pursuant to the Interim Administrative Measures for the Review of Advertisements for Drugs, Medical Devices, Health Food and Formula Food for Special Medical Purposes (《藥品、醫療器械、保健食品、特殊醫學用途配方食品廣告審查管理暫行辦法》), which was promulgated by the SAMR in December 2019 and came into effect on March 1, 2020, advertisements for drugs, medical devices, health food and formula food for special medical purposes shall be true and legitimate, and shall not contain any false or misleading contents. Holders of registration certificates or filing certificates of drugs, medical devices, health food and formula food for special medical purposes as well as the production enterprises and operating enterprises authorized by such holders of certificates shall be applicants for advertising (the “**Applicants**”). The advertisement review authorities shall review the materials submitted by the Applicants and shall complete the review within ten business days from the date of acceptance. After review, for advertisements that are in line with laws, administrative regulations and these Measures, approval decisions of review shall be made and advertisement approval numbers shall be issued. The validity period of the advertisement approval number for drugs, medical devices, health food and formula food for special medical purposes shall be consistent with the shortest validity period of the product registration certificate, filing certificate or production license. If no valid period is prescribed in the product registration certificate, filing certificate or production license, the valid period of the advertisement approval number shall be two years.

Insert Sheet, Labels and Packaging of Pharmaceutical Products

Pursuant to the Measures for the Administration of the Insert Sheets and Labels of Drugs (《藥品說明書和標籤管理規定》), which was promulgated by the SFDA and came effective on June 1, 2006, the insert sheets and labels of drugs should be reviewed and approved by the SFDA. Pursuant to the Measures for The Administration of Pharmaceutical Packaging (《藥品包裝管理辦法》) which came effective on September 1, 1988, pharmaceutical packaging must comply with the national and professional standards.

Regulations in Relation to Product Liability

Pursuant to the PRC Civil Code (《中華人民共和國民法典》) (the “**Civil Code**”) promulgated by the National People’s Congress of the PRC (the “**NPC of the PRC**”) on May 28, 2020 and came into effect on January 1, 2021, where a patient suffers damage due to defects in drugs, he 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 producer.

The Product Quality Law of the PRC (《中華人民共和國產品質量法》), promulgated by the Standing Committee of the National People’s Congress (the “**SCNPC**”) on February 22, 1993 and latest amended on December 29, 2018 (the “**Product Quality Law**”), is the principal governing law relating to the supervision and administration of product quality. According to the Product Quality Law, manufacturers shall be liable for the quality of products produced by them and sellers shall take measures to ensure the quality of the products sold by them. A person who is injured or whose property is damaged by the defects in the product may claim for compensation from the manufacturer or the seller.

The Law of the PRC on the Protection of the Rights and Interests of Consumers (《中華人民共和國消費者權益保護法》) was promulgated on October 31, 1993 and latest amended on October 25, 2013 and came into effect on March 15, 2014 to protect consumers’ rights when they purchase or use goods and accept services. All business operators must comply with this law when they manufacture or sell goods and/or provide services to customers. All business operators must pay high attention to protecting customers’ privacy and must strictly keep confidential any consumer information they obtain during their business operations.

REGULATORY OVERVIEW

The Company Law and Regulations

The Company Law, which was amended by the SCNPC on December 29, 2023 and became effective on July 1, 2024, provides for the establishment, corporate structure and corporate management of companies, which also applies to foreign-invested enterprises in the PRC.

Regulations in Relation to Foreign Direct Investment

Since January 1, 2020, the Foreign Investment Law of the PRC (《中華人民共和國外商投資法》) (the “**Foreign Investment Law**”) promulgated by the NPC of the PRC has come into effect and has become the basic law regulating foreign-invested enterprises wholly or partially invested by foreign investors, while the organization form, institutional framework and standard of conduct of foreign-invested enterprises shall be subject to the provisions of the Company Law and other laws. The PRC government implements the management system of pre-entry national treatment and the Negative List for foreign investment. The PRC accords national treatment to foreign investment outside of the Negative List. The current Negative List is the Special Management Measures (Negative List) for the Access of Foreign Investment (2024 Revision) (《外商投資准入特別管理措施(負面清單)(2024年版)》) issued by the NDRC and the MOFCOM on September 6, 2024 and came into effect on November 1, 2024, which lists the special management measures for foreign investment access for industries regulated by the Negative List, such as equity requirements and senior management requirements.

While strengthening investment promotion and protection, the Foreign Investment Law further regulates foreign investment management and proposes the establishment of a foreign investment information reporting system that replaces the original foreign investment enterprise approval and filing system of the MOFCOM subject to the Foreign Investment Information Reporting Method (《外商投資信息報告辦法》) jointly developed by the MOFCOM and the SAMR, which came into effect on January 1, 2020. Foreign-invested listed companies may report information on changes in investors and their shareholdings only when the cumulative change in the foreign investors’ shareholding ratio exceeds 5% or the foreign parties’ shareholding or relative holding status has changed.

Regulations relating to Outbound Investment

Pursuant to the Administrative Measures on Outbound Investments (境外投資管理辦法) issued by the MOFCOM on March 16, 2009 and amended on September 6, 2014, the MOFCOM and the provincial competent departments of commerce shall subject the outbound investments of enterprises to filing or approval, depending on the actual circumstances of such investments. Outbound investments of enterprises involving sensitive country or region, or sensitive industry shall be subject to approval. Other outbound investments of enterprises shall be subject to filing.

Pursuant to 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 territory of the PRC (the “**Investor**”) intends to make outbound investments, it shall go through the formalities, such as approval or filing, for the outbound investment project (the “**Project**”), report relevant information and cooperate in the supervisory inspections. The sensitive Projects invested directly by the Investor or through the foreign enterprises controlled by the Investor shall be subject to approval. The non-sensitive Projects invested directly by the Investor, which involve the direct contribution of assets, rights and interests, or provision of financing or guarantee by the Investor, shall be subject to filing. The aforementioned sensitive Projects include the Projects involving sensitive country or region, or sensitive industry. The Catalogue of Sensitive Sectors for Outbound Investment (2018 Edition) (境外投資敏感行業目錄(2018年版)) issued by the NDRC on January 31, 2018 and effective from March 1, 2018 listed in detail the sensitive sectors.

