

REGULATORY OVERVIEW

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

LAWS AND REGULATIONS ON PHARMACEUTICAL OPERATION

Pharmaceutical Operation License

According to the Drug Administration Law of the People’s Republic of China (《中華人民共和國藥品管理法》) (the “Drug Administration Law”) promulgated by the Standing Committee of the National People’s Congress (the “SCNPC”) on September 20, 1984, amended on February 28, 2001, December 28, 2013, April 24, 2015 and August 26, 2019, and effective as of December 1, 2019, no pharmaceutical operation, including pharmaceutical wholesale and pharmaceutical retail business, is permitted without obtaining the Pharmaceutical Operation License. According to the Regulations for Implementation of the Drug Administration Law of the People’s Republic of China (《中華人民共和國藥品管理法實施條例》) (the “Regulations for the Implementation of Drug Administration Law”) revised on December 6, 2024 and effective as of January 20, 2025 by the State Council, the regulations provide detailed rules for the implementation of drug management. According to the Measures for the Supervision and Administration of Drug Operation and Usage (《藥品經營和使用質量監督管理辦法》) issued by the State Administration for Market Regulation (the “SAMR”) on September 27, 2023 and effective as of January 1, 2024, the Measures stipulate the application procedures for the Pharmaceutical Operation License, the management system, quality requirements and qualifications of drug wholesalers or retailers, etc. The validity period of the Pharmaceutical Operation License is five years, and it must be renewed six months to two months prior to its expiration.

Pharmaceutical Business Quality Management

According to the Measures for the Supervision and Administration of Drug Quality of in Operation and Usage (《藥品經營和使用質量監督管理辦法》) promulgated by the SAMR on September 27, 2023 and effective on January 1, 2024, the pharmaceutical operation enterprises shall establish a quality management system that covers the whole process of pharmaceutical operation, carry out quality management activities and other measures to ensure the pharmaceutical quality. The newly revised Drug Administration Law (《藥品管理法》) in 2019 abolishes the restriction on online sale of prescription drugs and adopts the principle of keeping online and offline sales consistent. In addition, Regulations for Implementation of the Drug Administration Law (《藥品管理法實施條例》), revised on December 6, 2024 and effective as of January 20, 2025 further stipulates certain provisions to the online sale of drugs. Moreover, under the Good Supply Practice for Pharmaceutical Products (《藥品經營質量管理規範》), promulgated by the former China Food and Drug Administration (the “CFDA”) on April 30, 2000 and amended on November 6, 2012, May 18, 2015 and June 30, 2016 respectively, the pharmaceutical operation enterprises shall take effective quality control measures over the process of procurement, storage, transportation and sale of drugs in order to ensure their quality. Enterprises should establish a computer system capable of meeting the requirements for managing the entire business process and quality control, ensuring the traceability of pharmaceuticals.

Medical Institution Drug Supervision

According to the Administrative Measures for the Supervision of Drugs of the Medical Institutions (for Trial Implementation) (醫療機構藥品監督管理辦法(試行)) promulgated by the CFDA on October 11, 2011 and effective thereafter, medical institutions must purchase pharmaceuticals from enterprises qualified for the production or distribution of pharmaceuticals and comply with certain standards in respect of storage, safekeeping, preparations and use of such pharmaceuticals.

REGULATORY OVERVIEW

Internet Pharmaceutical Information Service

According to the Administrative Measures on Internet-based Drug Information Services (《互聯網藥品信息服務管理辦法》) revised and effective on November 17, 2017, by the CFDA, the Internet Drug Information Service refers to service activities of providing online users with drug (including medical devices) information via Internet. Any website operator that intends to provide drugs (including medical devices) information services shall, prior to applying for an operation permit or record-filing from the State Council's department in charge of information industry or the telecom administrative authority at the provincial level, file an application with the provincial FDA, and shall be subject to the examination and approval thereof for obtaining the qualifications for providing Internet drug information services. The validity term for the Internet Drug Information Service Qualification Certificate (互聯網藥品信息服務資格證書) is five years and may be renewed at least six months prior to its expiration date upon a re-examination by the relevant governmental authorities. According to the Administrative Measures on Internet-based Drug Information Services, such services are divided into commercial Internet drug information services and non-commercial Internet drug information services. The commercial Internet drug information service refers to the activities which provide online users with paid drug information and other services via Internet. The non-commercial Internet drug information service refers to the activities which provide online users with public and shared drug information and other services via Internet for free.

Internet Pharmaceutical Transaction Service

The Measures for the Supervision and Administration of Online Pharmaceuticals Sales (《藥品網絡銷售監督管理辦法》) promulgated by the SAMR on August 3, 2022, and effective on December 1, 2022, aim to enhance the supervision and administration of online drug sales and online drug trading platform services. According to the Measures for the Supervision and Administration of Online Pharmaceuticals Sales, an online drug seller shall (i) operate according to the approved business method and business scope; (ii) report such information as its corporate name, the name of its website, the name of its application program, its IP address, its domain name and its drug production permit or drug operation permit to the medical products administration concerned. Any change in the said information shall be reported within ten working days; (iii) constantly publicize information on its drug production license or business license on the homepage of its website or the main page of its business activities; (iv) completely keep the qualification documents of suppliers, electronic transaction records and other records; and (v) in the event of a public health emergency or any other emergency that poses a serious threat to public health, third-party platforms and online drug sales enterprises shall comply with the relevant emergency response provisions of the State, and adopt the corresponding control and handling measures pursuant to the law.

