OVERVIEW OF LAWS AND REGULATIONS IN THE PRC

Regulations Relating to Medical Devices

Definition of Medical Devices

In accordance with Regulation on the Supervision and Administration of Medical Devices (《醫療器械監督管理條例》), the term "medical devices" shall refer to the instruments, equipment, appliances, in vitro diagnostic reagents and calibrators, materials and other similar or relevant articles directly or indirectly used on the human body, including computer software needed.

Classification of Medical Devices

According to the Measures for the Supervision and Administration of the Operation of Medical Devices (《醫療器械經營監督管理辦法》), promulgated by the State Administration for Market Regulation (the "SAMR") on July 30, 2014, amended on March 10, 2022, and effective from May 1, 2022, and the Regulations on the Supervision and Administration of Medical Devices (《醫療器械監督管理條例》), promulgated by the State Council on February 9, 2021, most recently amended on December 6, 2024, and effective from January 20, 2025, the production and operation of medical devices in China are subject to risk-based classification management, with corresponding qualification requirements according to risk level. Medical devices are categorized into three classes: (i) Class I medical devices, which are considered low risk, can ensure safety and effectiveness through routine management, and therefore may be sold and circulated without the need for filing or obtaining an operating license from the drug regulatory authority; (ii) Class II medical devices, which are deemed moderate risk, require enterprises to establish strict management and quality control systems, and their production is contingent upon obtaining a Medical Device Production License; (iii) and Class III medical devices, which are considered high risk, may only be produced after securing the relevant production license, with enterprises further required to adopt special management measures to ensure their safety and effectiveness.

Registration and Record-Filing of Medical Devices

According to the Administrative Measures on the Registration and Record-filing of Medical Devices (《醫療器械註冊與備案管理辦法》), promulgated by the SAMR on August 26, 2021 and came into effect on October 1, 2021, the NMPA is responsible for the nationwide administration of medical device registration and record-filing.

In the PRC, record-filing is required for Class I medical devices and registration is required for Class II and Class III medical devices. Record-filing parties of domestic Class I medical devices shall submit record-filing materials to the drug regulatory authorities at cities with municipal districts. Domestic Class II medical devices shall be examined by the drug regulatory authorities of provinces which shall issue the medical device registration certificate upon approval. Domestic Class III medical devices shall be examined by the NMPA which shall issue the medical device registration certificate upon approval.

In accordance with Decree No. 47 of the State Administration for Market Regulation "Administrative Measures on the Registration and Record-filing of Medical Devices" (《醫療器械註冊與備案管理辦法》, "Decree 47"), for a Class II or III medical device that has been registered, in the event that there are material changes to the design, raw materials, production process, scope of application and method of use thereof, which might affect the safety and effectiveness of the medical device, the registrant of such medical device shall apply to the original registration authority for modification of registration; in the event of other changes, the registrant shall file the changes for record with the original registration authority within 30 days as of the date of change.

For an application for modification of registration, the technical review agency under the NMPA shall mainly review the modified part and give review opinions on whether the modified product is safe, effective and of controllable quality. Document on modification of registration of a medical device shall be used together with the original medical device registration certificate, and its expiry date shall be the same as that of the original medical device registration certificate.

According to the Regulation on the Supervision and Administration of Medical Devices (《醫療器械監督管理條例》), Class III medical devices are those devices that pose such a high degree of risk to users that the safety and effectiveness of the medical device can only be ensured through strict control and supervision of special measures. In line with this view, the Administrative Measures on the Registration and Record-filing of Medical Devices (《醫療器械註冊與備案管理辦法》) requires Class III medical devices to be examined by the NMPA, which shall issue the medical device registration certificate only after examination and approval. Similarly, according to the Measures for the Supervision and Administration of Medical Devices Manufacture (《醫療器械生產監督管理辦法》), those who intend to engage in the manufacture of Class III medical devices must first be approved by the drug regulatory authority of a province where they are located and obtain a medical device manufacturing permit in accordance with law.

Research and Clinical Evaluation of Medical Devices

In accordance with Regulation on the Supervision and Administration of Medical Devices (《醫療器械監督管理條例》) and Administrative Measures on the Registration and Record filing of Medical Devices (《醫療器械註冊與備案管理辦法》), the research and development and experiments of medical devices shall be in compliance with the relevant laws, regulations and mandatory standards of China.

According to the Administrative Measures on the Registration and Record-filing of Medical Devices (《醫療器械註冊與備案管理辦法》), promulgated by the SAMR on August 26, 2021 and came into effect on October 1, 2021, clinical evaluation shall be conducted for the registration or record-filing of medical devices, and clinical evaluation materials shall be submitted when applying for the registration of medical devices. Clinical evaluation of medical devices may be carried out through clinical trials or analysis and evaluation of clinical literature materials and clinical data of medical devices of the same kind to prove the safety and effectiveness of medical devices in light of product characteristics, clinical risks, existing clinical data and other circumstances. Clinical trials shall be carried out for medical devices for which the existing clinical literature materials and clinical data are insufficient to confirm their safety and effectiveness in the clinical evaluation of medical devices. Clinical trials for medical devices shall be conducted in clinical trial institutions for medical devices that meet the corresponding conditions and have been filed for record as required by the good clinical practice (GCP) for medical devices.

