

REGULATORY OVERVIEW

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

PRINCIPAL REGULATORY AUTHORITIES

NMPA and Center for Drug Evaluation

National Medical Products Administration (國家藥品監督管理局) (formerly known as the China Food and Drug Administration (國家食品藥品監督管理總局) (the "CFDA")) (the "NMPA") is the department in charge of the pharmaceutical industry of China. It is primarily responsible for supervision and management of safety of pharmaceuticals, medical devices and cosmetics, including drawing up the relevant laws and regulations; conducting standard management, registration management, quality management and post-market risk management for drugs, medical devices and cosmetics; and organizing and guiding the supervision and inspection of drugs, medical devices and cosmetics and etc.

Center for Drug Evaluation, NMPA (國家藥品監督管理局藥品審評中心) (the "CDE") is the technical evaluation unit for drug registration with NMPA. It is primarily responsible for conducting technical evaluation on the drugs application for registration and verifying the relevant drug registrations.

NHC

The National Health Commission (國家衛生健康委員會) (formerly known as the National Health and Family Planning Commission (國家衛生和計劃生育委員會)) (the "NHC"), is primary national regulator for national public health and medical system.

It is primarily responsible for drafting national health policies, supervising and regulating public health, healthcare services, and health emergency systems, coordinating the reform of medical and health system, organizing the formulation of national drug policies and national essential medicine system, launching an early warning mechanism for the monitoring of the use and clinical comprehensive evaluation of medicine as well as the drug shortage, giving suggestions on the pricing policy of national essential medicine, and regulating the operation of medical institutions and practicing of medical personnel.

NHSA

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

PRINCIPAL REGULATORY PROVISIONS

Laws and Regulations on New Drugs

Research and development of new drugs

The Drug Administration Law of the PRC (《中華人民共和國藥品管理法》) (the "Drug Administration Law") promulgated by the Standing Committee of the National People's Congress (the "SCNPC") in September 1984, last amended on August 26, 2019 and became effective on December 1, 2019, and the Implementation Regulations of the Drug Administration Law of the PRC (《中華人民共和國藥品管理法實施條例》) (the "Implementation Regulations") promulgated by the State Council in August 2002 and last amended on December 6, 2024 and became effective on January 20, 2025, have laid down the legal framework for the establishment and maintenance of pharmaceutical manufacturing and trading enterprises, as well as for the administration of

REGULATORY OVERVIEW

pharmaceutical products including the development and manufacturing of new drugs. According to the Drug Administration Law and the Implementation Regulations, the PRC encourages the research and development of new drugs, and protects the legal rights and interests in the research and development of new drugs. The developer and clinical trial applicant of any new drug shall truthfully submit the new drug's manufacturing method, quality specifications, results of pharmacological and toxicological tests and the related data, documents and samples to the NMPA for approval before any clinical trial is conducted.

In 2017, the drug regulatory system entered a new and significant period of reform. The General Office of the State Council and the General Committee of China Communist Party jointly issued the Opinions on Deepening the Reform of the Evaluation and Approval Systems and Encouraging Innovation on Drugs and Medical Devices (關於深化審評審批制度改革鼓勵藥品醫療器械創新的意見) (the "Innovation Opinions") on October 2017. According to the Innovation Opinions, institutions for drug clinical trials should establish an independent ethics committee and the clinical trial schemes are subject to examination, approval and signing with approval opinions by the ethics committee before implementation, in order to protect the rights and interests of human subjects in clinical trials. For a multi-center clinical trial conducted in the PRC, after ethical review by the leader unit of clinical trial, other member units should recognize the review results of the leader unit and may not conduct repeated review.

Non-clinical research

The non-clinical safety evaluation study for drugs for the purpose of applying for drug registration shall be conducted in accordance with the Administrative Measures for Good Laboratories Practice (《藥物非臨床研究質量管理規範》), which was promulgated in August 2003 and amended in July 2017 by the CFDA and became into effective on September 1, 2017. In April 2007, the CFDA issued the Circular on Measures for Certification of Good Laboratory Practice (《藥物非臨床研究質量管理規範認證管理辦法》), last amended on January 19, 2023 and taking effect on July 1, 2023, which set forth the requirements for an institution to apply for a Certification of Good Laboratory Practice to undertake non-clinical research on drugs.

Animal Testing

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

Application for clinical trial

According to the Decision on Adjusting the Approval Procedures of Certain Administrative Approval Items for Drugs (《關於調整部分藥品行政審批事項審批程序的決定》) promulgated by the CFDA on March 17, 2017, the decision on the approval of clinical trials of drugs shall be made by the CDE from May 1, 2017. According to the Administrative Measures for Drug Registration (《藥品註冊管理辦法》) (the "Circular 27"), which was promulgated on January 22, 2020 and took effect on July 1, 2020, drug clinical trials shall be divided into Phase I clinical trial, Phase II clinical trial, Phase III clinical trial, Phase IV clinical trial, and bioequivalence trial. In accordance with Circular 27 and the Announcement on Adjusting Evaluation and Approval Procedures for Clinical Trials for Drugs (《關於調整藥物臨床試驗審評審批程序的公告》) issued in July 2018, if a clinical trial applicant does not receive any negative or questioned opinions from the CDE within 60 days after the date when the trial application is accepted and the fees are paid, the applicant can proceed with the clinical trial in accordance with the trial protocol submitted to the CDE. According to the Announcement on Matters Related to Optimizing

REGULATORY OVERVIEW

the Review and Approval of Clinical Trials for Innovative Drugs (《國家藥監局關於優化創新藥臨床試驗審評審批有關事項的公告》) promulgated by the NMPA on September 12, 2025, the NMPA shall complete the review and approval process for qualifying innovative drug clinical trial applications within 30 working days.

After obtaining the approval of clinical trial from the NMPA, the applicant must complete the clinical trial registration at the Drug Clinical Trial Information Platform for public disclosure in accordance with the Circular on Drug Clinical Trial Information Platform (《關於藥物臨床試驗信息平台的公告》), which came into effect in September 2013. The applicant shall complete the initial registration of the trial within one month after obtaining the approval of clinical trial to obtain an exclusive trial registration number, and then complete the subsequent information registration before the first patient is enrolled in the trial and submit the registration for public disclosure for the first time.

Conduct of clinical trial

After obtaining clinical trial approval, the applicant shall conduct clinical trials at qualified clinical trial institutions. The qualified clinical trial institution refers to institutions that have the conditions to conduct clinical trials in accordance with the requirements and technical guidelines set forth in the Regulations for the Administration of Drug Clinical Trial Institutions (《藥物臨床試驗機構管理規定》), which came into effect on December 1, 2019.