Pricing

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, the former National Health and Family Planning Commission (the "NHFPC"), the Ministry of Human Resources and Social Security, the Ministry of Industry and Information Technology (the "MIIT"), the Ministry of Finance, the Ministry of Commerce (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 cancelled.

REGULATORY OVERVIEW

LAWS AND REGULATIONS ON MEDICAL DEVICES

Licensing and Filing of Business Operations of Medical Devices

According to the Measures on Supervision and Administration of Business Operations of Medical Devices (《醫療器械經營監督管理辦法》) (“the Measures on Medical Devices”) promulgated by the SAMR on July 30, 2014 (later revised on November 17, 2017 and March 10, 2022), medical devices are divided into three classes based on the degree of risk. Entities engaged in distribution activities of Class III medical devices must obtain a medical device operating license and entities engaged in distribution activities of Class II medical devices shall complete filings with the competent local MPA, while entities engaged in distribution activities of Class I medical devices are not required to conduct any filing or obtain any license.

According to the Regulations on Supervision and Administration of Medical Devices (《醫療器械監督管理條例》) promulgated by the State Council on January 4, 2000 (later revised on March 7, 2014, May 4, 2017, February 9, 2021 and December 6, 2024, and which entered into force on January 20, 2025), to engage in the business operation of medical devices, an enterprise shall have business premises and storage conditions in line with its business scale and scope, as well as the quality management system and quality management body or personnel suitable for the medical devices operated by it.

Quality Management of Medical Device Business Operations

According to the Medical device business in the PRC is also subject to the Good Supply Practice for Medical Devices (《醫療器械經營質量管理規範》) promulgated by the NMPA on December 4, 2023 and became effective on July 1, 2024, enterprises engaged in medical device business shall carry out risk management based on the risk categories of medical devices operated by it, take corresponding quality management measures and keep relevant records or archives. The medical device business enterprises, unless otherwise provided therein, shall also have business premises and warehouses that match its business scope and scale, and the area of business premises and warehouses shall meet the business and quality management requirements.

Online Sales of Medical Devices

According to the Measures for Supervision and Administration of Online Sales of Medical Devices (《醫療器械網絡銷售監督管理辦法》) (“the Online Medical Device Sales Measures”) promulgated on December 20, 2017 and coming into force on March 1, 2018 by the CFDA, enterprises engaged in online sales of medical devices must be medical device manufacture and operation enterprises with medical devices production licenses or operation licenses or being filed for record in accordance with laws and regulations, unless such licenses or record-filing is not required by laws and regulations. Pursuant to the Online Medical Devices Sales Measures, an enterprise engaging in online sales of medical devices shall carry out online sale of medical devices through its own website or a third-party platform for online trading services for medical devices. Pursuant to the Online Medical Devices Sales Measures, enterprises engaging in online sales of medical devices through its own website shall obtain a Qualification Certificate for Internet Drug Information Services (《互聯網藥品信息服務資格證書》).

REGULATORY OVERVIEW

LAWS AND REGULATIONS ON MEDICAL SERVICES

Medical Institutions

According to the Law of the People’s Republic of China on Basic Medical Care and Health Promotion (《基本醫療衛生與健康促進法》) (“Basic Medical Care and Health Promotion Law”) promulgated by the SCNPC on December 28, 2019 and coming into force on June 1, 2020, establishment of medical institutions is subject to approval or filing formalities pursuant to the relevant national regulations. Medical institutions shall legally obtain a practice license.

According to the Administrative Regulations on Medical Institutions (《醫療機構管理條例》) (the “Regulations on Medical Institutions”), which were revised by the State Council on March 29, 2022, and came into effect on May 1, 2022, as well as the Detailed Rules for the Implementation of the Medical Institute Management Regulations (《醫療機構管理條例實施細則》) revised by NHFPC on February 21, 2017, and effective from April 1, 2017, medical institutions include hospitals, health centers, sanatoriums, out-patient departments, clinics, health clinics, health posts (rooms), first-aid stations, nursing stations, medical imaging diagnostic centers, etc. According to the Regulations on Medical Institutions, medical institutions must be registered to practice and obtain a Practice License for Medical Institutions.

Foreign-Invested Medical Institutions

According to the Special Administrative Measures (Negative List) for Foreign Investment Access (Edition 2024) (《外商投資准入特別管理措施(負面清單)(2024年版)》) promulgated on September 6, 2024 and effective as of November 1, 2024 by the NDRC and the MOFCOM, medical institutions can only be established in the form of equity joint venture.

According to the Interim Administrative Measures on Sino-Foreign Equity Medical Institutions and Sino-Foreign Cooperative Medical Institutions (《中外合資、合作醫療機構管理暫行辦法》) promulgated on May 15, 2000 and effective as of July 1, 2000 by the former Ministry of Health and the former Ministry of Foreign Trade and Economic Cooperation, foreign investors are allowed to cooperate with Chinese entities to establish medical institutions in China by means of equity joint ventures (the “EJV”) or cooperative joint ventures (the “CJV”). An established medical institution in the form of equity joint venture or cooperative joint venture shall meet certain requirements, including the equity percentage of the Chinese partner in the joint venture shall not be less than 30%.