However, clinical evaluation of a medical device may be exempted when: (1) the medical device has a clear mechanism of action, a finalized design and a mature production process, and the medical devices of the same type have been used in clinical use for years without record of serious adverse events, and the new medical device does not deviate from the general purpose of the medical device with an established clinical record; or (2) if the safety and efficacy of the medical device can be proved through non-clinical evaluation. Where clinical evaluation is exempted, a submission of clinical evaluation materials is not required. The catalogue of medical devices exempted from clinical evaluation shall be formulated, adjusted and published by the NMPA.

The Guidelines for the Clinical Evaluation Techniques for Medical Devices (《醫療器械臨床評價技術指導原則》), promulgated by the NMPA on September 18, 2021, primarily introduces the concepts of clinical assessment and clinical evidence, elucidating the relationships among clinical trials, clinical data, clinical assessment, and clinical evidence. It guides applicants on how to conduct clinical evaluations, compile associated documentation, and incorporate them as integral components of the conformity assessment, as well as aims to instruct regulatory authorities on how to assess the clinical evidence submitted by applicants.

The Medical Devices — Application of Usability Engineering to Medical Device (《醫療器械可用性工程對醫療器械的應用》), promulgated by the NMPA on January 26, 2016 and came into effect on January 1, 2017, delineates the manufacturer's procedural framework for the analysis, determination, design, validation, and confirmation of usability that has a direct bearing on the safety of medical devices. The usability engineering process is deployed to assess and mitigate risks associated with normal usage, encompassing both correct and incorrect utilization. It serves the purpose of identifying, though not actively addressing, risks related to abnormal usage.

The Medical Devices — Application of Risk Management to Medical Device (《醫療器械 — 風險管理對醫療器械的應用》), promulgated by the SAMR on October 12, 2022 and came into effect on November 1, 2023, prescribes the terminology, principles, and procedures governing the risk management of medical devices, encompassing both medical device software and in vitro diagnostic medical devices. The delineated processes within this document are structured to aid manufacturers of medical devices in the identification of hazards associated with such devices, the estimation and assessment of pertinent risks, the implementation of risk controls, and the ongoing monitoring of the efficacy of these controls.

Production of Medical Devices

According to the Regulations on the Supervision and Administration of Medical Devices (《醫療器械監督管理條例》) and the Measures on the Supervision and Administration of Medical Devices Production (《醫療器械生產監督管理辦法》), which was promulgated by the SAMR on and effective from July 20, 2004, latest amended on March 10, 2022 and came into effect on May 1, 2022, in order to engage in the production of medical devices, an entity shall meet the following conditions: (1) having the production site, environmental conditions, production equipment and professional technicians that meet the needs of the medical devices to be produced; (2) having the facility or full-time personnel and testing equipment capable of testing the quality of the medical devices to be produced; (3) having a system of internal control that can ensure the quality of medical devices; (4) having the after-sale service capabilities that meet the needs of the medical devices to be produced; and (5) having the capability to meet the requirements as prescribed in the documents on product research and development and production techniques.

To engage in the production of Class II and Class III medical devices, an entity shall apply for a manufacturing licensing to the drug regulatory department of the people's government of the province where it is located and submit the relevant materials and the registration certificate of the medical devices to be produced. The manufacturing permit for medical devices is valid for five years. When it is necessary to renew the permit upon its expiration, the formalities for renewal shall be completed in accordance with the relevant laws on administrative licensing.

Operation of Medical Devices

According to the Regulations on the Supervision and Administration of Medical Devices (《醫療器械監督管理條例》) and the Measures for the Supervision and Administration of Medical Devices Operation (《醫療器械經營監督管理辦法》), promulgated by the SAMR on July 30, 2014 and effective from October 1, 2014, latest amended on March 10, 2022 and came into effect on May 1, 2022, a business operator shall file for record with the drug regulatory department of the government for the business operation of Class II medical devices and apply for operation licensing for the business operation of Class III medical devices. Furthermore, no business operator or using entity of medical devices may operate or use medical devices that have not been registered or filed for record in accordance with the law, or medical devices without conformity certificates, or expired, invalidated or obsolete. The valid period of the operating permit for medical devices is five years. Where it is necessary to renew the permit upon its expiration, the formalities for renewal shall be observed in accordance with the provisions of relevant laws on administrative licensing.

Centralised Procurement of High-value Medical Consumables

On March 5, 2018, six other government departments including the NHC issued the Notice on Consolidating the Achievements of Eradicating Pharmaceutical Compensation for Medical Treatment and Continuously Deepening the Comprehensive Reform of Public Hospitals (《關於鞏固破除以藥補醫成果持續深化公立醫院綜合改革的通知》), which states that the deepening of the comprehensive reform of public hospitals includes, among other things, the implementation of centralised purchasing of high-value medical consumables on a categorical basis.

On April 30, 2021, the NHSA, the NMPA and other relevant government authorities jointly issued the Guiding Opinions on the Implementation of the Centralised Volume-based Procurement and Use of High-value Medical Consumables Organised by the State (《關於開展國家組織高值醫用耗材集中帶量採購和使用的指導意見》). The State will focus on the procurement of some high-value medical consumables with large clinical consumption, high procurement amount, more mature clinical use, sufficient market competition and higher level of homogeneity. All public medical institutions shall participate in the centralised volume-based procurement of such high-value medical consumables.

