

REGULATORY OVERVIEW

This section sets out a summary of the most significant rules and regulations affecting our business activities in China.

REGULATIONS ON COMPANY ESTABLISHMENT AND FOREIGN INVESTMENT

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.

On March 15, 2019, the National People’s Congress (the “**NPC**”) approved the Foreign Investment Law of the PRC (《中華人民共和國外商投資法》), which sets out the regulatory framework for foreign investments and pursuant to which (i) foreign natural persons, enterprises or other organizations (collectively, the “**foreign investors**”) shall not invest in any sector prohibited as specified in the negative list for access of foreign investment, (ii) for any sector restricted by the negative list, foreign investors shall conform to the investment conditions provided in the negative list, and (iii) sectors not included in the negative list shall be managed under the principle of equality in treating domestic investments and foreign investments.

Investment activities in the PRC by foreign investors are governed by the Special Administrative Measures for the Access of Foreign Investment (Negative List) (2024 Edition) (《外商投資准入特別管理措施(負面清單)(2024年版)》), or the Negative List, which was jointly promulgated by the Ministry of Commerce (MOC) of the PRC and the NDRC, on September 6, 2024 and came into effect on November 1, 2024. The Negative List sets out the restrictive measures in a unified manner, such as the requirements on shareholding percentages. Pursuant to the Negative List, any field not falling under the Negative List shall be administered under the principle of equal treatment to domestic and foreign investment.

INTERNET HEALTHCARE INDUSTRY PLANNING AND POLICIES

The General Office of the State Council of the PRC promulgated the Notice on the Issuance of the Fourteenth Five-Year Plan for Universal Medical Care (《國務院辦公廳關於印發“十四五”全民醫療保障規劃的通知》) on September 23, 2021, which took effect on the same day. Improve the management of the “Internet + healthcare” medical insurance agreement, improve the price of “Internet +” medical services and medical insurance payment policies, and extend medical insurance management services to “Internet + healthcare” medical behavior, the formation of a relatively complete “Internet + medical health” medical insurance policy system, service system and evaluation system.

Opinions of the General Office of the State Council on Promoting the Development of “Internet plus Medical Care and Health” (《國務院辦公廳關於促進“互聯網+醫療健康”發展的意見》) was promulgated on April 25, 2018 and came into effect in the same day. The notice of the National Health Commission and the State Administration of Traditional Chinese Medicine (SATCM) on the in-depth implementation of the “Internet + Healthcare” for the convenience and benefit of the people (《國家衛生健康委員會、國家中醫藥管理局關於深入開展“互聯網+醫療健康”便民惠民活動的通知》) was promulgated on July 10, 2018 and came into effect on the same day. The Circular of the General Office of the NHC on Further Promoting the Pilot Work of “Internet + Nursing Service” (《國家衛生健康委辦公廳關於進一步推進“互聯網+護理服務”試點工作的通知》) was promulgated on December 8, 2020 and came into effect on the same day. Guiding Opinions of the National Healthcare Security Administration on Improving the Policies of “Internet Plus” Medical Service Prices and Medical Insurance Payment (《國家醫療保障局關於完善“互聯網+”醫療服務價格和醫保支付政策的指導意見》) was promulgated on August 17, 2019. The healthcare of the people shall be placed at the center; the development of “Internet + health care” shall be promoted; the policies of medical service prices and medical insurance payment shall be properly determined and dynamically adjusted; and the “Internet +” initiative shall play a positive role in realizing the mobility of high-quality medical resources across regions, supporting the cost reduction, efficiency increase, and equal accessibility of medical services, improving patient experiences in hospitals, and rebuilding the competitive relationship on the medical market.

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REGULATIONS ON INTERNET HEALTHCARE

The State Council of the PRC promulgated the Regulations on the Administration of Medical Institutions (2022 version) (《醫療機構管理條例(2022修訂)》) on February 26, 1994, which were last amended on March 29, 2022, and came into effect on May 1, 2022. This Regulation shall apply to hospitals, health centers, nursing homes, out-patient division, clinics, health center (or office), first aid stations and other medical institutions engaging in the diagnosis and treatment of diseases.

Notice by the NHC and the SATCM on Issuing the Measures for the Administration of Internet Diagnosis and Treatment (for Trial Implementation) and Other Two Documents (《國家衛生健康委員會、國家中醫藥管理局關於印發互聯網診療管理辦法(試行)等3個文件的通知》) promulgated on July 17, 2018 and came into effect on the same date. The Measures for the Administration of Internet Diagnosis and Treatment (for Trial Implementation) (《互聯網診療管理辦法(試行)》) makes it clear that Internet diagnosis and treatment refers to the use of physicians registered in medical institutions to carry out, through the Internet and other information technologies, part of the follow-up diagnosis of common diseases and chronic diseases and the “Internet +” family doctor contracting service. The State implements access management for Internet diagnosis and treatment activities. The Measures for the Administration of Internet Hospitals (for Trial Implementation) (《互聯網醫院管理辦法(試行)》) clarifies the concept of Internet hospitals, including Internet hospitals as the second name of physical medical institutions, and Internet hospitals independently relying on physical medical institutions. The state implements access management for Internet hospitals. Specifications for the Administration of Remote Medical Services (for Trial Implementation) (《遠端醫療服務管理規範(試行)》) specifies the two scenarios of telemedicine services, as well as the administration of such services in relation to Internet hospitals. It makes provisions for the basic conditions of medical institutions, personnel, equipment and facilities.