According to the Administrative Measures on Sino-Foreign Equity and Cooperative Medical Institutions in the Sichuan Province (《四川省中外合資合作醫療機構管理辦法》) promulgated on March 15, 2012 and implemented after 30 days from the date of promulgation, and partially amended on January 16, 2015 and took effect on the same day by the former Sichuan Provincial Department of Health and the Sichuan Provincial Department of Commerce, the Measures further regulates the application, establishment, practice, supervision, and other activities of medical institutions in the form of EJV or CJV in Sichuan Province, providing that the equity proportion or equity of the Chinese party in a medical institution in the form of EJV or CJV shall not be less than 10%.

REGULATORY OVERVIEW

Internet Medical Services

According to the Guiding Opinions on Vigorously Advancing the “Internet Plus” Action (《關於積極推進“互聯網+”行動的指導意見》) which was promulgated by the State Council and became effective on July 1, 2015, medical and health services based on the Internet shall be developed, and third-party institutions shall be supported to establish a service platform for sharing the medical information such as medical image, health archives, inspection reports and electronic medical records.

On July 17, 2018, the NHC and the National Administration of Traditional Chinese Medicine jointly promulgated three documents, including the Measures for the Administration of Internet Diagnosis and Treatment (Trial) (《互聯網診療管理辦法(試行)》), the Measures for the Administration of Internet Hospitals (Trial) (《互聯網醫院管理辦法(試行)》) and the Specifications for the Administration of Remote Medical Services (Trial) (《遠程醫療服務管理規範(試行)》). Pursuant to the Measures for the Administration of Internet Hospitals (Trial), “Internet hospitals” include: (1) Internet hospitals as the second name of physical medical institutions, and (2) Internet hospitals that are independently established on the support of physical medical institutions.

According to the Opinions on Promoting the Development of “Internet Plus Health Care” (《國務院辦公廳關於促進“互聯網+醫療健康”發展的意見》) promulgated by the General Office of the State Council on April 25, 2018, and effective from that date, Internet hospitals are allowed to be developed based on medical institutions. After reviewing a patient’s medical records and profile, the physician is allowed to issue prescriptions for certain common and chronic diseases online. The policy encourages the higher-level medical institution in a medical treatment partnership to adopt artificial intelligence (AI) and other technologies to provide services at grassroots level, such as remote group consultation, remote ECG diagnosis and remote image diagnosis, and to promote real-time access, mutual recognition and sharing of examination results among medical institutions in the same medical treatment partnership. For prescriptions issued online for common diseases and chronic conditions, after review by pharmacists, medical institutions and pharmaceutical enterprises may delegate qualified third-party organizations for delivery.

Internet Hospitals

According to the Notice on Issuing Three Documents Including the Administrative Measures for Internet-based Diagnosis (for Trial Implementation) (《關於印發《互聯網診療管理辦法(試行)》等3個文件的通知》), the state implements access management for Internet hospitals pursuant to the Administrative Regulations on Medical Institutions (《醫療機構管理條例》) and the Implementation Measures of the Administrative Regulations on Medical Institutions (《醫療機構管理條例實施細則》).

In terms of practicing rules on Internet hospitals, the Measures for the Administration of Internet Hospitals (Trial) (《互聯網醫院管理辦法(試行)》) provides that where a third-party institution jointly establishes an Internet hospital on the support of its physical medical institution, it shall provide the physical medical institution with professional services such as physicians and pharmacists, and information technology support services, and clarify the responsibilities and rights of all parties in respect of medical services, information security, and privacy protection through agreements and contracts. Internet hospitals shall adopt information security protection measures for Level 3 information system in accordance with relevant information security laws and regulations, including completion of filings with local public security authorities.

REGULATORY OVERVIEW

Patient Diagnosis Service

According to the Measures for the Administration of Internet Diagnosis and Treatment (Trial) (《互聯網診療管理辦法(試行)》), Internet diagnosis and treatment refers to the use of physicians registered in the institution using the Internet and other information technology to carry out diagnosis of some common diseases, chronic diseases, re-diagnosis and “Internet Plus” family doctor contract services. Internet diagnosis and treatment activities must be provided by a medical institution with Medical Institution Practicing License and the medical institution shall apply for registration of Internet diagnosis and treatment activities. Medical institutions carrying out Internet diagnosis and treatment activities should be consistent with their diagnosis and treatment subjects.

According to the Measures for the Administration of Internet Hospitals (Trial) (《互聯網醫院管理辦法(試行)》), Internet hospitals must inform the patients of the risks and obtain their consents. Internet diagnosis and treatment activities shall not be carried out for any patient receiving initial diagnosis.