On May 20, 2024, the National Healthcare Security Administration published the Notice of the National Healthcare Security Administration on Further Promotion of the Experience of Medical Reform in Sanming City and to Continuously Promote the Innovative Development of Medical Insurance (Yi Bao Han [2024] No. 25) (《國家醫療保障局關於進一步推廣三明醫改經驗持續推動醫保工作創新發展的通知》(醫保函[2024]25號)), providing instructions on the centralized procurement practice with an aim to continue the aggressive promotion of the centralized procurement of drugs and high-value medical consumables organized by national authorities, strengthen coordination among regions, guide and promote local governments to carry out centralized procurement in a regulated manner, support and coordinate targeted expansion of the scope of varieties of drugs and medical consumables under centralized procurement led by the willing and responsible provinces with the participation of all provinces, and form a new pattern of centralized procurement with the centralized procurement of drugs and high-value medical supplies organized by the State, and the centralized procurement of drugs and high-value medical supplies by the national alliance as the main body led by provinces, and centralized procurement of drugs and high-value medical supplies at the provincial level as the supplement.

On November 18, 2024, the National Healthcare Security Administration and the National Health Commission jointly issued the Notice on Improving the Mechanism for Centralised Volume-based Procurement and Implementation of Pharmaceuticals (《關於完善醫藥集中帶量採購和執行工作機制的通知》). This Notice further improves the working mechanism for centralised volume-based procurement and implementation of pharmaceuticals and medical consumables, consolidates and deepens the reform outcomes, refines management measures covering hospital admission, use, monitoring, assessment and feedback, and guides medical institutions and pharmaceutical enterprises to support and comply with the centralised volume-based procurement system.

Post-marketing Responsibility about Medical Devices

In accordance with Regulation on the Supervision and Administration of Medical Devices (《醫療器械監督管理條例》), a registrant or record-filing party of medical devices shall establish a monitoring system for adverse events of medical devices (醫療器械不良事件監測體系), be equipped with a monitoring body and personnel for adverse events suitable for its products, take the initiative to monitor adverse events of its products, and report the information on investigation, analysis, evaluation and product risk control to the technical monitoring agency for adverse events of medical devices in accordance with the provisions of the drug regulatory department under the State Council. The manufacturers or business operators and using entities of medical devices shall assist the registrant or record-filing party of medical devices in monitoring adverse events of the medical devices produced, operated or used by them; if any adverse event of medical devices or suspicious

adverse event is found, it shall be reported to the technical monitoring agency for adverse events of medical devices in accordance with the provisions of the drug regulatory department under the State Council.

In accordance with Administrative Measures on the Registration and Record-filing of Medical Devices (《醫療器械註冊與備案管理辦法》), a registrant of medical devices shall take the initiative to carry out post-marketing research, further confirm the safety, effectiveness and quality controllability of the medical devices and strengthen the continuous management of the medical devices on the market.

Advertisements of Medical Devices

Pursuant to the Interim Administrative Measures for the Review of Advertisements for Drugs, Medical Devices, Health Food and Formula Food for Special Medical Purposes (《藥品、醫療器械、保健食品、特殊醫學用途配方食品廣告審查管理暫行辦法》), which was promulgated by the SAMR on December 24, 2019 and came into effect on March 1, 2020, advertisements for medical devices shall not be released without being reviewed by the relevant administration for market regulation and drug administration of a province or other authorized administrative authorities. In addition, advertisers shall be responsible for the veracity and legitimacy of the contents of advertisements for medical devices.

The contents of a medical device advertisement shall be based on the contents of the registration certificate or filing certificate approved by the drug administrations, or the registered or filed product instructions. Where the medical device advertisement involves the name, scope of application, functional mechanism or structure or composition, etc. of the medical device, the scopes of the registration certificate or filing certificate, or registered or filed product instruction shall not be exceeded.

All advertisements for medical devices recommended for personal use must prominently display a disclaimer stating, "Please read the product instructions carefully or purchase and use the product as directed by a health care professional." If the product registration certificate of the medical device stipulates any contraindications or precautions, the advertisement shall include a disclaimer in a prominent position stating, "for contraindications and precautions, please refer to the instructions for details."

Regulations Relating to Foreign Investment

According to the Company Law of the PRC (《中華人民共和國公司法》 promulgated by the Standing Committee of the National People's Congress ("**SCNPC**") on December 29, 1993, and most recently amended on December 29, 2023, effective from July 1, 2024, the establishment, operation, and management of corporate entities in China are governed by the PRC Company Law. The PRC Company Law regulates two main corporate forms: limited liability companies and joint stock companies. Both forms enjoy the status of independent legal persons. Shareholders of a limited liability company bear liability to the extent of their subscribed capital contributions, while shareholders of a joint stock company bear liability to the extent of their subscribed shares. Unless otherwise provided by foreign investment laws, the PRC Company Law also applies to foreign-invested enterprises, including foreign-invested limited liability companies and joint stock companies.