The Provisions on Outbound Investment by the State Council (《國務院關於對外投資的規定》) issued by the Executive Meeting of the State Council in April 2026 and came into effect on July 1, 2026, further strengthen the regulation and administrative liability on the non-compliance of outbound investment.

REGULATORY OVERVIEW

Laws and Regulations in Relation to Intellectual Property

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》), latest amended on October 17, 2020 and came into effect 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》) (the “**Implementation Rules**”), latest amended on December 11, 2023 and came into effect on January 20, 2024. The Patent Law and the Implementation Rules provide for three types of patents, namely “invention,” “utility model” and “design.” The duration of a patent right for “invention” is twenty (20) years; the duration of a patent right for “utility model” is ten (10) years; and the duration of a patent right for “design” is fifteen (15) years, all of which duration is from the date of application.

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 last amended on January 30, 2013, and became effective on March 1, 2013. These law and regulation provide provisions on the classification of works and the obtaining and protection of copyright.

Trademarks

Registered trademarks in the PRC are mainly protected by the Trademark Law of the PRC (《中華人民共和國商標法》) amended by the SCNPC and came into effect in 2019 (which has been latest amended in June 2026 and will come into effect on January 1, 2027), and the Implementation Rules of the Trademark Law of the PRC (《中華人民共和國商標法實施條例》) and latest amended by the State Council and came into in 2014. The Trademark Office is responsible for the registration and administration of trademarks throughout China and grants a term of ten (10) years to registered trademarks. When it is necessary to continue using the registered trademark upon expiration of period of validity, a trademark registrant shall make an application for renewal within twelve (12) months before the expiration in accordance with the requirements. If such an application cannot be filed within that period, an extension period of six months may be granted. The period of validity for each renewal of registration shall be ten (10) years as of the next day of the previous period of validity. If the formalities for renewal have not been handled upon expiration of period of validity, the registered trademarks will be deregistered.

Domain Names

Domain names are regulated under the Administrative Measures on the Internet Domain Names (《互聯網域名管理辦法》) issued by the MIIT, on August 24, 2017 and effective from November 1, 2017. The MIIT is the main regulatory authority responsible for the administration of the PRC internet domain names. Domain names registrations are handled through domain name service agencies established under the relevant regulations, and the applicants become domain name holders upon successful registration.

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 SCNPC, as latest amended in June 2025 and came into effect as of 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. Under the Anti-Unfair Competition Law of the PRC, business persons are prohibited from infringing others’ trade secrets by: (i) acquiring a trade secret from the right holder by theft, bribery, fraud, coercion, electronic intrusion, or any other means; (ii) disclosing, using, or allowing another person to use a trade secret acquired from the right holder by any means as specified in the item (i) above; (iii) disclosing, using, or allowing another person use a trade secret in its possession, in violation of its confidentiality obligation or the requirements of the right holder for keeping the trade secret confidential; (iv) abetting a person, or tempting another person into or in acquiring, disclosing, using, or allowing another person to use the trade secret of the right holder in violation of his or her non-disclosure obligation or the requirements of the right holder for keeping the trade secret confidential. If a third party knows or should have known of the above-mentioned illegal conduct but nevertheless obtains, uses or discloses trade secrets of others, the third party may be deemed to have committed a misappropriation of the others’ trade secrets. The parties whose trade secrets are being misappropriated may petition for administrative corrections, and regulatory authorities may stop any illegal activities and impose fine on the infringing parties.

REGULATORY OVERVIEW

Laws and Regulations in Relation to Real Properties

Self-Owned Real Properties

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

According to the Land Administration Law of the PRC (《中華人民共和國土地管理法》), promulgated by the SCNPC on June 25, 1986, became effective on January 1, 1987 and last amended on August 26, 2019, China implements “socialist public ownership of land”, that is, ownership by the whole people or collective ownership by the working masses. The State formulates an overall land utilization plan to stipulate land use, classifying land into agricultural land, construction land, or unused land. Entities or individuals using land must use the land strictly in accordance with the purposes of land use determined in the overall land utilization plan.

Real Estate Leasing

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

According to Administrative Measures on Leasing of Commodity Housing (《商品房屋租賃管理辦法》) promulgated by the Ministry of Housing and Urban-Rural Development of PRC on December 1, 2010 and became effective on February 1, 2011, the lessor and the lessee shall complete property leasing registration and filing formalities within 30 days from execution of the property lease contract with the development (real estate) department of the People’s Government of the centrally-administered municipality, municipality or county where the leased property is located. Failure to comply with the above requirements may subject the relevant lessors and lessees to administrative penalties, including orders to make corrections within a certain period of time and fines.

Regulations in Relation to Environment, Health and Safety

Environmental Impact Assessment

According to the Code of the People’s Republic of China on the Ecological Environment promulgated by the SCNPC in March, 2026 and came into effect on August 15, 2026 (the “**Ecological Environment Code**”), and the Administrative Regulations on the Environmental Protection of Construction Project (《建設項目環境保護管理條例》), latest amended on July 16, 2017 and came into effect on October 1, 2017, enterprises which plan to construct projects shall engage qualified professionals to provide the assessment reports, assessment form, or registration form on the environmental impact of such projects. The assessment reports, assessment form, or registration form shall be filed with or approved by the relevant environmental protection bureau prior to the commencement of any construction work.