Medical Practitioners

According to the Administrative Measures for the Registration of Medical Practitioners (《醫師執業註冊管理辦法》), promulgated by the NHFPC on February 28, 2017, effective on April 1, 2017, medical practitioners shall obtain the Practice Certificate for Medical Practitioners to practice upon registration. Person who fails to obtain the Practice Certificate for Medical Practitioners shall not engage in medical treatment, prevention and healthcare activities. Moreover, under the Administrative Measures for the Registration of Medical Practitioners (《醫師執業註冊管理辦法》), a medical practitioner practicing in multiple institutions at the same place of practice shall determine one institution as his or her primary practicing institution, and apply for registration to the competent administrative authorities of health and family planning that approve the practice at such institution, and for other institutions where a medical practitioner intends to practice, he or she should apply for the record at the relevant administrative authorities of health and family planning that approve the practice of such institutions, which names should be indicated in the record.

Third-party Medical Testing

According to the Basic Standards of Medical Examination Laboratories (for Trial Implementation) (《醫學檢驗實驗室基本標準(試行)》) promulgated by the NHFPC on July 20, 2016 which became effective as of July 20, 2016, medical examination laboratories are categorized as separate medical institutions, and shall be examined and approved by the competent health and family planning authorities at the level of cities with district division or above. The Basic Standards for Medical Laboratory Laboratories (for Trial Implementation) provide for the establishment of departments and divisions, personnel, buildings, facilities and layout, equipment, rules and regulations of medical laboratory laboratories.

According to the Standards for the Administration of Medical Laboratory Laboratories (for Trial Implementation) (《醫學檢驗實驗室管理規範(試行)》) promulgated by the NHFPC on July 20, 2016 and entered into force, the Standards apply to independent medical institutions that conduct clinical testing on human blood, body fluids, and tissue specimens. The Standards also provide for the organization management, quality management, safety and infection prevention and control, personnel training and occupational safety protection of medical laboratories.

REGULATORY OVERVIEW

Pricing

According to the Notice on Issues Concerning the Application of Market-regulated Prices to Medical Services Provide by Non-public Medical Institutions (《關於非公立醫療機構醫療服務實行市場調節價有關問題的通知》), which was jointly promulgated by the NDRC, the NHFPC and the Ministry of Human Resources and Social Security on March 25, 2014 and became effective, the prices of medical services provided by non-public medical institutions are subject to market regulation.

LAWS AND REGULATIONS ON MEDICAL WASTES

According to Regulations on the Management of Medical Waste (《醫療廢物管理條例》) promulgated by the State Council on June 16, 2003, which was amended and entered into force on January 8, 2011, and the Implementation Measures of the Management of Medical Waste (《醫療衛生機構醫療廢物管理辦法》) promulgated by the former Ministry of Health on October 15, 2003, which became effective, “Medical wastes” refer to wastes, directly or indirectly infectious, toxic and harmful, generated by medical and health institutions in their medical treatment, prevention, health care and other relevant activities. The medical institution must timely deliver medical waste to a specially designated location for centralized disposal of medical waste and categorize the medical waste in accordance with the Classified Catalogue of Medical Waste.

LAWS AND REGULATIONS ON E-COMMERCE

According to the E-commerce Law of the People’s Republic of China (《中華人民共和國電子商務法》) (“E-Commerce Law”) promulgated by the SCNPC on August 31, 2018 and effective from January 1, 2019, specified that the natural persons, legal persons and other non-legal persons who sell goods or provide services through the Internet and other information networks in China are e-commerce operators. When engaging in operation activities, e-commerce operators shall adhere to the principles of voluntariness, equality, fairness and integrity, abide by laws and business ethics to participate in market competition fairly.

According to the Administrative Measures for Online Trading (《網絡交易監督管理辦法》) by the SAMR on March 15, 2021 and entering into force on May 1, 2021 (later revised on March 18, 2025 and entered into force on May 1, 2025), in the PRC, the business activities of selling goods or providing services through information networks such as the Internet will be supervised and administered by the law. Online transaction operators shall obtain relevant administrative licenses in accordance with the law.

LAWS AND REGULATIONS ON INTERNET INFORMATION SERVICES

According to the Administrative Measures on Internet Information Services (《互聯網信息服務管理辦法》) promulgated by the State Council on September 25, 2000, latest amended on December 6, 2024 and entered into force on January 20, 2025, and the Administrative Measures for the Filing of Not-for-profit Internet Information Services (《非經營性互聯網信息服務備案管理辦法》) promulgated by the former Ministry of Information Industry on February 8, 2005, and further amended and entered into force by the MIIT on January 18, 2024, Internet-based Information Services are divided into services of a commercial nature and services of a non-commercial nature. The state shall implement a filing-for-record system for non-commercial Internet-based information services.

REGULATORY OVERVIEW

According to the Provisions on the Administration of Mobile Internet Applications Information Services (《移動互聯網應用程序信息服務管理規定》) promulgated by the Cyberspace Administration of China (the “CAC”) on June 14, 2022 and effective from August 1, 2022, sets forth the relevant requirements for the App information service providers and App store service providers, including acquiring relevant qualifications in accordance with laws and regulations, establishing content review and management mechanism, and meeting the mandatory requirements of relevant national standards.