Foreign-invested entities in China are further subject to foreign investment laws and regulations. The Foreign Investment Law of the PRC (《中華人民共和國外商投資法》), promulgated by the NPC on March 15, 2019, together with the Regulation on the Implementation of the Foreign Investment Law of the PRC (《中華人民共和國外商投資法實施條例》), promulgated by the State Council on December 26, 2019, both came into effect on January 1, 2020. "Foreign investment" refers to investment activities directly or indirectly carried out within China by foreign investors, including foreign natural persons, foreign enterprises, or other foreign organizations. The

Foreign Investment Law establishes the basic institution for foreign investment, implementing a system of pre-establishment national treatment plus a negative list management model. The negative list is approved by the State Council and published or revised in due course.

The Special Administrative Measures (Negative List) for Foreign Investment Access (2024 Edition) (《外商投資准入特別管理措施(負面清單)(2024年版)》, the "2024 Negative List"), jointly issued by the National Development and Reform Commission and the Ministry of Commerce on September 6, 2024, and effective from November 1, 2024, provides unified rules on equity structure, management positions, and access to certain industries for foreign investment. Foreign investors are prohibited from entering industries listed in the prohibited category, while investments in restricted industries are subject to specified conditions. For industries and sectors not included in the negative list, foreign investment is managed on the principle of national treatment, consistent with domestic investment. The 2024 Negative List expressly provides that medical institutions may only be established in the form of Sino-foreign joint ventures and may not be wholly foreign-owned. Our business does not fall within the scope of industries restricted or prohibited for foreign investment.

Regulations Relating to Foreign Exchange

According to the Regulations of the PRC on Foreign Exchange Administration (《中華人民共和國外匯管理條例》), promulgated by the SCNPC on January 29, 1996, and most recently amended on August 5, 2008, the state implements a unified foreign exchange administration system. Under these Regulations, all foreign exchange receipts and payments must be conducted in accordance with the law and are subject to the supervision of the SAFE and its local branches. Foreign exchange receipts and payments under current accounts by domestic institutions and individuals are unrestricted, while cross-border capital flows under capital accounts are strictly regulated. Domestic conversion of RMB into foreign currencies and remittance of the converted foreign exchange abroad require prior approval from SAFE or its authorized institutions.

According to the Notice of the State Administration of Foreign Exchange on Reforming and Standardizing the Management Policy of Capital Account Foreign Exchange Settlement (《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》), promulgated by SAFE on June 9, 2016, and most recently amended on December 4, 2023, foreign exchange income under capital accounts may be settled in banks according to the actual operational needs of domestic institutions. The tentative proportion of voluntary settlement of capital account foreign exchange income by domestic institutions is set at 100%, and SAFE may adjust this proportion as appropriate based on the balance of payments situation.

According to the Notice of the State Administration of Foreign Exchange on Further Facilitating Cross-border 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》), promulgated on October 23, 2019, and most recently amended on December 4, 2023, non-investment foreign-invested enterprises are allowed, under the premise of compliance with the current negative list and the authenticity and legality of relevant domestic investment projects, to lawfully settle their foreign exchange capital in RMB and use the RMB funds for equity investment within China, removing previous restrictions on the use of capital.

According to the Notice of the State Administration of Foreign Exchange on Optimizing Foreign Exchange Administration to Support the Development of Foreign-related Business (《國家外匯管理局關於優化外匯管理支持涉外業務發展的通知》), promulgated in April 10, 2020, subject to ensuring the authenticity and compliance of fund use and conformity with current capital account income management rules, qualified enterprises are allowed to use capital funds, foreign debt, and capital account income from overseas listings for domestic payments without providing authenticity proof for each transaction to the bank in advance; the handling bank may conduct post-event checks as required.

Regulations Relating to Taxation

Regulations Relating to Enterprise Income Tax (the "EIT")

According to the Enterprise Income Tax Law of the PRC (《中華人民共和國企業所得税法》, the "Enterprise Income Tax Law"), promulgated by the SCNPC on March 16, 2007, came into effect from January 1, 2008, revised and took effect on December 29, 2018 and the Implementation Regulations of the Enterprise Income Tax Law of the PRC (《中華人民共和國企業所得税法實施條例》, the "Implementation Regulations of the Enterprise Income Tax Law"), promulgated by the State Council on December 6, 2007, most recently revised on December 6, 2024, and effective as of January 20, 2025, enterprises established within China, as well as foreign enterprises that have establishments or places in China and derive income, are required to pay EIT in accordance with the law. The statutory EIT rate is 25%, applied equally to domestic and foreign-invested enterprises. Qualified small and low-profit enterprises may be taxed at a reduced rate of 20%, and high-tech enterprises may be taxed at a reduced rate of 15%. Non-resident enterprises that have establishments or places in China and derive income are subject to EIT at a rate of 20%. Non-resident enterprises that do not have establishments or places in China, or have establishments or places but earn income not effectively connected to them, shall pay EIT at a rate of 10% on income sourced within China.