Pollutant Discharge

According to the Ecological Environment Code and 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 came into effect on March 1, 2021, and the Administrative Measures on Pollutant Discharge Permit (《排污許可管理辦法》) issued by the Ministry of Ecology and Environment on April 1, 2024 and came into effect on July 1, 2024, enterprises, public institutions and other producers and operators that are subject to the administration of pollutant discharge permits shall apply for pollutant discharge permit and discharge pollutants in accordance with the requirements of the pollutant discharge permit; and those who have not obtained the pollutant discharge permits shall not discharge pollutants. According to the Classification Management List for Fixed Source Pollution Permits (2019 Edition) (《固定污染源排污許可分類管理名錄(2019年版)》), the manufacturing of biological drugs and products falls into the classification management scope for fixed source pollution permits.

REGULATORY OVERVIEW

Disposal of Hazardous Wastes

According to the Ecological Environment Code, entities generating hazardous wastes shall store, utilize and dispose of hazardous wastes pursuant to the relevant provisions of the State and the requirements of environmental protection standards, and shall not arbitrarily dump or pile up such wastes. Entities that undertake the collection, storage, utilization and treatment of hazardous wastes shall apply for and obtain a permit. The hazardous wastes shall be defined by the National Catalogue of Hazardous Wastes (《國家危險廢物名錄》), of which the latest version was issued by the Minister of Ecology and Environment and other authorities on November 26, 2024 and entered into force as of January 1, 2025.

Discharge of Urban Sewage

Enterprises that engage in the activities of industry, construction, catering, and medical treatment, etc. that discharges sewage into urban drainage facilities shall apply to the relevant competent urban drainage department for the permit for discharging sewage into drainage pipelines under the Ecological Environment Code and the Regulations on Urban Drainage and Sewage Disposal (《城鎮排水與污水處理條例》), which was promulgated on October 2, 2013 and came into effect on January 1, 2014, and the Measures for the Administration of Permits for the Discharge of Urban Sewage into the Drainage Network (《城鎮污水排入排水管網許可管理辦法》), recently amended on December 1, 2022 and came into effect on February 1, 2023. Where a drainage entity needs to discharge sewage into urban drainage facilities, it shall apply for a drainage license in accordance with the provisions of these Measures.

Fire Safety

According to the Fire Safety Law of the PRC (《中華人民共和國消防法》) last amended and effective on April 29, 2021, and the Interim Provisions on Administration of Fire Protection Design Review and Acceptance of Construction Projects (《建設工程消防設計審查驗收管理暫行規定》) (the “**Interim Provisions**”) last amended on August 21, 2023, the fire protection design or construction of a construction project must conform to the national fire protection technical standards for project construction and construction projects shall undergo the fire protection design review and acceptance system. The special construction projects as defined in the Interim Provisions must apply to the fire control department for fire protection design review, and complete the fire protection acceptance procedures after the completion of the construction project. The construction unit of other construction projects must complete the fire protection filing of the fire protection design and the completion acceptance within five (5) business days after the completion acceptance of the construction project. If a construction project fails to pass the fire safety inspection before it is put into use, or does not meet the fire safety requirements after the inspection, it will be ordered to suspend the construction and use of such project, or suspend production and business, and be imposed a fine.

Production Safety

The Production Safety 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 and came into effect on September 1, 2021, is the basic law for governing production safety. It provides that, any entity whose production safety conditions do not meet the requirements may not engage in production and business operation activities. The production and business operation entities shall educate and train employees regarding production safety so as to ensure that the employees have the necessary knowledge of production safety, are familiar with the relevant regulations and rules for safe production and the rules for safe operation, master the skills of safe operation in their own positions, understand the emergency measures, and know their own rights and duties in terms of production safety. Employees who fail the education and training programs on production safety may not commence working in their positions. Safety facilities of new building, rebuilding or expanding project (as the construction project) shall be designed, constructed and put into operation simultaneously with the main body of the project. Investment in safety facilities shall be included in the budget of the construction project.

Hazardous Chemicals

The Regulation on Safety Administration of Hazardous Chemicals (《危險化學品安全管理條例》) (the “**Hazardous Chemicals Regulation**”) was promulgated by the State Council on January 26, 2002 and newly revised on December 7, 2013. The Hazardous Chemicals Regulation provides regulatory requirements on the safe production, storage, use, operation and transportation of hazardous chemicals. Any entity other than the producer of civil explosives, when purchasing hyper-toxic chemicals, shall apply to the public security organ of the local people’s government at the county level for a permit for purchasing hyper-toxic chemicals; when hazardous chemicals that can be used to make explosives are purchased, the explanations on the legal use of such chemicals issued by such entity shall be presented.

REGULATORY OVERVIEW

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 and latest revised on September 18, 2018, stipulates and regulates the production, operation, purchase, transportation, import and export of precursor chemicals. The precursor chemicals are classified into three categories. An enterprise that applies for purchasing the precursor chemicals in Category I, which refers to the major materials that may be used to produce drugs, shall submit the related certificates and shall obtain the purchase license upon the examination and approval of the supervisory and administrative department of drugs of the people's government of the province, autonomous region or centrally administered municipality where the applicant is located. An entity that purchases any precursor chemicals in Category II or III, which refers to the chemical auxiliary substances that may be used to produce drugs, shall, before the purchase, report the variety and quantity in demand to the public security organ of the local people's government at the county level for archival filing.

According to the Measures for the Public Security Management of Explosives Precursors (《易製爆危險化學品治安管理办法》) issued by the Ministry of Public Security on July 6, 2019 and effective on August 10, 2019, enterprises which have obtained permits for safe production of hazardous chemicals, permits for the safe use of hazardous chemicals and permits for business operation of hazardous chemicals in accordance with the law shall purchase explosive precursor hazardous chemicals with the corresponding licenses. A buyer of explosives precursors shall, within five days after purchasing, report the information about the types, quantity and flowing direction of explosives precursors purchased to the local county-level public security organ for filing through the Explosive Precursors Information System.