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

According to the Announcement on Adjusting Evaluation and Approval Procedures for Clinical Trials for Drugs (《關於調整藥物臨床試驗審評審批程序的公告》), where the application for clinical trial of new drug has been approved, upon the completion of Phases I and II clinical trials and prior to Phase III clinical trial, the applicant shall submit the application for communication meetings to CDE to discuss with CDE the key technical questions including the design of Phase III clinical trial protocol. According to the Administrative Measures for Communication on the Research, Development and Technical Evaluation of Drugs (《藥物研發與技術審評溝通交流管理辦法》), revised by the NMPA on December 10, 2020, during the research and development periods and in the registration applications of, among others, the innovative new drugs, the applicants may propose to conduct communication meetings with the CDE. The communication meetings can be classified into three types. Type I meetings are convened to address key safety issues in clinical trials of drugs and key technical issues in the research and development of breakthrough therapeutic drugs. Type II meetings are held during the key research and development stages of drugs, mainly including meetings before submitting the clinical trial application, meetings upon the completion of Phase II trials and prior to Phase III trials and meetings before submitting the marketing application for a new drug. Type III meetings refer to other meetings not classified as Type I or Type II.

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

New drug registration

Pursuant to Circular 27, upon completion of clinical trials, determination of quality standards, completion of validation of commercial-scale production processes and completion of other related preparation works, the applicant may apply with the NMPA for the marketing authorization. The NMPA then determines whether to approve the application according to applicable laws and regulations. The applicant must obtain the marketing authorization for a new drug before the drug can be sold in the China market. According to Circular 27, the holders of any of the following drugs can apply for conditional approval of such drugs: (1) drugs which are used for the treatment of severe

REGULATORY OVERVIEW

life-threatening diseases currently lacking effective treatment and the data of clinical trials can confirm their efficacy and forecast their clinical value; (2) drugs which are urgently needed for public health and data of clinical trials can demonstrate their efficacy and forecast their clinical value; and (3) vaccines which are urgently needed to deal with major public health emergencies or other vaccines which the NHC deems to be urgently needed, the benefits of both of which are assessed to be outweigh the risk.

Pursuant to the Reform Plan for Registration Category of Chemical Medicine (《化學藥品註冊分類改革工作方案》) issued by the CFDA on March 4, 2016, new registration of chemical drugs are divided into 5 categories: (i) Category 1: innovative drugs that have not been marketed in the PRC or abroad which shall contain new compounds with clear structure and pharmacological effects and clinical value; (ii) Category 2: improved new drugs that have not been marketed in the PRC or abroad with optimization in structure, dosage form, prescription technology, route of drug administration and indications on the basis of known active ingredients as well as obvious clinical advantages; (iii) Category 3: drugs imitated by domestic applicants which are marketed overseas while originator's drugs are not marketed in the PRC. Such drugs should possess quality and efficacy in line with that of the originator's drugs (i.e. the first drugs approved to be marketed in the PRC or overseas with complete and sufficient safety and efficacy data to serve as the basis for its launch); (iv) Category 4: drugs imitated by domestic applicants while originator's drugs have been marketed in the PRC. The quality and efficacy of such drugs should be consistent with that of the originator's drugs; and (v) Category 5: drugs which have been marketed abroad with the applications to be marketed in the PRC. Among them, the reporting procedure for Category 1 and 2 shall comply with those for new drugs and for Category 3 and 4 it shall be in accordance with those for generic drugs, while Category 5 shall be reported pursuant to the procedures for imported drugs.

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

Accelerated Approval for Clinical Trial and New Drug Registration

The Opinions of the State Council on the Reform of Evaluation and Approval System for Drugs and Medical Devices (《國務院關於改革藥品醫療器械審評審批制度的意見》) issued by the State Council on August 9, 2015, established a reform framework of the evaluation and approval system for drugs and medical devices, and specified the tasks of enhancing the standards of approval for, among others, drug registration, accelerating the evaluation and approval process for innovative drugs, and improving the approval for clinical trials of drugs.

The Announcement on Several Policies on Drug Registration Review and Approval (《關於藥品註冊審評審批若干政策的公告》) issued by the CFDA on November 11, 2015, provided fast-track clinical trial approvals and drug registration pathways for the following new drug applications: (i) registration of innovative new drugs treating HIV, malignant tumors (cancers), severe infectious diseases and rare diseases; (ii) registration of pediatric drugs; (iii) registration of geriatric drugs and drugs treating diseases specially or commonly contracted by the senior population; (iv) registration of drugs listed in national major science and technology projects or national key research and development plan; (v) registration of innovative drugs using advanced technology or innovative treatment methods, or having distinctive clinical benefits; (vi) registration of foreign innovative drugs to be manufactured locally in China; (vii) concurrent applications for new drug clinical trials which are already approved in the United States or the European Union or concurrent drug registration applications for drugs which have applied to the competent drug approval authorities for marketing authorization and passed such authorities' onsite inspections in the United States or European Union and are manufactured using the same production line in China; and (viii) clinical trial applications for drugs with urgent clinical need and patent expiry within three years, and manufacturing authorization applications for drugs with urgent clinical need and patent expiry within one year.

On October 8, 2017, the General Office of the Central Committee of the Communist Party of China and the General Office of the State Council jointly issued the Opinions on

REGULATORY OVERVIEW

Deepening the Reform of the Evaluation and Approval System and Encouraging Innovation of Drugs and Medical Devices (《關於深化審評審批制度改革鼓勵藥品醫療器械創新的意見》), aiming to simplify the clinical trial procedures and shorten the time.

Furthermore, according to the Announcement on Matters Concerning the Optimization of Drug Registration Review and Approval (《關於優化藥品註冊審評審批有關事宜的公告》) jointly issued by the NMPA and the NHC on May 17, 2018, the drug approval process shall be further streamlined and expedited.

Pursuant to the provisions of the Procedures for the Evaluation of Breakthrough Therapeutic Drugs (Trial) (《突破性治療藥物審評工作程序(試行)》) issued by the NMPA on July 7, 2020, during the clinical drug trials, the applicant is allowed to apply for the breakthrough therapeutic drug procedure during Phase I and Phase II clinical trials and normally no later than the commencement of Phase III clinical trials for the innovative or improved drugs etc. which are used for the prevention and treatment of diseases that seriously endanger life or seriously affect quality of life and there is no effective means of prevention and treatment or there is sufficient evidence to show a significant clinical advantage over existing treatment approach.

Marketing Authorization Holder Mechanism

Pursuant to the Drug Administration Law, China implements the marketing authorization holder mechanism for management of the drug industry. The drug marketing authorization holder shall be responsible for non-clinical research, clinical trials, production and operation, post-marketing research, adverse reaction monitoring, reporting and processing of drugs in accordance with the provisions of the law.

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

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

Where the marketing authorization holder is an overseas enterprise, its designated domestic enterprise shall perform the obligations of the marketing authorization holder and jointly assume responsibilities of the marketing authorization holder with the overseas enterprise.