Regulations Relating to Value-added Tax (the "VAT")

According to the Provisional Regulations of the PRC on Value-Added Tax (《中華人民共和國增值税暫行條例》, the "VAT Provisional Regulations"), promulgated by the State Council on December 13, 1993, and most recently revised on November 19, 2017, effective on the same date, and the Implementation Rules of the Provisional Regulations on Value-Added Tax (《中華人民共和國增值税暫行條例實施細則》), promulgated by the Ministry of Finance on December 25, 1993, and most recently revised on October 28, 2011, effective from November 1, 2011, units and individuals selling goods, providing processing, repair, and replacement services, selling services, intangible assets, or real estate, as well as importing goods in China, are required to pay VAT in accordance with the law. Unless otherwise provided, the applicable VAT rate for the sale of goods, labor services, and leasing of tangible movable property, or for imported goods, is 17%, while the applicable rate for the sale of services and intangible assets is 6%. Exported goods are subject to a zero tax rate, and domestic units and individuals providing cross-border services or intangible assets within the scope prescribed by the State Council are also subject to a zero tax rate.

Subsequently, according to the Notice on Adjusting VAT Rates (《關於調整增值税税率的通知》), promulgated by the Ministry of Finance and the State Taxation Administration on April 4, 2018, and effective from May 1, 2018, the original VAT rates of 17% and 11% for taxable sales or imported goods were adjusted to 16% and 10%, respectively. Further, according to the Announcement on Policies Related to Deepening VAT Reform (《關於深化增值税改革有關政策的公告》), promulgated by the Ministry of Finance, the State Taxation Administration, and the General Administration of Customs on March 20, 2019, and effective from April 1, 2019, the original 16% rate was adjusted to 13%, and the original 10% rate was adjusted to 9%.

Finally, the Value-Added Tax Law of the PRC (《中華人民共和國增值税法》, the "VAT Law"), promulgated by the SCNPC on December 25, 2024, and effective from January 1, 2026, replaces the original VAT Provisional Regulations. The VAT Law clarifies that, unless otherwise provided, the applicable VAT rate for the sale of goods, processing, repair and replacement services, leasing of tangible movable property, and imported goods is 13%, while the sale of other services and intangible assets is subject to a 6% rate. Taxpayers generally calculate VAT payable by deducting input VAT from output VAT. Only three categories of items are non-deductible: catering services for direct consumption, daily services for residents, and entertainment services.

Regulations Relating to Withholding Income Tax

According to the Enterprise Income Tax Law and the Implementation Regulations of the Enterprise Income Tax Law, non-resident enterprises deriving income from China, such as dividends, interest, and royalties, are generally subject to a withholding income tax at a rate of 10%. Under the Arrangement between the Mainland of China and the Hong Kong Special Administrative Region for the Avoidance of Double Taxation and the Prevention of Fiscal Evasion with Respect to Taxes on Income, if a Hong Kong enterprise directly holds at least 25% of the equity of a Chinese enterprise, it may enjoy a reduced withholding tax rate of 5%, benefiting from a 50% tax reduction.

In addition, the Announcement of the State Taxation Administration on the Issuance of the Administrative Measures for Non-Resident Taxpayers to Enjoy Treaty Benefits (《關於發佈〈非居民納税人享受協議待遇管理辦法〉的公告》), issued by the State Taxation Administration on October 14, 2019, and effective from January 1, 2020, simplified the procedures for non-resident taxpayers to enjoy treaty benefits. Non-resident taxpayers do not need approval from the tax authorities to enjoy treaty benefits; if they determine that they meet the conditions, they may claim treaty benefits when filing tax returns or through the withholding agent during withholding declaration. Relevant materials must be collected and retained for record-keeping, and the taxpayers remain subject to subsequent management by the tax authorities.

Furthermore, according to the Announcement on Issues Regarding the "Beneficial Owner" in Tax Treaties (《關於税收協議中「受益所有人」有關問題的公告》), promulgated by the State Taxation Administration on February 3, 2018, and effective from April 1, 2018, applicants must submit documents to the relevant tax authorities under the Administrative Measures to Demonstrate their "beneficial owner" status. When determining the applicant's "Beneficial owner" status for dividends, interest, and royalties under a tax treaty, multiple factors are considered, including, but not limited to: whether the applicant is obligated to pay more than 50% of the received income to residents of a third country (or region) within 12 months; whether the applicant's business activities constitute substantive business operations; and whether the treaty partner jurisdiction does not tax, exempts, or imposes an extremely low effective tax rate on the relevant income. Applicants failing to meet the beneficial owner criteria are not entitled to preferential tax rates under the treaty.

Regulations Relating to Intellectual Property Rights

Regulations Relating to Trademark

According to the Trademark Law of the PRC (《中華人民共和國商標法》, the "Trademark Law"), promulgated by the SCNPC on August 23, 1982, and most recently revised on April 23, 2019, and the Implementation Regulations of the Trademark Law of the PRC (《中華人民共和國商標法實施條例》, the "Trademark Law Implementation Regulations"), promulgated by the State Council on August 3, 2002, revised on April 29, 2014, and effective as of May 1, 2024, trademarks approved and registered by the Trademark Office of the National Intellectual Property Administration (the "NIPA") are considered registered trademarks, including commodity trademarks, service trademarks, collective trademarks, and certification trademarks. Registered trademarks are valid for ten years and may be renewed for another ten years upon expiration. Trademark owners enjoy exclusive rights to their registered trademarks. Unauthorized use of identical or similar trademarks on the same or similar goods constitutes infringement and requires the infringer to cease infringement and compensate for damages; in severe cases, criminal liability may also apply.