According to the Notice on Carrying out the Filing of Mobile Internet Applications (《關於開展移動互聯網應用程序備案工作的通知》), issued by the MIIT and effective on July 21, 2023, any APPs sponsor engaging in Internet information services in the PRC shall go through the record-filing formalities with the provincial-level communications administration of the place where it is located, and the network access service provider and the APPs distribution platform shall submit an application online and have the application inspected and approved via the national Internet basic resources management system (i.e. ICP/IP address/domain name information record-filing administration system).

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》) (the “Patent Law”), which was promulgated by the SCNPC on March 12, 1984 and 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”), promulgated by the State Council on June 15, 2001 and 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 are from the date of application.

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》), which was promulgated by the SCNPC on August 23, 1982 and latest amended on April 23, 2019 and came into effect on November 1, 2019, 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》), which were promulgated by the State Council on August 3, 2002 and latest amended on April 29, 2014 and came into effect on May 1, 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. Upon approval, it can be renewed for ten years.

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 Ministry of Industry and Information Technology (the “MIIT”), on August 24, 2017 and effective from November 1, 2017 and the Implementation Rules for the Registration of National Top-level Domain Names (《國家頂級域名註冊實施細則》) promulgated by China Internet Network Information Center and

REGULATORY OVERVIEW

effective on June 18, 2019, 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.

Copyright

Pursuant to the Copyright Law of the People’s Republic of China (中華人民共和國著作權法) promulgated by the SCNPC on September 7, 1990, last amended on November 11, 2020 and effective from June 1, 2021, and the Implementing Rules of the Copyright Law of the People’s Republic of China (中華人民共和國著作權法實施條例) promulgated by the State Council on August 2, 2002, last amended on January 30, 2013 and effective from March 1, 2013, Chinese citizens, legal persons or other organizations enjoy copyright protection over their works, whether published or not, in the domain of literature, art and science.

THE COMPANY LAW AND REGULATIONS

The Company Law of the PRC (《中華人民共和國公司法》) (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 PRC.

LAWS AND 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 National People’s Congress (the “NPC”) has come into effect. The Foreign Investment Law has become the basic law regulating foreign-invested enterprises wholly or partially invested by foreign investors. 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.

The foreign investment information reporting is 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 State Administration for Market Regulation, which came into effect on January 1, 2020. Foreign investors and foreign investment enterprises in the PRC shall submit investment information in a timely manner, follow the principles of truthfulness, accuracy and completeness, and shall not make false or misleading reports or material omissions.

LAWS AND REGULATIONS ON THE SECURITY REVIEW OF FOREIGN INVESTMENT

On December 19, 2020, the NDRC and the MOFCOM jointly promulgated the Measures on the Security Review of Foreign Investment (《外商投資安全審查辦法》), effective on January 18, 2021, setting forth provisions concerning the security review mechanism on foreign investment, including the types of investments subject to review, the scopes of review and procedures to review, among others.

REGULATORY OVERVIEW

LAWS AND REGULATIONS IN RELATION TO PRODUCT LIABILITY

The Product Quality Law of the PRC (《中華人民共和國產品質量法》), promulgated by 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.

LAWS AND REGULATIONS RELATED TO ENVIRONMENTAL PROTECTION

According to the Administrative Measures on Pollutant Discharge Permit issued by the MEE (《排污許可管理辦法》) 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)》) issued by the MEE of the People’s Republic of China (hereinafter referred to as the “MEE”) 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 quantity of pollutants generated and discharged, their impacts on the environment and other factors. A pollutant discharge unit under registration management does not need to apply for a pollutant discharge license.

LAWS AND REGULATIONS RELATED 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.

According to Social Security Law of the PRC (《中華人民共和國社會保險法》), which was promulgated on October 28, 2010 and amended on December 29, 2018, and the Interim Regulations on the Collection of Social Insurance (《社會保險費徵繳暫行條例》) issued by the State Council on January 22, 1999 and last amended on March 24, 2019, 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 Reform Plan of the State Tax and Local Tax Collection Administration System (《國稅地稅徵管體制改革方案》), which was promulgated on July 20, 2018, commencing from January 1, 2019, all the social insurance premiums including the premiums of the basic pension insurance, unemployment insurance, maternity insurance, work injury insurance and basic medical insurance shall be collected by the tax authorities. According to

REGULATORY OVERVIEW

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》) promulgated by the General Office of the State Administration of Taxation on September 13, 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 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》), promulgated by the State Taxation Administration on November 16, 2018, repeats that tax authorities at all levels may not organize self-collection of arrears of taxpayers including private enterprises from the previous years. The Notice of General Office of the State Council on Promulgation of the Comprehensive Plan for the Reduction of Social Insurance Premium Rate (《國務院辦公廳關於印發降低社會保險費率綜合方案的通知》), promulgated on April 1, 2019, requires steady advancement of the reform of the system of social security collection. In the process of reformation of the collection system, it is not allowed to conduct self-collection of historical unpaid arrears from enterprises, and it is not allowed to adopt any method of increasing the actual payment burden of small and micro enterprises to avoid causing difficulties in the production and operation of the enterprises.

According to the Administrative Regulations on Housing Provident Funds (《住房公積金管理條例》), which was promulgated on April 3, 1999 and latest amended on March 24, 2019, 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.

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)》), promulgated by the Supreme People's Court on July 31, 2025 and became effective on September 1, 2025, where the employer and the employee agree, or the employee promises the employer, that there is no need to make social insurance contributions, the people's court shall determine that such agreement or promise is invalid. 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 PRC, the people's court shall uphold such claim.