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

On June 10, 1998, the Ministry of Science and Technology (the "MOST") and the Ministry of Health (the "MOH", which was canceled in the institutional reform of the State Council in 2013, its functions were first inherited by the National Health and Family Planning Commission and then by the NHC, which was established in 2018) promulgated the Interim Measures for the Management of Human Genetic Resources (《人類遺傳資源管理暫行辦法》), which sets out rules for the protection and use of human genetic resources in China. Pursuant to the Service Guide for Administrative Licensing of Gathering, Collection, Deal, Export and Exit Approval of Human Genetic Resources of Human genetic resources (《人類遺傳資源採集、收集、買賣、出口、出境審批行政許可事項服務指南》) promulgated by the MOST on July 2, 2015 and the Notice on the Implementation of the Administrative License for the Gathering, Collection, Deal, Export and Exit of Human Genetic Resources (《關於實施人類遺傳資源採集、收集、買賣、出口、出境行政許可的通知》) promulgated by the MOST on August 24, 2015, the gathering and collection of human genetic resources through clinical trials by a foreign-invested sponsor shall be filed for record with the China Human Genetic Resources Management Office through an online system. The Ministry of Science and Technology promulgated the Circular on Optimizing

REGULATORY OVERVIEW

the Administrative Examination and Approval of Human Genetic Resources (《關於優化人類遺傳資源行政審批流程的通知》) on October 26, 2017, which became effective on December 1, 2017, simplifying the approval of sampling and collecting human genetic resources for the purpose of marketing a drug in the PRC.

Pursuant to the Regulations on the Management of Human Genetic Resources of the PRC (《中華人民共和國人類遺傳資源管理條例》), last amended by the State Council on March 10, 2024 and came into effect on May 1, 2024, the State supports the rational use of human genetic resources for scientific research, development of the biomedical industry, improvement of diagnosis and treatment technology, improvement of China's ability to guarantee biosafety and improvement of the level of people's health. Foreign organizations, individuals and institutions established or actually controlled by them shall not gather or preserve Chinese genetic resources in China, or provide Chinese genetic resources to foreign countries. In addition, the gathering, preservation, utilization and external provision of Chinese genetic resources shall conform to ethical principles and conduct ethical review in accordance with relevant regulations. The Implementing Rules of the Regulation on the Administration of Human Genetic Resources (《人類遺傳資源管理條例實施細則》), which was promulgated by the MOST on May 26, 2023 and became effective on July 1, 2023, further provides specific requirements on the collection, preservation, utilization and external provision of China's human genetic resources.

The Biosecurity Law of the PRC (《中華人民共和國生物安全法》) (the "Biosecurity Law"), which was promulgated by SCNPC on October 17, 2020 and last amended on April 26, 2024, establishes a comprehensive legislative framework for the pre-existing regulations in such areas as epidemic control of infectious diseases for humans, animals and plants, research, development, and application of biology technology, biosecurity management of pathogenic microbial laboratories, security management of human genetic resources and biological resources, countermeasures for microbial resistance, and prevention of bioterrorism and defending threats of biological weapons. According to the Biosecurity Law, the research and development activities of high-risk and medium-risk biotechnology shall be carried out by a legal person organization established within the territory of the PRC in accordance with the law, upon obtaining the approval or record-filing. The following activities are subject to approval of the competent health department: (i) collecting human genetic resources of important genetic families or specific areas in the PRC, or collecting human genetic resources of which the types and quantities are subject to provisions of the competent health department under the State Council, (ii) preserving China's human genetic resources, (iii) using China's human genetic resources to carry out international scientific research cooperation, or (iv) transporting, mailing, and carrying China's human genetic resource materials out of the country.

Laws and Regulations on the Manufacturing of Drugs

Drug Manufacturing Certificate

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

Contract manufacturing of drugs

Pursuant to the Administrative Regulations for the Contract Manufacturing of Drugs (《藥品委託生產監督管理規定》) (the "Contract Manufacturing Regulations") issued by the CFDA in August 2014, only when a drug manufacturer temporarily lacks manufacturing conditions due to technology upgrade or is unable to ensure market supply due to insufficient manufacturing capabilities, can such drug manufacturer entrust the manufacturing of the drug to another domestic drug manufacturer. 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》) (the "Revised Administrative Measures of Drug Manufacturing")

REGULATORY OVERVIEW

promulgated by the State Administration for Market Regulation on January 22, 2020 and effective on July 1, 2020 further implements the drug marketing authorization holder system as stipulated in the Drug Administration Law. Drug 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.

Drug Operation License

According to the Drug Administration Law, the Measures for the Supervision and Administration of Drug Quality in Operation and Usage (《藥品經營和使用質量監督管理辦法》), which was issued by the SAMR on September 27, 2023 and came into effect on January 1, 2024, whoever engages in the wholesale or retail of drugs shall be subject to the approval of the drug regulatory authority, obtain a Drug Operation License in accordance with the law. The drug marketing authorization holders may sell the drugs for which they have obtained drug registration certificate on their own or entrust a drug operating enterprise with the sale of such drugs. However, the drug marketing authorization holders engaged in retail activities of drugs shall obtain a Drug Operation License. Each Drug Operation License is valid for five years. Where it is necessary to continue the operation of drugs upon the expiration of the period of validity of the Drug Operation License, a drug operating enterprise shall file an application with the license-issuing organ for re-examination and issuance of license in 6 to 2 months before the expiration of the period of validity.

Laws and Regulations on Drug Supply

Drug Purchases by Hospitals

According to the Opinion on the Guidance of the Reform of Urban Medical and Health Care System (《關於城鎮醫藥衛生體制改革的指導意見》) promulgated and took into effect on February 16, 2000 and the Opinion on the Implementation of Classification Management of Urban Medical Institutions (《關於城鎮醫療機構分類管理的實施意見》) promulgated on July 18, 2000 and became effective from September 1, 2000, a medical institution must be defined as a profit-making or non-profit-making institution at the time when it is established. A non-profit-making medical institution is established to provide services to the general public, with its revenue used for maintaining and developing such institution, while a profit-making medical institution is established by investors for the purpose of investment return. The PRC government does not establish any profit-making medical institutions, while non-government entities may establish profit-making medical institutions. Any non-profit-making medical institutions must implement a collective tender system in respect of any drug purchases and any profit-making medical institutions need not to implement such a system according to PRC law.

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 became effective 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 became effective on July 23, 2001 and the Opinions concerning Further Regulating Purchase of Medicines by Medical Institutions through Centralized Tendering (《進一步規範醫療機構藥品集中採購工作的意見》) promulgated and took into effect on January 17, 2009, any non-profit-making medical institutions established and/or controlled by any government at a county level or above must implement the centralized tender system in respect of purchase of any drugs which are contained in the Medicines List for National Basic Medical Insurance and are generally used for clinical purposes and purchased in relatively large amount.