Prevention and Control of Occupational Diseases

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

According to the Law of the PRC on the Prevention and Control of Occupational Diseases, in the event that any newly built, expanded or renovated construction project, or technology renovation or introduction project (as the construction project) may generate occupational disease hazards, the owner shall conduct the assessment of occupational disease hazards during the feasibility study stage. The occupational disease hazard preassessment report shall assess the construction project as to possible occupational disease hazard factors and their impact on the workplace and health of the workers, and determine the type of the hazards and the measures for protection against occupational diseases.

Regulations in Relation to Employment and Social Securities

Pursuant to 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 latest 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 by the SCNPC on June 29, 2007 and latest amended on December 28, 2012 and came into effect on July 1, 2013, employers shall execute written labor contracts with full-time employees. All employers shall comply with local minimum wage standards. Employers shall establish a comprehensive management system to protect the rights of their employees, including a system governing occupational health and safety to provide employees with occupational training to prevent occupational injury, and employers are required to truthfully inform prospective employees of the job description, working conditions, working location, occupational hazards, and status of safe production as well as remuneration and other conditions.

REGULATORY OVERVIEW

According to the Social Security Law of the PRC (《中華人民共和國社會保險法》), which was promulgated on 28 October 2010 and amended on 29 December 2018, an employer is required to make contributions to social insurance schemes for its employees, including basic pension insurance, basic medical insurance, unemployment insurance, maternity insurance and work-related injury insurance. If the employer fails to make social insurance contributions in full and on time, the social insurance authorities may demand the employer to make payments or supplementary payments for the unpaid social insurance premium within a prescribed time limit together with a 0.05% surcharge of the unpaid social insurance premium from the due date. If the payment is not made within such time limit, the relevant administrative authorities will impose a fine ranging from one to three times the total outstanding amount.

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 became effective on September 1, 2025, where the employer fails to make social insurance contributions in accordance with the law, and the employee requests to terminate the labor contract and claim economic compensation in accordance with item (3) of Article 38 of the Labor Contract Law of the People's Republic of China (《中華人民共和國勞動合同法》), the people's court shall uphold such claim.

According to the Administrative Regulations on Housing Provident Funds (《住房公積金管理條例》) currently effective from 24 March 2019 (which has been latest amended in August, 2026 and will come into effect on September 20, 2026), employers are required to make contribution to housing provident funds for their employees. Where an employer fails to pay up housing provident funds, the housing provident fund administration center may order it to make payment within a prescribed time limit. If the employer still fails to do so, the housing provident fund administration center may apply to the court for compulsory enforcement of the unpaid amount.

Regulations in relation to Import and Export of Goods

According to the Provisions of the PRC on the Administration of Recordation of Customs Declaration Entities (《中華人民共和國海關報關單位備案管理規定》) promulgated by the General Administration of Customs on November 19, 2021 and come into effect on January 1, 2022, and the Announcement of the General Administration of Customs on Further Clarifying Issues Concerning the Record-filing of Customs Declaration Entities (《海關總署關於進一步明確報關單位備案有關事宜的公告》) promulgated on November 16, 2022 and come into effect on December 1, 2022, where the consignee or consignor of imported or exported goods or a customs declaration enterprise applies for recordation, it shall obtain the qualification of market entities; particularly where the consignee or consignor of imported or exported goods applies for recordation, it shall be filed as a foreign trade business. Where the consignee or consignor of imported or exported goods or a customs declaration enterprise has undergone the formalities of recordation for customs declaration entities, branches that meet the requirements of the preceding paragraph may also apply for recordation for customs declaration entities.

Regulations in Relation to Information Security and Data Privacy

Data Security and Export

The SCNPC promulgated the Data Security Law of the People's Republic of China (《中華人民共和國數據安全法》), on June 10, 2021 (effective from September 1, 2021), for the establishment of a data classification and grading protection system to conduct classified and hierarchical protection of data. Entities engaged in data processing activities shall, in accordance with laws and regulations, establish a sound full-process data security management system, organize data security education and training, and take corresponding technical measures and other necessary measures to ensure data security.

According to the Measures for Security Assessment of Data Export (《數據出境安全評估辦法》) issued by the Cyberspace Administration of China on July 7, 2022 and came into effect 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 critical information infrastructure operator 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.

REGULATORY OVERVIEW

According to the Provisions on Facilitating and Regulating Cross-border Data Flows (《促進和規範數據跨境流動規定》), a data handler that is not a critical information infrastructure operator, will be exempted from declaring for security assessment for outbound data transfer, signing a standard contract with overseas recipient or passing the personal protection certification, if such data handler accumulatively transfers overseas ordinary personal information (excluding sensitive personal information) of less than 100,000 individuals since the January 1 of the current year.

Personal Information Protection

According to the Civil Code, personal information of natural persons is protected by law. If any organization or individual needs to obtain other people’s personal information, they should obtain it in accordance with the law and ensure the security of the information. They must not illegally collect, use, process, or transmit other people’s personal information, and must not illegally buy, sell, provide, or disclose the information. The Personal Information Protection Law of the People’s Republic of China 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 People’s Republic of China (《中華人民共和國網絡安全法》) latest amended by the SCNPC in 2025 and effective on January 1, 2026, network operators must follow the principles of legality, legitimacy and necessity when collecting and using personal information, and 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 in Relation to Anti-money Laundering, Anti-corruption and Anti-bribery

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》) promulgated by the SCNPC on November 8, 2024 and effective from January 1, 2025, financial institutions shall, according to the provisions of the present law, establish a sound internal control system for anti-money laundering, set up a special body or designate an internal body to take the lead to take charge of the anti-money laundering work. The entities and individuals in business relationship with a financial institution shall cooperate with the financial institution in conducting customer due diligence by providing authentic and valid identity documents or other identity certificates, filling in identity information accurately and completely, 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 according to the present 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.