Regulations Relating to Copyright

According to the Copyright Law of the PRC (《中華人民共和國著作權法》, the "Copyright Law"), promulgated by the SCNPC on September 7, 1990, and most recently revised on November 11, 2020, and the Implementation Regulations of the Copyright Law of the PRC (《中華人民共和國著作權法實施條例》, the "Copyright Law Implementation Regulations"), promulgated by the State Council on May 30, 1991, and most recently revised on January 30, 2013, effective March 1, 2013,

Chinese citizens, legal persons, or other organizations enjoy copyright in their works, including literary works, artistic works, engineering and technical works, and computer software. Copyright arises from the moment a work is created. Copyright holders have moral and economic rights over their protected works, including the right of publication, authorship, modification, protection of integrity, reproduction, distribution, rental, exhibition, performance, broadcasting, information network dissemination, cinematography, adaptation, translation, compilation, and other rights granted by law.

According to the Regulations on the Protection of Computer Software (《計算器軟件保護條例》), promulgated by the State Council on June 4, 1991, and most recently revised on January 30, 2013, and the Measures for the Registration of Computer Software Copyright (《計算器軟件著作權登記辦法》), promulgated by the National Copyright Administration (the "NCA") on February 20, 2002, and most recently revised on June 18, 2004, the NCA is responsible for the registration and administration of computer software copyright and authorizes the China Copyright Protection Center (the "CCPC") as the software copyright registration authority. The CCPC may establish local software registration offices and issue registration certificates to applicants in accordance with relevant regulations. For legal persons or other organizations, the protection period of software copyright is fifty years, expiring on December 31 of the 50th year after publication; if the software is not published within fifty years of completion, copyright protection ceases.

Regulations Relating to Patent

According to the Patent Law of the PRC (《中華人民共和國專利法》, the "Patent Law"), promulgated by the SCNPC on March 12, 1984, and most recently revised on October 17, 2020, 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, revised on December 11, 2023 and became effective on January 20, 2024, the NIPA is responsible for patent examination and authorization. The Chinese patent system follows a "first-to-file" principle, meaning that if more than one person applies for a patent for the same invention, the patent is granted to the first applicant. Invention and utility model patents must meet the requirements of novelty, inventiveness, and industrial applicability to be eligible for patent protection. Third parties may only use a patent with the consent or formal authorization of the patent holder; otherwise, unauthorized use constitutes patent infringement. Under the Patent Law, authorized patent holders enjoy exclusive rights to implement their patents and may prohibit unauthorized use.

The Patent Law and its Implementation Rules provide for three types of patents: invention, utility model, and design. The term of protection for invention patents is 20 years from the date of application, for utility model patents is 10 years, and for design patents filed on or after June 1, 2021, the term of protection is 15 years.

Pursuant to the Measures for the Recordal of Patent Licensing Contracts (《專利實施許可合同備案辦法》), promulgated by NIPA on June 27, 2011, and effective from August 1, 2011, NIPA is responsible for the recordal of patent licensing contracts nationwide. Parties must complete the recordal procedures within three months from the effective date of a patent licensing contract.

Regulations Relating to Trade Secret

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

right holder for keeping the trade secret confidential; (iv) abetting a person, or tempting another person into or in acquiring, disclosing, using, or allowing another person to use the trade secret of the right holder in violation of his or her non-disclosure obligation of the requirements of the right holder for keeping the trade secret confidential. If a third party knows or should have known of the above-mentioned illegal conduct but nevertheless obtains, uses or discloses trade secrets of others, the third party may be deemed to have committed a misappropriation of the others' trade secrets. The parties whose trade secrets are being misappropriated may petition for administrative corrections, and regulatory authorities may stop any illegal activities and impose fine on the infringing parties.

Regulations Relating to Domain Name

According to the Administrative Measures for Internet Domain Names (《互聯網域名管理辦法》), promulgated by the MIIT on August 24, 2017, and effective from November 1, 2017, MIIT is the primary regulatory authority for domain name services in China. Domain name registration follows the principle of "first apply, first register." Applicants must register through authorized domain name registration service providers and submit true, accurate, and complete identity information. Upon registration, the applicant becomes the domain name holder and enjoys lawful usage rights.

In the Notice of the Ministry of Industry and Information Technology on Regulating the Use of Domain Names in Internet Information Services (《工業和信息化部關於規範互聯網信息服務使用域名的通知》), promulgated by the MIIT in November 2017 and effective from January 1, 2018, it is stipulated that domain names used by Internet information service providers must be legally registered and owned by them. Where an entity engages in Internet information services, the domain name registrant shall be the entity itself (including its shareholders), the entity's principal responsible person, or its senior management personnel.

Regulations Relating To Employment and Social Welfare

Regulations Relating to Employment

According to the Labor Law of the PRC (《中華人民共和國勞動法》), promulgated by the SCNPC in July 1994 and most recently amended in December 2018, employers shall establish and improve labor rules and regulations in accordance with the law, strictly comply with national standards, provide necessary training to employees, ensure that employees enjoy labor rights, and fulfill their labor obligations.