The Circular on 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 was effective on July 7, 2010, provides stipulations in detail in respect of the catalog for centralized procurement and methods, procedures, evaluators, expert database construction and management of drugs, further regulating the centralized drug procurement and clarifying the code of conduct on the part of purchasing parties.

REGULATORY OVERVIEW

According to the Good Practice of Medical Institutions with respect to Centralized Procurement of Drugs, any non-profit-making medical institutions established by the government at the county level or above or state-owned enterprises (including stock-holding enterprises) must participate in the centralized procurement of medical institutions. The centralized procurement management authority at provincial (municipal or district) level is responsible for compiling the catalog of drugs for centralized procurement by medical institutions within its own administrative region, and narcotic drugs and first class psychoactive drugs with respect to which the special administration is carried out by the state are not included in such catalog for centralized procurement; second class psychoactive drugs, radioactive pharmaceuticals, toxic drugs for medical use, crude drugs, traditional Chinese medicinal materials and traditional Chinese medicine decoction pieces may be excluded from such catalog for centralized procurement.

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 classification purchase of drugs. 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 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 with 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 manufacturers.

According to the Opinions of the General Office of the State Council on Further Reform and Improvement of Policy on Drug Production, Circulation and Use (《國務院辦公廳關於進一步改革完善藥品生產流通使用政策的若干意見》) promulgated by the General Office of the State Council on January 24, 2017, cross-regional and specialized hospitals are encouraged to make joint purchases; in areas where the reform of the payment method of health insurance is comprehensively implemented or where the payment standard for drugs under health insurance has already been formulated, public hospitals are allowed to jointly carry out volume- and budget-based procurement on the provincial centralized drug procurement platform (the provincial public resources trading platform).

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

The Opinions of the General Office of the State Council on Promoting the Centralized Volume-based Procurement of Drugs in a Normalized and Institutionalized Manner (《國務院辦公廳關於推動藥品集中帶量採購工作常態化制度化開展的意見》), which was promulgated by the General Office of the State Council on January 22, 2021, set out the promotion of the normalization and institutionalization of the centralized procurement of drugs. All public medical institutions (including military medical institutions, hereinafter referred to as the same) shall participate in the centralized procurement of drugs, with reference to the requirements of the management of designated social medical institutions and designated pharmacies in accordance with the management of designated agreements for medical insurance. In accordance with the principles of preserving the basics and the clinical care, emphasis shall be placed on including drugs that are listed in the Drug Catalogue of Basic Medical Insurance with large consumption and high procurement price in the procurement scope, and gradually covering various drugs which are clinically necessary and reliable, so as to achieve the procurement of all medicines as much as possible.

REGULATORY OVERVIEW

Drug Price Management

Pursuant to the Opinions on Promoting Drug Pricing Reform (《推進藥品價格改革的意見》), which was jointly promulgated by the authorities including the NDRC on May 4, 2015, from June 1, 2015, the original prices of the drugs formulated by the government will be canceled, except for narcotic drugs and Class I psychotropic drugs. The prices of narcotic drugs and Class I psychotropic drugs are still temporarily managed by the NDRC through the implementation of maximum factory prices and maximum retail prices. The drugs other than the narcotic drugs and Class I psychotropic drugs no longer adopted government-designated pricing. Such notice aimed to improve the mechanism of the drug purchase, give play to the role of health care insurance in drug fees controlling, and actual transaction prices of the drugs are mainly determined by the market competition.

Two-invoice System

In order to further optimize the order of purchasing and selling pharmaceutical products and reduce circulation steps, as required at the executive meeting of the State Council dated April 6, 2016 and under the 2016 List of Major Tasks in Furtherance of the Healthcare and Pharmaceutical Reforms (《深化醫藥衛生體制改革2016年重點工作任務》) issued by the General Office of the State Council on April 21, 2016, the "two-invoice System" (兩票制) will be fully implemented in the PRC. According to the Circular on Issuing the Implementing Opinions on Carrying out the Two-invoice System for Drug Procurement among Public Medical Institutions (for Trial Implementation) (《印發〈關於在公立醫療機構藥品採購中推行「兩票制」的實施意見(試行)〉的通知》) (the "Circular"), which was effective from December 26, 2016, the two-invoice system means one invoice between the pharmaceutical manufacturer and the pharmaceutical distributor, and one invoice between the pharmaceutical distributor and the hospital, and thereby only allows a single level of distributor for the sale of pharmaceutical products from the pharmaceutical manufacturer to the hospital. According to the Circular, two-invoice system will be promoted in pilot provinces (autonomous regions and municipalities directly under the Central Government) involved in the comprehensive medical reform program and pilot cities for public hospital reform on a priority basis, while other regions are encouraged to implement such system, so that such system can be promoted in full swing nationwide in 2018.

Commercial Briberies in Pharmaceutical Industry

According to the Anti-Unfair Competition Law of the People's Republic of China (《中華人民共和國反不正當競爭法》), as amended on 27 June 2025 and implemented on 15 October 2025, promulgated by the Standing Committee of the National People's Congress, operators shall not bribe the following entities or individuals by means of offering money or other benefits in order to seek out transactional opportunities or competitive advantages: (i) Staff members of the counterparty to the transaction; (ii) Entities or individuals entrusted by the counterparty to handle relevant affairs; and (iii) Entities or individuals who may influence transactions through their authority or influence. Pursuant to the Provisional Regulations on Prohibiting Commercial Bribery (《關於禁止商業賄賂行為的暫行規定》) issued by the former State Administration for Industry and Commerce on 15 November 1996, commercial bribery is defined as the offering of financial and material assets or other means by an operator to another organization or individual with the aim of influencing the sale or purchase of goods.

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

REGULATORY OVERVIEW

Regulations in relation to the Medical Insurance Program

Coverage of the national medical insurance program

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

Medical Insurance Catalogue

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

The National Drug Catalog for Basic Medical Insurance, Work-related 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》), or the National Reimbursement Drug List (the "NRDL"), which promulgated by the NHSA and last amended on January 6, 2025, sets forth the payment standard for pharmaceutical products under the basic medical insurance, work-related injury insurance and maternity insurance funds. The local government shall strictly implement the NRDL and shall not adjust the contents contained in the NRDL at their own discretion. Medicines listed in the NRDL are divided into two parts, List A and List B. List A drugs are widely used clinical treatments with good efficacy and lower prices compared to similar drugs, while List B drugs are clinical treatments with good efficacy and slightly higher prices compared to List A drugs.