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 SCNPC on December 29, 2023, the crime of job appropriation means that an employee of any company, enterprise or any other organization unlawfully takes possession of the money or property of the organization by taking advantage of office, if the amount is relatively large, he shall be sentenced to fixed-term imprisonment of not more than three years or criminal detention and shall be fined concurrently; if the amount is huge, he shall be sentenced to fixed-term imprisonment of not less than three years but not more than 10 years and shall be fined concurrently; or if the amount is extremely huge, he shall be sentenced to fixed-term imprisonment of not less than 10 years or life imprisonment and shall be fined concurrently.

Anti-bribery

According to the Anti-Unfair Competition Law of the PRC and the Interim Provisions on the Prohibition of Commercial Bribery (《關於禁止商業賄賂行為的暫行規定》) promulgated by the SAIC on November 15, 1996, any business operator shall not provide or promise to provide economic benefits (including cash, other property or by other means) to a counter-party in a transaction or a third party that may be able to influence the transaction, in order to entice such party to secure a transactional opportunity or competitive advantages for the business operator. Any business operator breaching the relevant anti-bribery rules above-mentioned may be subject to administrative punishment or criminal liability depending on the seriousness of the cases.

REGULATORY OVERVIEW

Pursuant 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, any medicine production and operation enterprises or agents that are involved in criminal, investigational or administrative procedures for commercial bribery will be listed in the adverse records of commercial bribes by the relevant government authorities, as a result of which, for two years from the date the list of adverse records of commercial bribes is published, (i) their products cannot be purchased by public medical institutions or medical and health institutions receiving financial subsidies within the relevant provinces, and (ii) the scores of their products in the centralized tender processes of public medical institutions or medical and health institutions receiving financial subsidies in other provinces will be reduced. As for those enterprises or agents listed in adverse records twice within five years, their products cannot be purchased by public medical institutions or medical and health institutions receiving financial subsidies throughout China for two years from the date the list of adverse records of commercial bribes is published.

Regulations on Taxation

Enterprise Income Tax

According to the Enterprise Income Tax Law of the People's Republic of China, which was promulgated by the NPCSC and was latest amended on December 29, 2018, and the Regulation on the Implementation of the Enterprise Income Tax Law, which was promulgated by the State Council and was effective from January 1, 2008, a uniform 25% enterprise income tax rate is imposed on both foreign invested enterprises and domestic enterprises, except where tax incentives are granted to special industries and projects. The enterprise income tax rate is reduced to 20% for qualifying small low-profit enterprises. Key high-tech enterprises that are supported by the PRC's government may enjoy a reduced tax rate of 15% for enterprise income tax.

Value-added Tax

Pursuant to the Value-Added Tax Law of the People's Republic of China (《中華人民共和國增值稅法》), promulgated by the NPCSC on December 25, 2008 and effective from January 1, 2009, and the Implementation Rules for the Provisional Regulations the PRC on Value-added Tax (《中華人民共和國增值稅暫行條例實施細則》), which was promulgated by the Ministry of Finance and was latest amended on October 28, 2011 and effective from November 1, 2011, entities and individuals engaging in selling goods, providing processing, repairing or replacement services or importing goods within the territory of the PRC are taxpayers of the VAT.

According to the Notice of the Ministry of Finance and the State Taxation Administration on the Adjusting Value-added Tax Rates (《財政部稅務總局關於調整增值稅稅率的通知》) effective in May 2018, the VAT rates of 17% and 11% on sales, imported goods shall be adjusted to 16% and 10%, respectively.

According to the Announcement of the Ministry of Finance, the State Taxation Administration and the General Administration of Customs on Relevant Policies for Deepening the Value-Added Tax Reform (《財政部稅務總局海關總署關於深化增值稅改革有關政策的公告》) promulgated on March 20, 2019 and effective from April 1, 2019, the VAT rates of 16% and 10% on sales, imported goods shall be adjusted to 13% and 9%, respectively.

According to the Provisional Regulations of the People's Republic of China on Value-added Tax (《中華人民共和國增值稅暫行條例》) promulgated on and effective from November 19, 2008, the tax rate for taxpayers engaging in sale of services and intangible assets shall be 6%, unless otherwise stipulated under this regulation.

According to the Notice on VAT Policies for Anti-cancer Drugs (《關於抗癌藥品增值稅政策的通知》) promulgated on April 27, 2018 by the Ministry of Finance, the General Administration of Customs, the State Administration of Taxation and the NMPA, VAT general taxpayers engaging in manufacturing and sale, wholesale and retail of anti-cancer drugs may opt to compute and pay VAT at the tax rate of 3% under the simplified method.

Regulation on 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. Foreign exchange payments under current account items shall, pursuant to the administrative provisions of the foreign

REGULATORY OVERVIEW

exchange control department of the State Council on payments of foreign currencies and purchase of foreign currencies, be made using self-owned foreign currency or foreign currency purchased from financial institutions engaging in conversion and sale of foreign currencies by presenting the valid document. Domestic entities and domestic individuals making overseas direct investments or engaging in issuance and trading of overseas securities and derivatives shall process registration formalities pursuant to the provisions of the foreign exchange control department of the State Council.

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》) in February 2015 and further amended in 2019, 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.

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》), latest amended on October 10, 2018, 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 People's Bank of China and the State Administration of Foreign Exchange on Issues Concerning the Administration of Funds Raised by Domestic Enterprises Listed Overseas (《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》) issued by the People's Bank of China and the SAFE in 2025 and came into effective on April 1, 2026, the domestic companies shall register the overseas listed with the foreign exchange control bureau located at its registered address in 30 working days after completion of the overseas listing and issuance. The funds raised by the domestic companies through overseas listing may be repatriated to China or deposited overseas, provided that the intended use of the fund shall be consistent with the contents of the document and other public disclosure documents.