LAWS AND REGULATIONS IN RELATION TO INFORMATION SECURITY AND DATA PRIVACY

Government authorities of mainland China have enacted laws and regulations with respect to Internet information security and protection of personal information from any abuse or unauthorized disclosure, and which includes the Decision of the Standing Committee of the National People's Congress on Internet Security Protection (《全國人民代表大會常務委員會關於維護互聯網安全的決定》) enacted and amended by the SCNPC on December 28, 2000 and August 27, 2009, respectively, the Provisions on the Technical Measures for Internet Security Protection (《互聯網安全保護技術措施規定》) issued by the Ministry of Public Security on December 13, 2005 and took effect on March 1, 2006, the Decision of the Standing Committee of the National People's Congress on Strengthening Network Information Protection (《全國人民代表大會常務委員會關於加強網絡信息保護的決定》) promulgated by the SCNPC on December 28, 2012, the Several Provisions on Regulating the Market Order of Internet Information Services (《規範互聯網信息服務市場秩序若干規定》) promulgated by the MIIT on December 29, 2011, and the Provisions on Protection of Personal Information of

REGULATORY OVERVIEW

Telecommunication and Internet Users (《電信和互聯網用戶個人信息保護規定》) released by the MIIT on July 16, 2013. Internet information in mainland China is regulated and restricted from a national security standpoint.

The Provisions on Protection of Personal Information of Telecommunication and Internet Users regulate the collection and use of users’ personal information in the provision of telecommunications services and Internet information services in mainland China. Telecommunication business operators and Internet service providers are required to institute and disclose their own rules for the collecting and use of users’ information.

On June 22, 2007, the Ministry of Public Security, National Administration of State Secrets Protection and other governmental authorities issued the Administrative Measures for the Graded Protection of Information Security (《信息安全等級保護管理辦法》), which regulates that the security protection of an information system may be graded into five. For an information system of Grade II or above newly built, its operator or user shall, within 30 days after it is put into operation, complete the record-filing procedures at the local public security organ at the level of municipality divided into districts or above.

On June 1, 2017, the Cyber Security Law of the PRC, or the Cyber Security Law (《中華人民共和國網絡安全法》), promulgated by SCNPC became effective, which is formulated to maintain the network security, safeguard the cyberspace sovereignty, national security and public interests, protects the lawful rights and interests of citizens, legal persons and other organizations and requires that a network operator, which includes, among others, Internet information services providers, take technical measures and other necessary measures to safeguard the safe and stable operation of the networks, effectively respond to the network security incidents, prevent illegal and criminal activities, and maintain the integrity, confidentiality and availability of network data. On October 28, 2025, the SCNPC adopted the decision to amend the Cyber Security Law and such amendment took effective on January 1, 2026.

On June 10, 2021, the Standing Committee of the National People’s Congress of China promulgated the Data Security Law of the PRC, or the Data Security Law (《中華人民共和國數據安全法》), which became effective in September 2021. The Data Security Law provides for data security and privacy obligations on entities and individuals carrying out data activities. The Data Security Law also introduces a data classification and hierarchical protection system based on the importance of data in economic and social development, as well as the degree of harm it will cause to national security, public interests, or legitimate rights and interests of individuals or organizations when such data is tampered with, destroyed, leaked, or illegally acquired or used. The appropriate level of protection measures is required to be taken for each respective category of data.

On September 24, 2024, the State Council promulgated the Regulations on the Administration of Cyber Data Security (《網絡數據安全管理條例》) (the “Data Security Regulations”), which is applicable to network data processing activities and the security supervision and administration thereof conducted within the territory of the People’s Republic of China and will take effect on January 1, 2025. The Data Security Regulations stipulate that data processors engaging in data processing activities that affect or may affect national security shall be subject to cyber security review in accordance with relevant laws and regulations.

December 28, 2021, the CAC, the NDRC, the MIIT, the Ministry of Public Security, the Ministry of National Security, the Ministry of Finance, the MOFCOM, the People’s Bank of China, the SAMR, the National Radio and Television Administration, the CSRC, the National Administration of State Secrets Protection and the State Cryptography Administration jointly released the Cybersecurity Review Measures (2021) (《網絡安全審查辦法(2021)》), which became effective on February 15, 2022. The Cybersecurity Review Measures provide that (i)

REGULATORY OVERVIEW

a “network platform operator” holding over one million members’ personal information shall apply for a cybersecurity review when listing their securities in a foreign country, and (ii) a “network platform operator” carrying out data processing activities that affect or may affect national security shall apply for a cybersecurity review.

On May 28, 2020, the National People’s Congress adopted the Civil Code of the PRC (《中華人民共和國民法典》), which came into effect on January 1, 2021. Pursuant to the Civil Code, the personal information of a natural person shall be protected by the law. Any organization or individual shall legally obtain such personal information of others when necessary and ensure the safety of such information, and shall not illegally collect, use, process or transmit personal information of others, or illegally purchase or sell, provide or disclose personal information of others.