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

National Essential Drug List

On August 18, 2009, the Ministry of Health (the "MOH") and eight other ministries and commissions in the PRC issued the Provisional Measures on the Administration of the National Essential Drug List (《國家基本藥物目錄管理辦法(暫行)》), which was amended on February 13, 2015, and the Guidelines on the Implementation of the National Essential Drug List System (《關於建立國家基本藥物制度的實施意見》), which aims to promote essential medicines sold to consumers at fair prices in the PRC and ensure that the general public in the PRC has equal access to the drugs contained in the National Essential Drug List. The NHC promulgated the National Essential Drug List (2018) (《國家基本藥物目錄(2018年版)》), the "National Essential Drug List" on September 30, 2018, replacing the National Essential Drug List (2012) (《國家基本藥物目錄(2012年版)》) which was promulgated on March 13, 2013. According to these regulations, basic healthcare institutions funded by government shall store up and use drugs listed in National Essential Drug List. The drugs listed in National Essential Drug List shall be purchased by

REGULATORY OVERVIEW

centralized tender process and shall be subject to the price control by the National Development and Reform Commission of the PRC (中華人民共和國國家發展和改革委員會 (the "NDRC")). Remedial drugs in the National Essential Drug List are all listed in the Medical Insurance Catalogue and the entire amount of the purchase price of such drugs is entitled to reimbursement.

Laws and Regulations on Intellectual Properties

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

Patent

Patents in the PRC are mainly protected by the Patent Law of the PRC (《中華人民共和國專利法》), which was promulgated by the SCNPC on March 12, 1984, last amended on October 17, 2020 and became effective on June 1, 2021, and the Implementation Rules of the Patent Law of the PRC (《中華人民共和國專利法實施細則》), which were promulgated by the State Council on June 15, 2001, last amended on December 11, 2023 and became effective on January 20, 2024. The Patent Law of the PRC and its Implementation Rules provide for three types of patents, "invention", "utility model" and "design." "Invention" refers to any new technical solution relating to a product, a process or improvement thereof; "utility model" refers to any new technical solution relating to the shape, structure, or their combination, of a product, which is suitable for practical use; and "design" refers to any new design of the shape, pattern, color or the combination of any two of them, of a product, which creates an aesthetic feeling and is suitable for industrial application. The duration of a patent right for "invention" is 20 years, the duration of a patent right for "utility model" is 10 years, and the duration of a patent right for "design" is 15 years, from the date of application. According to the Patent Law of the PRC, for the purpose of public health, the patent administrative department of the State Council may grant mandatory licensing to manufacture and export patented drugs to countries or regions in comply with provisions of the relevant international treaty participated by the PRC.

Trade Secret

According to the Anti-Unfair Competition Law of the PRC (《中華人民共和國反不正當競爭法》), promulgated by the SCNPC in September 1993 and subsequently amended on November 4, 2017, April 23, 2019, June 27, 2025 and which will become effective on October 15, 2025, the term "trade secrets" refers to technical and business information that is unknown to the public, has utility, may create business interests or profits for its legal owners or holders, and is maintained as a secret by its legal owners or holders. Under the Anti-Unfair Competition Law of the PRC, business persons are prohibited from infringing others' trade secrets by: (1) acquiring a trade secret from the right holder by theft, bribery, fraud, coercion, electronic intrusion, or any other means; (2) disclosing, using, or allowing another person to use a trade secret acquired from the right holder by any means as specified in the item (1) above; (3) 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; (4) 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 of the requirements of the right holder for keeping the trade secret confidential.

Trademark

Pursuant to the Trademark Law of the PRC (《中華人民共和國商標法》) promulgated by the SCNPC on August 23, 1982, last amended on April 23, 2019 and became effective on November 1, 2019, the period of validity for a registered trademark is 10 years, commencing from the date of registration. Upon expiry of the period of validity, the registrant shall go through the formalities for renewal within twelve months prior to the date of expiry as required if the registrant needs to continue to use the trademark. Where the registrant fails to do so, a grace period of six months may be granted. The period of

REGULATORY OVERVIEW

validity for each renewal of registration is 10 years, commencing from the day immediately after the expiry of the preceding period of validity for the trademark. In the absence of a renewal upon expiry, the registered trademark shall be canceled. Industrial and commercial administrative authorities have the authority to investigate any behavior in infringement of the exclusive right under a registered trademark in accordance with the law. In case of a suspected criminal offense, the case shall be timely referred to a judicial authority and decided in accordance with applicable laws.

Copyright

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

Domain Names

In accordance with the Measures for the Administration of Internet Domain Names (《互聯網域名管理辦法》) which was issued by the Ministry of Information Industry on August 24, 2017 and came into effect on November 1, 2017, the Ministry of Industry and Information Technology is responsible for supervision and administration of domain name services in the PRC. Communications administrative bureaus at provincial levels shall conduct supervision and administration of the domain name services within their respective administrative jurisdictions. Domain name registration services shall, in principle, be subject to the principle of "first apply, first register." A domain name registrar shall, in the process of providing domain name registration services, ask the applicant for which the registration is made to provide authentic, accurate and complete identity information on the holder of the domain name and other domain name registration related information.

Laws and Regulations on Labor Protection and Social Insurance

General Labor Contracts Rules

According to the Labor Law of the PRC (《中華人民共和國勞動法》), which was promulgated by the SCNPC in July 1994 and last amended and came into effect in December 2018, the Labor Contract Law of the PRC (《中華人民共和國勞動合同法》), which was promulgated by the SCNPC in June 2007 and amended in December 2012 and came into effect in July 2013, and the Implementing Regulations of the Labor Contracts Law of the PRC (《中華人民共和國勞動合同法實施條例》), which was promulgated by the State Council and came into effect in September 2008, labor contracts in written form shall be executed to establish labor relationships between employers and employees. In addition, wages shall not be lower than local minimum wages. The employers must establish a system for labor safety and sanitation, strictly comply with national rules and standards, provide education regarding labor safety and sanitation to its employees, provide employees with labor safety and sanitation conditions and necessary protection materials in compliance with national rules, and carry out regular health examinations for employees engaged in work involving occupational hazards.

Labor, Social Insurance and Housing Provident Funds

According to the Social Insurance Law of PRC (《中華人民共和國社會保險法》), which was promulgated by the SCNPC in October 2010 and last amended and came into effect in December 2018, and the Interim Regulations on the Collection and Payment of Social Security Funds (《社會保險費徵繳暫行條例》), which was promulgated by the State Council in January 1999 and last amended in March 2019, and the Regulations on the Administration of Housing Provident Funds (《住房公積金管理條例》), which was promulgated by the State Council in April 1999 and last amended in March 2019, employers are required to contribute, on behalf of their employees, to a number of social security funds, including funds for basic pension insurance, unemployment insurance, basic medical insurance, occupational injury insurance and maternity insurance and to housing provident funds. Any employer who fails to make the required contributions may be fined and ordered to compensate the deficit within a stipulated time limit.