According to 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 most recently amended on December 28, 2012, and its implementing regulations, employers and employees shall conclude written labor contracts when establishing labor relations. Labor contracts may be fixed-term, open-ended, or based on the completion of specific work tasks. If a labor relationship has been established without a written labor contract, a written contract must be signed within one month from the date of employment. Employers shall not force employees to work overtime, shall legally control working hours, and shall pay overtime wages. Employee wages shall not be lower than the local minimum wage standard and must be paid in full and on time. Employers may legally terminate labor contracts upon mutual agreement with employees or in accordance with statutory conditions.

According to the Interim Provisions on Labor Dispatch (《勞務派遣暫行規定》), promulgated by the Ministry of Human Resources and Social Security and effective from March 1, 2014, employers may only use dispatched employees for temporary, auxiliary, or substitutive positions and must ensure that they enjoy equal pay for equal work compared to similar employees of the employer. The number of dispatched employees shall not exceed 10% of the total workforce. Employers failing to comply with the proportion limit shall be fined RMB5,000 to 10,000 per employee.

Regulations Relating to Social Insurance

According to the Social Insurance Law of the PRC (《中華人民共和國社會保險法》), promulgated by the SCNPC on October 28, 2010, and most recently amended on December 29, 2018, and the Interim Regulations on the Collection of Social Insurance Premiums (《社會保險費徵繳暫行條例》), promulgated by the State Council on January 22, 1999, and most recently amended on March 24, 2019, the state establishes basic pension insurance, basic medical insurance, work injury insurance, unemployment insurance, and maternity insurance. Employers shall enroll their employees in social insurance in accordance with the law and register with the social insurance agency within 30 days from the date of employment. Employers who fail to pay social insurance contributions on time or in full may be ordered by the social insurance collection agency to pay within a time limit or make up the shortfall; if still unpaid after the deadline, late fees will be charged, and fines of 1 to 3 times the unpaid amount may be imposed.

In addition to general social insurance requirements, enterprises are specifically required to provide maternity insurance for eligible employees in accordance with the Trial Measures for Maternity Insurance for Enterprise Employees (《企業職工生育保險試行辦法》), promulgated by the Ministry of Labor on December 14, 1994, and effective from January 1, 1995; enroll employees in basic pension insurance in accordance with the Decision of the State Council on Establishing a Unified Basic Pension Insurance System for Enterprise Employees (《國務院關於建立統一的企業職工基本養老保險制度的決定》), promulgated and effective on July 16, 1997; enroll employees in basic medical insurance in accordance with the Decision of the State Council on Establishing the Basic Medical Insurance System for Urban Employees (《國務院關於建立城鎮職工基本醫療保險制度的決定》), promulgated and effective on December 14, 1998; enroll employees in unemployment insurance in accordance with the Unemployment Insurance Regulations (《失業保險條例》), promulgated and effective on January 22, 1999; and enroll employees in work-related injury insurance in accordance with the Work-Related Injury Insurance Regulations (《工傷保險條例》), promulgated on April 27, 2003, revised on December 20, 2010, and effective from January 1, 2011.

Regulations Relating to Housing Provident Fund

According to the Administrative Regulations on Housing Provident Fund (《住房公積金管理條例》), promulgated by the State Council on April 3, 1999, and most recently amended on March 24, 2019, enterprises must register with the designated housing provident fund management centers and open bank accounts for the deposit of employees' housing provident funds. Employers shall make contributions in accordance with national regulations, with the contribution generally not less than 5% of the employees' average monthly salary of the previous year.

Employers who fail to register for housing provident fund contributions or fail to open accounts for employees may be ordered by the housing provident fund management center to complete the registration within a time limit; if overdue, they may be fined RMB10,000 to 50,000. Employers who delay or underpay contributions may be ordered to make payments within a specified period, and if still unpaid, the housing provident fund management center may apply to the People's Court for compulsory enforcement.

Regulations on Lease of Real Property

According to the Civil Code, a lease contract generally shall contain clauses specifying the name, quantity and purpose of use of the leased object, the term of the lease, rent, the schedule and method of its payment, the maintenance and repair of the leased object, etc. The lessee of a lease may, with the consent of the lessor, sublease the leased object to a third party.

According to the Administrative Measures for Leasing of Commodity Housing (《商品房屋租賃管理辦法》) promulgated by the MOHURD on December 1, 2010 and became effective on February 1, 2011, a commodity housing lease contract should be registered and filed with the competent construction (real estate) departments of the municipalities directly under the central government, cities and counties where the house is located within 30 days after the execution of the lease contract.

Those who fail to comply with the aforementioned filing regulations may be ordered by the competent authority to correct within a time limit. If the entity does not correct within the specified period, it may be subject to a fine ranging from RMB1,000 to RMB10,000.

Regulations Relating to Securities and Overseas Securities Offering

Regulations Relating to Securities

According to the Securities Law of the PRC (《中華人民共和國證券法》), promulgated by the SCNPC on December 29, 1998, and most recently amended on December 28, 2019, the securities law implements a registration-based system with information disclosure as its core. Issuers are required to ensure that disclosed information is true, accurate, and complete, and shall not contain false records, misleading statements, or material omissions. Domestic enterprises issuing securities directly or indirectly overseas, or having their securities listed abroad, must comply with the relevant regulations of the State Council; the CSRC is responsible for the legal supervision and administration of the securities market. The issuance and trading of H-shares are primarily governed by regulations and rules issued by the State Council and CSRC.