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 partially amended on December 4, 2023 and effective since then. The notice canceled restrictions on domestic equity investments made with capital funds by non-investing foreign-funded enterprises. In addition, restrictions on the use of funds for foreign exchange settlement of domestic accounts for the realization of assets have been removed and restrictions on the use and foreign exchange settlement of foreign investors' security deposits have been relaxed. Eligible enterprises in the pilot area are also allowed to use revenues under capital accounts, such as capital funds, foreign debts and overseas listing revenues for domestic payments without providing materials to the bank in advance for authenticity verification on an item-by-item basis, while the use of funds should be true, in compliance with applicable rules and conforming to the current capital revenue management regulations.

According to the Circular on Optimizing Administration of Foreign Exchange to Support the Development of Foreign-related Business (《關於優化外匯管理支持涉外業務發展的通知》) issued by the SAFE on April 10, 2020, eligible enterprises are allowed to make domestic payments by using their capital funds, foreign credits and the income under capital accounts of overseas listing, without submitting the evidentiary materials concerning authenticity of such capital for banks in advance, provided that their capital use is authentic and in compliance with administrative regulations on the use of income under capital accounts. The bank in charge shall conduct post spot checking in accordance with the relevant requirements.

Regulations in Relation to Overseas Securities Offering and Listing by Domestic Companies

According to 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》) issued by the CSRC on February 17, 2023 and effective from March 31, 2023, where a domestic company seeks overseas securities issuance and listing, the issuer shall file with the CSRC in accordance with the Trial Measure for Overseas Listing. If an issuer procures an overseas initial public offering or listing, it shall file with the CSRC within three (3) business days after submitting application documents for overseas securities issuance and listing.

REGULATORY OVERVIEW

According to the Provisions on Strengthening 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》) jointly issued by the CSRC and other departments on February 24, 2023 and effective on March 31, 2023, in the overseas offering and listing activities of domestic enterprises, domestic enterprises, and securities companies and securities service institutions that provide corresponding services shall strictly comply with the applicable laws and regulations of the People’s Republic of China and satisfy the requirements of these Provisions, enhance the legal awareness of safeguarding state secrets and strengthening archives administration, establish and improve the confidentiality and archives work 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. A domestic enterprise that, either directly or through its overseas listed entity, publicly discloses or provides to relevant securities companies, securities service institutions, overseas regulators, and other entities and individuals, any documents and materials that involve state secrets or work secrets of state organs, shall obtain approval from the competent department with the power of examination and approval according to the law, and report to the administrative department of confidentiality at the same level for filing. A domestic enterprise that, either directly or through its overseas listed entity, publicly discloses or provides to relevant securities companies, securities service institutions, overseas regulators, and other entities and individuals, other documents and materials whose divulgence will have adverse impact on national security or public interest, shall strictly undergo the relevant procedures in accordance with the relevant regulations of the state.

OVERVIEW OF LAWS AND REGULATIONS IN THE UNITED STATES

This section summarizes the principal laws and regulations in the United States that are relevant to our business.

U.S. Government Regulation of Drug and Biological Products

In the United States, the FDA regulates drugs under the Federal Food Drug and Cosmetic Act (the “FDCA”), its implementing regulations, and biologics under the FDCA and the Public Health Service Act (the “PHSA”) and their implementing regulations. Both drugs and biologics also are subject to other federal, state and local statutes and regulations, such as those related to competition. Failure to comply with the applicable U.S. requirements at any time during the product development process, approval process or following approval may subject an applicant to administrative actions or judicial sanctions.

Once a product candidate is identified for development, it enters preclinical testing. Preclinical testing is conducted in accordance with FDA’s Good Laboratory Practice regulations. A sponsor of an investigational new drug application (IND) to conduct clinical studies in the United States must typically submit the results of the preclinical tests, manufacturing information, analytical data, the clinical trial protocol, and any available clinical data or literature to the FDA before commencing the studies described in the IND. The IND automatically becomes effective 30 days after receipt by the FDA, unless the FDA raises concerns or questions and places the trial on a clinical hold within that 30-day period. FDA may also impose clinical holds or partial clinical holds at any time during clinical trials including due to safety concerns or non-compliance.

All clinical trials, which involve the administration of the investigational product to humans, must be conducted under the supervision of one or more qualified investigators in accordance with Good Clinical Practice regulations, including the requirement that all research subjects provide informed consent in writing before their participation in any clinical trial.

Clinical trials are conducted under protocols detailing, among other things, the objectives of the study, the parameters to be used in monitoring safety and the effectiveness criteria to be evaluated. An Institutional Review Board (the “IRB”), must review and approve the plan for any clinical trial before it commences at any institution, and the IRB must conduct continuing review and re-approve the study at least annually. Each new clinical protocol and any amendments to the protocol must be submitted for FDA review, and to the IRBs for approval. An IRB can suspend or terminate approval of a clinical trial at its institution if the trial is not being conducted in accordance with the IRB’s requirements or if the product has been associated with unexpected serious harm to subjects.

REGULATORY OVERVIEW

Progress reports detailing the results of the clinical trials must be submitted at least annually to the FDA. Safety reports must be submitted to the FDA and the investigators 15 calendar days after the trial sponsor determines that the information qualifies for reporting. The sponsor also must notify FDA of any unexpected fatal or life-threatening suspected adverse reaction as soon as possible. Sponsors of clinical trials of FDA-regulated products, including drugs, are required to register and disclose certain clinical trial information, which is publicly available at www.clinicaltrials.gov.

A number of other requirements also apply to FDA regulated clinical trials. For instance, FDA seeks to ensure that clinical trial data is meaningful for and applicable to a U.S. population and medical practice, which may impact FDA's acceptance of data from foreign clinical studies. Sponsors or distributors of investigational products for the diagnosis, monitoring, or treatment of one or more serious disease or conditions must also have a public policy on expanded access. Sponsors must further make certain disclosure statements to FDA with respect to investigator conflicts of interest.

Additionally, the manufacture of investigational drugs and biologics for clinical trials is subject to Good Manufacturing Practice ("cGMP") requirements. Investigational drugs/biologics and active ingredients/substances that are imported into the United States must also comply with FDA requirements. Further, the export of investigational products from the United States is subject to regulatory requirements of the receiving country as well as U.S. export requirements. Concurrent with clinical trials, companies usually complete additional animal studies and must also finalize a process for manufacturing the product in commercial quantities in accordance with cGMP.