REGULATORY OVERVIEW

On July 20, 2018, the General Office of the Communist Party of China and the General Office of the PRC State Council jointly issued the Reform Plan of the State Tax and Local Tax Collection Administration System (《國稅地稅徵管體制改革方案》), under which, starting from January 1, 2019, tax authorities are responsible for the collection of social insurance contributions in China. According to the Notice on Conducting the Relevant Work Concerning the Administration of Collection of Social Insurance Premiums in a Steady, Orderly and Effective Manner (《關於穩妥有序做好社會保險費徵管有關工作的通知》) issued by the SAT in September 2018 and the Urgent Notice on Implementing the Spirit of the Executive Meeting of the State Council in Stabilizing the Collection of Social Security Contributions (《關於貫徹落實國務院常務會議精神切實做好穩定社保費徵收工作的緊急通知》) issued by the General Office of the Ministry of Human Resources and Social Security in September 2018, all the local authorities responsible for the collection of social insurance are strictly forbidden to conduct self-collection of historical unpaid social insurance contributions from enterprises. The Notice on Implementing Several Measures to Further Support and Serve the Development of Private Economy (《關於實施進一步支持和服務民營經濟發展若干措施的通知》) issued by the SAT in November 2018, repeats that tax authorities at all levels may not organize self-collection of unpaid social insurance contributions of taxpayers including private enterprises in the previous years. The Notice on Issuing the Comprehensive Plan for the Reduction of Social Insurance Premium Rate (《關於印發降低社會保險費率綜合方案的通知》) promulgated by the General Office of the PRC State Council in April 2019, generally reduces the social insurance contribution burden of enterprises, underlines that the duties for collection of social insurances premium paid by the enterprises in any province shall not be transferred to tax authorities until the condition of the province is mature, and re-emphasizes that local authorities shall not conduct self collection of historical unpaid social insurance contributions from enterprises.

According to the Interpretation (II) of the Supreme People's Court on Issues Concerning the Application of Law in the Trial of Labor Dispute Cases (最高人民法院關於審理勞動爭議案件適用法律問題的解釋(二)), which was promulgated by the Supreme People's Court in July 2025 and came into effect in September 2025, an employer and an employee conclude an agreement, or an employee promises to an employer, that there is no need to pay social insurance premiums, such agreement or promise shall be determined invalid; where an employer fails to pay social insurance premiums in accordance with the law, and the relevant employee requests to terminate the labor contract and requests for the employer to pay economic compensation, the people's court shall support such requests in accordance with the law. Where an employer, after making up the social insurance contributions in accordance with the law under the circumstances stipulated in the preceding paragraph, requests the employee to return the social insurance compensation already paid, the people's court shall support such request in accordance with the law.

Prevention and Control of Occupational Diseases

The Prevention and Control of Occupational Diseases Law of the PRC (《中華人民共和國職業病防治法》), which was promulgated by the SCNPC on October 27, 2001 and latest amended on December 29, 2018 (the "Prevention and Control of Occupational Diseases Law"), is the basic law for the prevention and control of occupational diseases. According to the Prevention and Control of Occupational Diseases Law, budget for facilities for the prevention and control of occupational diseases of a construction project shall be included in the budget of the project and those facilities shall be designed, constructed and put into operation simultaneously with the main body of the project. The entity that takes charge of the project should carry out the assessment of the effectiveness of measures for the prevention and control of occupational diseases before the final acceptance of the construction project. In addition, employers shall take required administrative measures to prevent and control occupational diseases in work.

Laws and Regulations on Leasing

On December 1, 2010, the Ministry of Housing and Urban-Rural Development promulgated the Administrative Measures on Leasing of Commodity Housing (《商品房屋租賃管理辦法》), which became effective on February 1, 2011. According to such measures, the lessor and the lessee are required to complete property leasing registration and filing formalities within 30 days from execution of the property lease contract with the development authorities or real estate authorities of the municipality or county where the

REGULATORY OVERVIEW

leased property is located. If a company fails to do as aforesaid, it may be ordered to rectify within a stipulated period, and if such company fails to rectify, a fine ranging from RMB1,000 to RMB10,000 may be imposed on each lease agreement.

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

Laws and Regulations on Environmental Protection, Health and Safety

Environment Protection

The Environmental Protection Law of the PRC (《中華人民共和國環境保護法》) ("the Environmental Protection Law"), which was promulgated by the SCNPC on December 26, 1989 and last amended on April 24, 2014, came into effect on January 1, 2015, outlines the authorities and duties of various environmental protection regulatory agencies. The Ministry of Ecology and Environment is authorized to issue national standards for environmental quality and emissions, and to monitor the environmental protection scheme of the PRC. Meanwhile, local environment protection authorities may formulate local standards which are more rigorous than the national standards, in which case, the concerned enterprises must comply with both the national standards and the local standards.

Environmental Impact Appraisal

According to the Administration Rules on Environmental Protection of Construction Projects (《建設項目環境保護管理條例》), which was promulgated by the State Council on November 29, 1998, amended on July 16, 2017 and became effective on October 1, 2017, depending on the impact of the construction project on the environment, a construction employer shall submit an environmental impact report or an environmental impact statement, or file a registration form. As to a construction project, for which an environmental impact report or the environmental impact statement is required, the construction employer shall, before the commencement of construction, submit the environmental impact report or the environmental impact statement to the relevant authority at the environmental protection administrative department for approval. If the environmental impact assessment documents of the construction project have not been examined or approved upon examination by the approval authority in accordance with the law, the construction employer shall not commence the construction. According to the Environmental Impact Appraisal Law of PRC (《中華人民共和國環境影響評價法》) ("the Environmental Impact Appraisal Law"), which was promulgated by the SCNPC on October 28, 2002, amended on July 2, 2016 and December 29, 2018, for any construction projects that have an impact on the environment, an entity is required to produce either a report, or a statement, or a registration form of such environmental impacts depending on the seriousness of effect that may be exerted on the environment.

Completion and Acceptance

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

Fire Prevention

According to the Fire Prevention Law of the PRC (《中華人民共和國消防法》), promulgated by the SCNPC on April 29, 1998 and last amended with effect from April 29, 2021, design and construction of the fire control facilities for a construction work shall comply with the national fire control technical standards. The developer, designer, constructors and project supervisor of a construction project shall be responsible for the quality of the design and construction of the fire control facilities for the construction work according to the relevant laws. If the design of fire control of a construction project has not been examined pursuant to the relevant laws or failed to pass the examination, the construction of such project is not allowed. If a completed construction project has not

REGULATORY OVERVIEW

gone through the fire safety inspection or failed to satisfy the requirements of fire safety upon inspection, such project is not allowed to be put to use or business.