On August 20, 2021, the SCNPC promulgated the Personal Information Protection Law of the PRC, or the Personal Information Protection Law (《中華人民共和國個人信息保護法》), which integrates the scattered rules with respect to personal information rights and privacy protection and became effective on November 1, 2021. The Personal Information Protection Law applies to personal information processing activities within mainland China, as well as certain personal information processing activities outside mainland China, including those for provision of products and services to natural persons within mainland China or for analyzing and assessing acts of natural persons within mainland China. The Personal Information Protection Law provides the circumstances under which a personal information processor could process personal information, which include but not limited to, where the consent of the individual concerned is obtained and where it is necessary for the conclusion or performance of a contract to which the individual is a contractual party.

On July 7 2022, the CAC promulgated Measures for the Security Assessment of Outbound Data Transfer (《數據出境安全評估辦法》), which became effective on September 1, 2022. The Measures for the Security Assessment of Outbound Data Transfer specified that when data processors engage in outbound data transfer under any of the following circumstances, they shall apply for security assessment to the CAC in accordance with the relevant national regulations: (i) where a data processor transfers critical information abroad; (ii) where a critical information infrastructure operator or a data processor processing the personal information of more than one million individuals transfers personal information abroad; (iii) where a data processor has transferred personal information of 100,000 individuals or sensitive personal information of 10,000 individuals in total abroad since January 1 of the previous year, and (iv) other circumstances prescribed by the CAC for which declaration for security assessment for outbound data transfers is required.

On February 22, 2023, the CAC promulgated Measures for the Standard Contract for Outbound Transfer of Personal Information (《個人信息出境標準合同辦法》), which came into effect on June 1, 2023. Pursuant to Measures for the Standard Contract for Outbound Transfer of Personal Information, personal information processor transferring personal information abroad shall conclude Standard Contract if satisfy all the following conditions: (1) the data processor who intends to transfer personal information abroad is not a critical information infrastructure operator; (2) the data processor processes personal information of less than one million individuals; (3) the data processor has cumulatively transferred abroad the personal information of less than 100,000 individuals since January 1 of the previous year; and (4) the data processor has cumulatively transferred abroad the sensitive personal information of less than 10,000 individuals since January 1 of the previous year.

On March 22, 2024, the CAC promulgated the Provisions on Promoting and Regulating Cross-border Data Flow (《促進和規範數據跨境流動規定》), which became effective on the date of promulgation. According to the provisions, where a data processor transfers data abroad, it may be exempted from applying for a cross-border transfer security assessment,

REGULATORY OVERVIEW

concluding a standard contract for personal information to be provided abroad or passing a security certificate for protection of personal information if it satisfies any of the following conditions: (i) where it is really necessary to provide personal information abroad for the purpose of concluding or performing a contract to which an individual concerned is a party, such as cross-border shopping, cross-border delivery, cross-border remittance, cross-border payment, cross-border account opening, air ticket and hotel reservation, visa handling and examination services; (ii) where it is really necessary to provide employees' personal information abroad for the purpose of conducting cross-border human resources management in accordance with the employment rules and regulations and collective contracts formulated in accordance with the law; (iii) where it is really necessary to provide personal information abroad in an emergency to protect the life, health and property safety of a natural person; or (iv) where a data processor other than a critical information infrastructure operator provides abroad the personal information (excluding sensitive personal information) of not more than 100,000 persons accumulatively as of January 1 of the current year.

On February 12, 2025, the Cyberspace Administration of China issued the Administrative Measures for the Compliance Audit of Personal Information Protection (個人信息保護合規審計管理辦法), which took effect on May 1, 2025. According to the Administrative Measures for the Compliance Audit of Personal Information Protection, the term "compliance audit of personal information protection" refers to supervisory activities that review and evaluate whether the personal information processing activities of personal information processors comply with laws and administrative regulations.

On December 8, 2022, the MIIT promulgated the Measures for Data Security Management in the Industrial and Information Technology Sector (Trial) (《工業和信息化領域數據安全管理辦法(試行)》), which came into effect on January 1, 2023. The Measures for Data Security Management in the Industrial and Information Technology Sector (Trial) makes detailed provisions on classified and tiered data management, data lifecycle security management, data security monitoring and early warning and contingency management. It clearly stipulates that the data in the industrial and information fields can be divided into three levels: general data, important data and core data, and stipulates that the data processors in the industrial and information fields have the obligation to file with the relevant authorities their catalogs of important data and core data recognized according to the identification criteria for important data and core data in industrial and information technology sector.

The National Health and Family Planning Commission issued the Measures for Administration of Population Health Information (Trial) (《人口健康信息管理辦法(試行)》) on May 5, 2014, which refers the medical health service information as the population healthcare information, and emphasizes that such information cannot be stored in offshore servers, and the offshore servers shall not be hosted or leased. Pursuant to the Management Measures of Standards, Safety and Service of National Health and Medical Big Data (Trial) (《國家健康醫療大數據標準、安全和服務管理辦法(試行)》), promulgated by the National Health Commission on July 12, 2018, the medical institutions should establish relevant safety management systems, operation instructions and technical specifications to safeguard the safety of healthcare big data generated in the process of health management service or prevention and cure service of diseases. And it also stipulates that such healthcare big data should be stored in onshore servers and shall not be provided overseas without safety assessment.