U.S. Review and Approval Processes

The results of product development, preclinical studies and clinical trials, along with descriptions of the manufacturing process, analytical tests conducted on the product, proposed labeling and other relevant information, are submitted to the FDA as part of a NDA or BLA. Unless deferred or waived, NDA or BLAs (and after approval, supplements to NDAs or BLAs) must contain data adequate to assess the safety and effectiveness of the product for the claimed indications in all relevant subpopulations and to support dosing and administration for each subpopulation for which the product is found to be safe and effective. The submission of an NDA or BLA is subject to the payment of a substantial user fee and an annual prescription drug program fee.

Within 60 days of its receipt, the FDA reviews the NDA or BLA to ensure that it is sufficiently complete for substantive review before it accepts the application for filing. After accepting the application for filing, the FDA begins an in-depth substantive review to determine, among other things, whether a product is safe and effective for its intended use. The FDA also evaluates whether the product's manufacturing processes are cGMP-compliant and is sufficient to ensure the product's identity, strength, quality and purity. Before approving the application, the FDA typically will inspect whether the manufacturing processes and facilities are in compliance with cGMP requirements and adequate to ensure consistent production of the product within required specifications.

The FDA may refuse to approve the application if the applicable regulatory criteria are not satisfied or may require additional clinical data or other data and information. The FDA will issue a complete response letter describing all of the specific deficiencies that the FDA identified in the application that must be satisfactorily addressed before it can be approved. The deficiencies identified may be minor; for example, requiring labeling changes, or major, for example, requiring additional clinical trials. Additionally, the complete response letter may include recommended actions that the applicant might take to place the application in a condition for approval. The applicant may either resubmit the application, addressing all of the deficiencies identified in the letter, or withdraw the application or request an opportunity for a hearing.

The regulatory approval may be limited to specific diseases and dosages or the indications for use may otherwise be limited, which could restrict the commercial value of the product. Further, the FDA may require that certain contraindications, warnings or precautions be included in the product labeling. In addition, the FDA may require post-approval studies, including phase IV clinical trials, to further assess a product's safety and effectiveness after approval and may require testing and surveillance programs to monitor the safety of approved products that have been commercialized.

REGULATORY OVERVIEW

Expedited Development and Review Programs

The FDA has various programs that are intended to expedite or streamline the process for the development and FDA review of drugs and biologics that are intended for the treatment of serious or life-threatening diseases or conditions and demonstrate the potential to address unmet medical needs, such as fast-track designations, priority review designations, accelerated approvals, breakthrough therapy designations and orphan drug designations. The purpose of these programs is to provide important new therapies to patients earlier than under standard FDA review procedures.

Post-Marketing Requirements

Following the approval of a new product, the manufacturer and the approved product are subject to continuing regulation by the FDA, including, among other things, monitoring and record-keeping activities, reporting of adverse experiences, complying with promotion and advertising requirements, which include restrictions on promoting products for unapproved uses or patient populations, known as "off-label use," and limitations on industry-sponsored scientific and educational activities. Although FDA does not regulate off-label prescription by physicians, FDA restricts the marketing and promotion of such uses by manufacturers. The FDA and other agencies actively enforce the laws and regulations prohibiting the promotion of off-label uses, and a company that is found to have improperly promoted off-label uses may be subject to significant liability, including investigation by federal and state authorities. Prescription drug promotional materials must be submitted to the FDA in conjunction with their first use or first publication. Further, if there are any modifications to the drug or biologic, including changes in indications, labeling or manufacturing processes or facilities, the applicant may be required to submit and obtain FDA approval of a new BLA or BLA supplement, which may require the development of additional data or preclinical studies and clinical trials. FDA regulations require that products be manufactured in specific approved facilities and in accordance with cGMP regulations. These manufacturers must comply with cGMP regulations on an on-going basis, which require, among other things, quality control and quality assurance, the maintenance of records and documentation and the obligation to investigate and correct any deviations from cGMP. Once an approval is granted, the FDA may issue enforcement letters or withdraw the approval of the product if compliance with statutory or regulatory requirements and standards is not maintained or if safety or efficacy problems occur or come to light after the drug or biologic reaches the market.

Coverage and Reimbursement

In the United States, sales of any product depend, in part, on the extent to which such product will be covered by third-party payers, such as federal, state and foreign government healthcare programs, commercial insurance and managed healthcare organizations, and the level of reimbursement for such product by third-party payers. Significant uncertainty exists as to the coverage and reimbursement status of any pharmaceutical or biological product which obtains regulatory approval. Decisions regarding the extent of coverage and amount of reimbursement to be provided are made on a plan-by-plan basis. As there is no uniform policy of coverage and reimbursement for drug products among third-party payers in the United States, coverage and reimbursement policies for drug products can differ significantly from payer to payer.

In the United States, the principal decisions about reimbursement for new products are typically made by the Centers for Medicare & Medicaid Services (CMS), an agency within the Department of Health & Human Services (HHS). CMS decides whether and to what extent a new product will be covered and reimbursed under Medicare, and private payors tend to follow CMS to a substantial degree. As a condition of participating in, and having products covered under, certain federal healthcare programs, such as Medicare and Medicaid, the business will be subject to federal laws and regulations that require drug manufacturers to calculate and report certain price reporting metrics to the government, such as Medicaid Average Manufacturer Price, or AMP, and Best Price, Medicare Average Sales Price, the 340B Ceiling Price and Non-Federal AMP reported to the Department of Veteran Affairs, and with respect to Medicaid, pay statutory rebates on utilization of manufacturers' products by Medicaid beneficiaries. Compliance with such laws and regulations require significant resources and any findings of non-compliance could have a material adverse effect on the business' revenues. In addition, the U.S. government, state legislatures and foreign governments have continued implementing cost-containment programs, including price controls, restrictions on coverage and reimbursement and requirements for substitution of generic products.