Management of Waste Discharge

Pursuant to the Catalog of Classified Management of Pollutant Discharge Permits for Stationary Pollution Sources (2019 Version) (《固定污染源排污許可分類管理名錄(2019年版)》) issued by the Ministry of Ecology and Environment of the PRC and became effective on December 20, 2019, the State implements the primary management, simplified management and registration management of pollutant discharge permits based on the pollutant production, emission amount and the extent of environmental impact of the pollutant discharge entities. A pollutant discharge unit under registration management does not need to apply for a pollutant discharge license.

Pursuant to the Regulations on the Administration of Pollutant Discharge Permits (《排污許可管理條例》) promulgated by the State Council on January 24, 2021 and became effective on March 1, 2021, based on the quantity of pollutants generated and discharged, their impacts on the environment and other factors, categorical administration of pollutant discharge permit system is implemented to regulate pollutant-discharging entities: (1) key administration of pollutant discharge permits shall be implemented for pollutant discharging entities which generate and discharge relatively large quantities of pollutants or have a relatively serious impact on the environment; and (2) administration of pollutant discharge permits shall be simplified for pollutant-discharging entities which generate and discharge relatively small quantities of pollutants and have a relatively small impact on the environment. The entities that generate and discharge relatively small quantities of pollutants and have a relatively small impact on the environment shall fill in the waste discharge registration form (排污登記表) and are no longer required to obtain a waste discharge license (排污許可證).

Laws and Regulations on Foreign Investment

Company Law of the PRC

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

Foreign Investment

On December 30, 2019, the Ministry of Commerce and the SAMR, jointly promulgated the Measures for Information Reporting on Foreign Investment (《外商投資信息報告辦法》), which became effective on January 1, 2020. Pursuant to the Measures for Information Reporting on Foreign Investment, where a foreign investor carries out investment activities in China directly or indirectly, the foreign investor or the foreign-invested enterprise shall submit the investment information to the competent commerce department through the enterprise registration system and the National Enterprise Credit Information Publicity System, and the reporting methods include initial reports, change reports, cancellation reports, and annual reports.

Laws and Regulations on 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, and the Administrative Measures for the Outbound Investments of Enterprises (《企業境外投資管理辦法》) issued by the NDRC on December 26, 2017, and effective from March 1, 2018, if an enterprise in the PRC intends to make outbound investments, it shall be subject to approval or filing for the project, report relevant information, and cooperate in the supervisory inspections. Non-sensitive projects directly conducted by domestic enterprise in China, involving direct contribution of assets or rights and interests or provision of financing or security, shall be subject to filing.

REGULATORY OVERVIEW

Laws and Regulations on Foreign Exchange and Taxation

Foreign Exchange

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

On November 19, 2012, the SAFE issued the Circular of Further Improving and Adjusting Foreign Exchange Administration Policies on Foreign Direct Investment (《國家外匯管理局關於進一步改進和調整直接投資外匯管理政策的通知》) ("the SAFE Circular 59"), which came into effect on December 17, 2012 and was revised on May 4, 2015, October 10, 2018 and partially abolished on December 30, 2019. The SAFE Circular 59 aims to simplify the foreign exchange procedure and promote the facilitation of investment and trade. According to the SAFE Circular 59, the opening of various special purpose foreign exchange accounts, such as pre-establishment expenses accounts, foreign exchange capital accounts and guarantee accounts, the reinvestment of RMB proceeds derived by foreign investors in the PRC, and remittance of foreign exchange profits and dividends by a foreign-invested enterprise to its foreign shareholders no longer require the approval or verification of SAFE, as well multiple capital accounts for the same entity may be opened in different provinces. Later, the SAFE promulgated the Circular on Further Simplifying and Improving Foreign Exchange Administration Policies in Respect of Direct Investment (《關於進一步簡化和改進直接投資外匯管理政策的通知》) on February 13, 2015, which was partially abolished on December 30, 2019 and prescribed that the bank instead of SAFE can directly handle the foreign exchange registration and approval under foreign direct investment while SAFE and its branches indirectly supervise the foreign exchange registration and approval under foreign direct investment through the bank.

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

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

According to the Notice of the State Administration of Foreign Exchange on Reforming the Management Mode of Foreign Exchange Capital Settlement of Foreign Investment Enterprises (《國家外匯管理局關於改革外商投資企業外匯資本金結匯管理方式的通知》) ("the SAFE Circular 19") promulgated on March 30, 2015, coming effective on June 1, 2015, partially abolished on December 30, 2019 and partially amended on March 23, 2023, foreign-invested enterprises could settle their foreign exchange capital on a discretionary basis according to the actual needs of their business operations.

On June 9, 2016, SAFE issued the Notice of the State Administration of Foreign Exchange on Reforming and Standardizing the Foreign Exchange Settlement Management

REGULATORY OVERVIEW

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

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

On September 15, 2025, SAFE promulgated the Notice of the State Administration of Foreign Exchange on Matters Concerning Deepening the Reform of Foreign Exchange Administration for Cross-Border Investment and Financing (《國家外匯管理局關於深化跨境投融資外匯管理改革有關事宜的通知》). This notice cancels the registration of basic information on pre-investment expenses for domestic direct investment and the registration of domestic reinvestment by foreign-invested enterprises, allows the domestic reinvestment of foreign exchange profits under foreign direct investment, expands cross-border financing convenience, simplifies the registration management requirements for cross-border financing facilitation business, and reduces the negative list for the use of income from capital projects.

Taxation

Enterprise Income Tax

The Enterprise Income Tax Law of the PRC (《中華人民共和國企業所得稅法》) ("the EIT Law"), promulgated by the NPC on March 16, 2007, came into effect on January 1, 2008 and amended on February 24, 2017 and December 29, 2018, as well as the Implementation Rules of the EIT Law (《中華人民共和國企業所得稅法實施條例》) ("the Implementation Rules"), promulgated by the State Council on December 6, 2007, came into force on January 1, 2008 and last amended on December 6, 2024, are the principal law and regulation governing enterprise income tax in the PRC. According to the EIT Law and its Implementation Rules, enterprises are classified into resident enterprises and non-resident enterprises. Resident enterprises refer to enterprises that are legally established in the PRC, or are established under foreign laws but whose actual management bodies are located in the PRC. And non-resident enterprises refer to enterprises that are legally established under foreign laws and have set up institutions or sites in the PRC but with no actual management body in the PRC, or enterprises that have not set up institutions or sites in the PRC but have derived incomes from the PRC. A uniform income tax rate of 25% applies to all resident enterprises and non-resident enterprises that have set up institutions or sites in the PRC to the extent that such incomes are derived from their set-up institutions or sites in the PRC, or such income are obtained outside the PRC but have an actual connection with the set-up institutions or sites. And non-resident enterprises that have not set up institutions or sites in the PRC or have set up institutions or sites but the incomes obtained by the said enterprises have no actual connection with the set-up institutions or sites, shall pay enterprise income tax at the rate of 10% in relation to their income sources from the PRC.