On August 8, 2022, the National Health Commission, National Administration of Traditional Chinese Medicine, and National Disease Control and Prevention Administration jointly promulgated the Administrative Measures for the Cybersecurity of Medical and Healthcare Institution (《醫療衛生機構網絡安全管理辦法》) with immediate effect. Administrative Measures for the Cybersecurity of Medical and Healthcare Institutions require

REGULATORY OVERVIEW

strengthening management of cyber security and data security, including but not limited to strengthening management of system development, implementing daily network maintenance and monitoring, conducting annual self-inspection and rectification, and classifying and grading data assets.

LAWS AND REGULATIONS ON TAXATION

Enterprise Income Tax

According to the CIT Law (《中華人民共和國企業所得稅法》), which was promulgated by the SCNPC and was latest amended on December 29, 2018, and the *Regulation on the Implementation of the CIT Law* (《中華人民共和國企業所得稅法實施條例》), which was promulgated by the State Council and was latest amended on December 6, 2024 and came into force on January 20, 2025, a uniform 25% enterprise income tax rate is imposed to 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. The high-tech enterprises that need full support from the PRC’s government will enjoy a reduced tax rate of 15% for enterprise income tax.

Value-added Tax

Pursuant to the PRC Value-added Tax Law (《中華人民共和國增值稅法》), which was latest amended by the SCNPC on December 25, 2024, and became effective on January 1, 2026, 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 value-added tax (“VAT”).

LAWS AND REGULATIONS ON FOREIGN EXCHANGE

According to the Notice on Issues Concerning the Administration of Capital Raised by Domestic Enterprises from Overseas Listings (《關於境內企業境外上市資金管理有關問題的通知》), promulgated by the People’s Bank of China and the State Administration of Foreign Exchange (the “SAFE”) on December 24, 2025, and implemented on April 1, 2026, domestic companies listed overseas shall submit the registration documents for their overseas listings to the bank located in the registered place to open capital account-settlement accounts regarding their initial or follow-on offerings and share repurchases, and handle the exchange, transfer and remittance of relevant funds through such designated accounts, and the proceeds raised from overseas listings of a domestic company shall, in principle, be promptly remitted into the PRC or deposited overseas, and the use of such proceeds shall be consistent with those set out in the prospectus or other publicly disclosed documents such as the corporate bonds offering documentations, board resolutions or shareholders’ resolutions. For share repurchases using domestic funds, companies shall complete the relevant change registration prior to the proposed repurchase.

According to the Foreign Exchange Business Guidelines for Capital Account (2024 version) (《資本項目外匯業務指引(2024年版)》) promulgated by the SAFE on April 3, 2024, and implemented on May 6, 2024, funds raised by domestic companies through overseas listings shall, in principle, be remitted back to China in a timely manner, either in Renminbi or foreign currency. The use of such funds shall be consistent with the relevant content disclosed in public documents such as prospectuses, corporate bond issuance documents, shareholder circulars, or board of directors or shareholders’ meeting resolutions. Domestic companies using funds raised from overseas listings for outbound direct investment, overseas securities investment, or overseas lending shall comply with the relevant foreign exchange management regulations.

REGULATORY OVERVIEW

LAWS AND 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 Enterprises (《境內企業境外發行證券和上市管理試行辦法》) issued by the China Securities Regulatory Commission (the “CSRC”) on February 17, 2023 and effective from March 31, 2023 (hereinafter referred to as the “Trial Measures”), where a domestic company seeks overseas securities issuance and listing, the issuer shall file with the CSRC in accordance with the Trial Measures. 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.

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.

REGULATIONS IN RELATION TO THE “FULL CIRCULATION” OF H SHARE

In accordance with the Guidelines for the Application by H-share Companies for “Full Circulation” of Unlisted Shares (《H股公司境內未上市股份申請“全流通”業務指引》) which was promulgated by the CSRC on 14 November 2019 and came into effect on the same date, 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檔的決定》), the term “full circulation” means the circulation of domestically unlisted shares (including domestically unlisted shares held by domestic shareholders prior to the listing abroad, additional domestically unlisted shares issued domestically after listing abroad and unlisted shares held by foreign shareholders) of H-share companies on the Hong Kong Stock Exchange. On the premise of complying with relevant laws and regulations as well as policies governing state-owned asset management, foreign investment and industrial supervision, the shareholders of domestically unlisted shares may determine the number and proportion of shares under application for circulation through negotiation at their discretion and entrust a H-share company to file an application for “full circulation”. After the domestically unlisted shares are listed for circulation on the Hong Kong Stock Exchange, they shall not be transferred back to the Mainland China.

In accordance with the Notice on Promulgation of the Implementing Rules for “Full Circulation” of H-shares (《關於發佈〈H股“全流通”業務實施細則〉的通知》) which was promulgated by China Securities Depository and Clearing Co., Ltd (the “CSDC”) and Shenzhen Stock Exchange on December 31, 2019 and came into effect on the same date, it shall apply to the relevant businesses involved in “full circulation” of H-shares, such as cross-border re-registration, custodian and maintenance of holding details, entrustment of transactions and order routing, settlement, management of clearing participants, services of nominee holders etc.