REGULATORY OVERVIEW

Privacy and Security

The business may be subject to data privacy and security regulations by both the federal government and the states in which the business is conducted. For example, under the administrative simplification provisions of HIPAA, as amended by the Health Information Technology for Economic and Clinical Health Act of 2009, or HITECH, HHS issued regulations that establish uniform standards governing the conduct of certain electronic healthcare transactions and requirements for protecting the privacy and security of protected health information, or PHI, used or disclosed by covered entities. Covered entities and their business associates (and their covered subcontractors) are subject to HIPAA and HITECH.

HIPAA and HITECH include privacy and security rules, breach notification requirements and electronic transaction standards. The HIPAA Privacy Rule generally prohibits the use or disclosure of PHI except as permitted under the rule. The rule also sets forth individual patient rights, such as the right to access or amend certain records containing his or her PHI, or to request restrictions on the use or disclosure of his or her PHI. The HIPAA Security Rule requires those subject to HIPAA to safeguard the confidentiality, integrity, and availability of electronically transmitted or stored PHI by implementing administrative, physical, and technical safeguards. Under HIPAA's Breach Notification Rule, a covered entity must notify individuals, the Secretary of the HHS, and in some circumstances, the media of breaches of unsecured PHI.

If found to be in violation of HIPAA as the result of a breach of unsecured PHI, a complaint about their privacy practices or an audit by HHS, entities may be subject to significant civil and criminal fines and penalties and/or additional reporting and oversight obligations if such entities are required to enter into a resolution agreement and corrective action plan with HHS to settle allegations of HIPAA non-compliance.

In addition, the business may be subject to federal laws, including federal health information privacy laws and consumer protection laws (e.g., Section 5 of the Federal Trade Commission Act) and state health information privacy, security and data breach notification laws, which may govern the collection, use, disclosure and protection of health-related and other personal information.

The U.S. regulatory framework for privacy, data security and data transfers is rapidly evolving, and there has been an increasing focus on privacy and data protection issues. As a result, interpretation and implementation standards and enforcement practices are likely to remain uncertain for the foreseeable future.

Foreign Research Activities

Recently, certain foreign activities related to drugs, biologics, and research, especially with respect to China, have come under increased scrutiny in the United States. This scrutiny and regulation may continue or may increase which may make the conduct of our business more difficult. Solely by example, some of the recent United States actions include:

- Steps to encourage use of U.S. domestic manufacturing and supply chains.
- FDA restrictions on certain foreign research, such as an immediate review of new clinical trials that involve sending American citizens' living cells to China and other hostile countries for genetic engineering.
- The issuance of a final rule (the DSP Rule) by the U.S. Department of Justice, or DOJ, which took effect in April 2025 and for which enforcement began in July 2025, to impose restrictions on access to US bulk sensitive personal data and government-related data by certain foreign countries and persons. The DSP Rule prohibits and restricts "bulk" data transactions involving China (including Hong Kong and Macau) and other specified "countries of concern" and individuals and entities under their control. Bulk U.S. sensitive personal data includes covered personal identifiers, precise geolocation data, biometric identifiers, human 'omic (including genomic) data, personal health data, personal financial data, or any combination thereof that exceeds certain specified thresholds of number of U.S. persons. To be subject to the DSP Rule, the data transaction must involve providing a "country of concern" or "covered person" with "access" to such controlled data. Exemptions to the prohibitions and restrictions of the DSP Rule include certain data transactions that involve "regulatory approval data" necessary to obtain or maintain regulatory authorization or approval to research or market a drug, biological product, device, or combination product, if reporting and recordkeeping

REGULATORY OVERVIEW

requirements are met. There is also an exemption for data transactions to the extent that they are ordinarily incident to and part of certain clinical investigations or the collection and processing of certain clinical care data or post-marketing surveillance data.

- Many biological agents, toxins, and related technology are restricted by the United States for export to China for national security reasons and require an export authorization from the U.S. Department of Commerce. Export controls also apply to genetic elements and genetically modified organisms that contain DNA associated with the pathogenicity of these biological materials.
- Chinese-origin goods imported into the United States have recently become subject to fluctuating tariffs, and these tariff regimes continue to change rapidly, which may impact trade in drugs and biologics, and other goods between the two countries.

The BIOSECURE Act

On December 18, 2025, the U.S. Senate passed the BIOSECURE Act (the “**Act**”) as a part of the National Defense Authorization Act for Fiscal Year 2026, which was signed into law by the U.S. President. This version of the Act materially mitigates potential impacts, specifically, the Act eliminates the prior, explicit designation of “biotechnology company of concern” (“**BCC**”) and instead adopts a dynamic identification framework tied to the U.S. Department of Defense’s annual List of Chinese Military Companies, also known as the 1260H List, and the U.S. Government also has the ability to designate entities as BCCs through a separate designation process. In addition, the legislation narrows the definition of restricted “biotechnology equipment or services,” expressly excluding certain core technologies, including mass spectrometry and PCR instruments, from the scope of prohibitions.

Specifically, the Act prohibits the U.S. Government from procuring or obtaining biotechnology equipment or services produced or provided by a “BCC”; entering into, extending, or renewing government contracts with an entity that directly or indirectly (e.g., via a subcontractor) uses biotechnology equipment or services from a BCC in performance of that federal contract; and/or issuing grants or loans to purchase, obtain, or use biotechnology equipment or services produced by a BCC. The Act also prohibits U.S. government loan and grant recipients from using federal loan or grant money to enter into contracts with entities that use equipment from BCCs in the performance of any federal prime contract or subcontract.

Now in the implementation phase, U.S. agencies will further define compliance obligations under the Act through the U.S. regulation approval process known as notice and comment rulemaking or through other procedures. The President of the United States may also issue executive orders with respect to the content of the Act.