Regulations Relating to Overseas Listing

On July 6, 2021, the General Office of the State Council and General Office of the Central Committee of the Communist Party of China issued Opinions on Strictly Cracking Down Illegal Securities Activities in Accordance with the Law (《關於依法從嚴打擊證券違法活動的意見》). The opinions emphasized the need to strengthen the administration over illegal securities activities and the supervision on overseas listings by China-based companies and proposed to take effective measures, such as promoting the construction of relevant regulatory systems to deal with the risks and incidents faced by China-based overseas-listed companies.

The Measures for the Administration of Overseas Securities Issuance and Listing by Domestic Enterprises (Trial) (《境內企業境外發行證券和上市管理試行辦法》), promulgated by CSRC on February 17, 2023, and effective from March 31, 2023, together with five supporting guidelines, establishes a filing management system. Domestic enterprises intending to directly or indirectly issue and list securities overseas shall submit filing materials to CSRC within three working days after submitting the overseas listing application.

The Trial Measures stipulate that domestic enterprises shall not issue or list securities overseas under any of the following circumstances: (i) explicitly prohibited by laws, administrative regulations, or relevant national provisions; (ii) deemed by the competent authorities of the State Council to potentially endanger national security; (iii) in the past three years, the domestic enterprise or its controlling shareholder or actual controller has committed criminal offenses such as embezzlement, bribery, misappropriation of property, or disruption of the socialist market economy order; (iv) the domestic enterprise is under legal investigation for suspected criminal or major illegal acts, without a clear conclusion; (v) there exist major ownership disputes over shares held by controlling shareholders or shareholders under the actual control of the controlling person.

Furthermore, the Trial Measures require that issuers report to CSRC within three working days after the overseas listing if any of the following occurs: (i) change of control; (ii) investigation or penalty measures taken by overseas securities regulators or competent authorities; (iii) conversion of listing status or board segment; (iv) voluntary or involuntary termination of listing. Overseas listed enterprises must also strictly comply with national laws and regulations concerning foreign investment, cybersecurity, data security, and national security, and duly fulfill the obligation to safeguard national security.

Regulations Relating to Confidentiality and Archival Management

According to the Notice on Strengthening Confidentiality and Archival Management Related to Overseas Securities Issuance and Listing by Domestic Enterprises (《關於加強境內企業境外發行證券和上市相關保密和檔案管理工作的規定》), jointly issued by CSRC and three other relevant departments on February 24, 2023, and effective from March 31, 2023, during the process of direct or indirect overseas issuance and listing by domestic enterprises, when domestic enterprises provide or publicly disclose documents or materials to securities companies, accounting firms, other securities service institutions, or overseas regulatory authorities that may involve state secrets, confidential information of state agencies, or could adversely affect national security or public interest, they must strictly comply with national regulations regarding approval and filing procedures. The Notice further requires that securities companies and securities service institutions providing services for overseas issuance and listing by domestic enterprises must retain working papers generated within China in the Chinese Mainland. Such working papers may not be carried, mailed, or transferred outside the Chinese Mainland without prior approval from the competent authorities. If it is necessary to transfer the working papers abroad, approval must be obtained from the competent authorities. The Notice also establishes and strengthens a cross-border regulatory cooperation mechanism, shifting the overall approach to cross-border supervision of overseas issuance and listing from "domestic regulatory authorities taking the lead or relying on conclusions from domestic inspections" to a "cross-border regulatory cooperation" mechanism.

The specific provisions include: (i) During overseas issuance and listing, domestic enterprises must strictly comply with requirements for safeguarding state secrets and managing archives, establish and maintain sound confidentiality and archival systems, and take necessary measures to fulfill their confidentiality and archival management responsibilities; (ii) When providing or publicly disclosing documents or materials involving state secrets, confidential information of state agencies, or materials that could adversely affect national security or public interest, domestic enterprises must complete the relevant approval, filing, or other regulatory procedures; (iii) Securities companies and securities service institutions must retain working papers generated within the Chinese Mainland, and if it is necessary to transfer such materials abroad, prior approval must be obtained from the competent authorities in the Chinese Mainland.

Regulations on the 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 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 amended on August 10, 2023.

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 filing procedures necessary for the Measures for the Administration of Overseas Securities Issuance and Listing by Domestic Enterprises (Trial). 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 China Securities Depository and Clearing Limited (the "CSDC") of the shares related to the application has been completed. After domestic unlisted shares are listed and circulated on the Hong Kong Stock Exchange, they may not be transferred back to China.

REGULATORY OVERVIEW

On December 31, 2019, CSDC and the Shenzhen Stock Exchange jointly announced the Measures for Implementation of H-share Full Circulation Business (《H股「全流通」業務實施細則》) (the "Measures for Implementation") to regulate 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.

In addition, the Guide for "Full Circulation" Business of H Shares by the 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》), promulgated by the Shenzhen Branch of CSDC and effective on June 30, 2025, which clearly provides for business arrangements and procedures related to H-share full circulation business, including business preparation, cross-border transfer registration, overseas depository of shares and initial maintenance and change in maintenance of domestic holding details, corporate behavior processing, clearing and settlement, risk management and business charges.