Value-Added Tax (the "VAT")

Pursuant to the Provisional Regulations of the PRC on Value-added Tax (《中華人民共和國增值稅暫行條例》) amended in November 2017, and the Detailed Rules for the Implementation of the Interim Regulations of the PRC on Value-Added Taxes (《中華人民共和國增值稅暫行條例實施細則》) amended in October 2011, all entities or individuals

REGULATORY OVERVIEW

engaged in the sale of goods, provision of processing, repair and maintenance services, or importation of goods within China shall be value-added tax taxpayers and subject to value-added tax in accordance with relevant laws and regulations. Through the value-added tax reform in China, value-added tax rates have undergone multiple adjustments and value-added tax are regulated by the Value-Added Tax Law of the PRC (《中華人民共和國增值稅法》), which was implemented in January 2026.

Laws and Regulations on Information Security and Data

Privacy Data Security and Data Export

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

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

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

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

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

Personal Information Protection

According to the Civil Code of the PRC (《中華人民共和國民法典》), personal information of natural persons is protected by law. If any organization or individual needs

REGULATORY OVERVIEW

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

According to the Cybersecurity Law of the PRC (《中華人民共和國網絡安全法》) promulgated by the SCNPC on November 7, 2016 and effective on June 1, 2017, network operators must follow the principles of legality, legitimacy and necessity when collecting and using personal information, publicly disclose the rules for collection and use, clearly state the purpose, method and scope of collecting and using information, and obtain the consent of the person whose data is being collected. Network operators shall not collect personal information unrelated to the services they provide. Network operators are not allowed to leak, tamper with, or damage the personal information they collect, and are not allowed to provide personal information to others without the consent of the person whose data is being collected. However, this does not apply to cases where a specific individual cannot be identified, and the identity cannot be recovered after processing. Network operators should take technical measures and other necessary measures to ensure the security of the personal information they collect and prevent leakage, damage and loss of information.

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

Securities Law of the PRC

The Securities Law of the People's Republic of China (《中華人民共和國證券法》) (the "Securities Law") took effect on July 1, 1999 and was revised on August 28, 2004, October 27, 2005, June 29, 2013, August 31, 2014 and December 28, 2019, respectively. The latest revised Securities Law came into effect on March 1, 2020. This is the first national securities law in the PRC, which is divided into 14 chapters and 226 articles regulating, among other things, the issuance and trading of securities, takeovers by listed companies, securities exchanges, securities companies and the duties and responsibilities of the State Council's securities regulatory authorities. The Securities Law comprehensively regulates activities in the PRC securities market. Article 224 of the Securities Law provides that domestic enterprises shall comply with the relevant provisions of the State Council to list its shares outside the PRC. Currently, the issuance and trading of foreign issued shares (including H shares) are mainly governed by the rules and regulations promulgated by the State Council and the CSRC.

Overseas Listing

On February 17, 2023, the CSRC promulgated the Overseas Listing Trial Measures (《境內企業境外發行證券和上市管理試行辦法》), and relevant supporting guidelines, which came into effect on March 31, 2023. The Overseas Listing Trial Measures comprehensively improves and reforms the existing regulatory regime for overseas offering and listing of PRC domestic companies' securities and regulates both direct and indirect overseas offering and listing of PRC domestic companies' securities. Any domestic company that is deemed to conduct overseas offering and listing activities shall file with the CSRC in accordance with the Overseas Listing Trial Measures.

The Overseas Listing Trial Measures provide that the overseas securities offering and listing will be considered a direct overseas offering by a PRC domestic company if the issuer is a company limited by shares registered and established in mainland China.

Pursuant to the Overseas Listing Trial Measures, an issuer shall file with the CSRC within three business days after its application for initial public offering is submitted to competent overseas securities regulators.

H-share Full Circulation

"Full circulation" means listing and circulating on the stock exchange of the domestic unlisted shares of an H-share listed company, including unlisted domestic

REGULATORY OVERVIEW

shares held by domestic shareholders prior to overseas listing, unlisted domestic shares additionally issued after overseas listing, and unlisted shares held by foreign shareholders. On November 14, 2019, the CSRC issued the Guidelines for the "Full Circulation" Program for Domestic Unlisted Shares of H-share Listed Companies (《H股公司境內未上市股份申請「全流通」業務指引》) (the "Guidelines for the Full Circulation"), which was partly revised on August 10, 2023 according to the Decision on Revising and Abolishing Part of Securities and Futures Policy Documents by CSRC (《中國證券監督管理委員會關於修改、廢止部分證券期貨制度文件的決定》).

According to the Guidelines for the Full Circulation, shareholders of domestic unlisted shares may determine by themselves through consultation the amount and proportion of shares, for which an application will be filed for circulation, provided that the requirements laid down in the relevant laws and regulations and set out in the policies for state-owned asset administration, foreign investment and industry regulation are met, and the corresponding H-share listed company may be entrusted to file the said application for full circulation. To apply for full circulation, an H-share listed company shall file the application with the CSRC according to the administrative filing procedures necessary for the Overseas Listing Trial Measures. After the application for full circulation has been approved by the CSRC, the H-share listed company shall submit a report on the relevant situation to the CSRC within 15 days after the registration with CSDCC of the shares related to the application has been completed.

On December 31, 2019, CSDCC and the Shenzhen Stock Exchange ("SZSE") jointly announced the Measures for Implementation of H-share Full Circulation Business (《H股「全流通」業務實施細則》) (the "Measures for Implementation"). The businesses in relation to the H-share full circulation business, such as cross-border transfer registration, maintenance of deposit and holding details, transaction entrustment and instruction transmission, settlement, management of settlement participants, services of nominal holders, etc. are subject to the Measures for Implementation.

On June 30, 2025, the Shenzhen Branch of CSDC issued the latest Guidelines to the Program for "Full Circulation" of H-shares of Shenzhen Branch of China Securities Depository and Clearing Corporation Limited (《中國證券登記結算有限責任公司深圳分公司H股「全流通」業務指南》), which are applicable to the business preparation, cross-border share transfer registration and overseas centralized custody, the initial maintenance of details of domestic shareholding and the maintenance of its changes, corporate actions, clearing, settlement and risk management measures. On the same day, China Securities Depository and Clearing (Hong Kong) Company Limited issued the H-Share Full Circulation Business Guide of China Securities Depository and Clearing (Hong Kong) Limited (《中國證券登記結算(香港)有限公司H股「全流通」業務指南》), which is applicable to businesses such as share custody and depository, agent service, arrangement for settlement and delivery, and risk management measures.

Confidentiality and Archives Administration

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

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