Regulations on Generative Artificial Intelligence Services

The regulations concerning generative artificial intelligence services in China mainly include *the Interim Measures for the Administration of Generative Artificial Intelligence Services*, *Provisions on the Administration of Algorithm-generated Recommendations for Internet Information Services*, *Provisions on the Administration of Deep Synthesis of Internet-Based Information Services*, and *the Measures for the Labeling of Artificial Intelligence Generated and Synthesized Content* (enter into force on September 1, 2025). Pursuant to the Interim Measures for the Administration of Generative Artificial Intelligence Services (hereinafter referred to as “**Interim Measures**”), these Measures shall apply to the utilization of generative AI technology to provide services that generate texts, images, audio and video, and other content to the public within the territory of the People’s Republic of China (hereinafter referred to as “**PRC**”). The company, using generative AI technology of Care AI, provides text generation services to users, which constitutes the provision of Generative AI services to the public within the territory of the PRC. Therefore, the Interim Measures is applicable.

REGULATIONS ON THE MANAGEMENT OF INTERNET PHARMACEUTICAL BUSINESS

Pharmaceutical Administration Law of the PRC (2019 Revision) (《中華人民共和國藥品管理法》) was promulgated by the SCNPC of the PRC on September 20, 1984, with the most recent amendment dated August 26, 2019, and came into effect on December 1, 2019. This law is formulated to enhance the supervision and control of pharmaceuticals, ensure their quality, guarantee safety in medication, and safeguard the health and legal rights and interests of the people. This law shall be applicable to any units or individuals engaged in research, production, trade, use, supervision and management of pharmaceuticals within the territory of the PRC.

In addition, the Quality Management Standard for Drug Distribution (also known as the Good Supply Practice for Drugs, GSP) (《藥品經營質量管理規範》), which was promulgated by the National Medical Products Administration in June 2015 and newly revised in July 2016, stipulates that drug distributors should implement effective quality management in the purchase, storage, transportation, and sales of drugs to ensure drug quality. It also requires the establishment of a drug traceability system in accordance with relevant requirements in China to achieve drug traceability. Once a drug has been sold, it shall not be returned or exchanged for any reason, except for quality issues. If a sold drug has serious quality problems, the drug distributor shall take timely measures to recover the drug, keep records, and report to the relevant food and drug regulatory department.

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Notice by the Department of Comprehensive Affairs of the National Medical Products Administration of Effectively Implementing the Measures for the Supervision and Administration of Online Sales of Medicinal Products (《國家藥監局綜合司關於做好《藥品網絡銷售監督管理辦法》貫徹落實工作的通知》) was promulgated on November 24, 2022 and came into effect on the same day. Drug regulatory authorities at all levels shall supervise and guide drug network sales enterprises to effectively fulfill their main responsibilities, establish and implement systems for drug quality and safety management, risk control, traceability, storage and distribution, online pharmacy services, etc.; where electronic prescriptions are used to sell prescription drugs to individuals, they shall enter into an agreement with the medical institution or the electronic prescription flow platform to ensure that the source of the prescription is true and reliable, and that the drugs can be traced back to the consumer or the patient; and be equipped with pharmacists or other pharmacy technicians who have been qualified in accordance with the law to carry out prescription review and allocation, and shall not provide services related to the purchase of prescription drugs without passing the prescription review.

The Measures Regarding the Administration of Drug Information Service over the Internet (2017 Amendment) 《互聯網藥品信息服務管理辦法 (2017修正)》 which was promulgated on July 8, 2004 amended on November 17, 2017 and came into effect on the same day. Internet drug information services are divided into two categories: operational and non-operational. The State Food and Drug Administration implements supervision and management of websites providing Internet drug information service activities nationwide.

Notice of the General Office of the China Food and Drug Administration on Strengthening the Regulation of Internet Drug and Medical Device Trading (《國家食品藥品監管總局辦公廳關於加強互聯網藥品醫療器械交易監管工作的通知》) was promulgated on November 1, 2017 and became effective on the same day. Implementing regulatory responsibilities. Establish and improve the Internet drug and medical device trading service enterprises (third-party) regulatory system, in accordance with the principle of “online and offline consistency”, to regulate the Internet drug and medical device trading behavior.

DATA AND PRIVACY COMPLIANCE

In December 1997, the Ministry of Public Security promulgated the Measures for the Administration of Computer Information Network International Networking Security Protection (《計算機信息網絡國際聯網安全保護管理辦法》) (further revised on January 8, 2011), which prohibits the use of the Internet (including) to disclose state secrets and disseminate content that disturbs social order. The Measures for the Administration of Classified Protection of Information Security (《信息安全等級保護管理辦法》), which came into effect on June 22, 2007, stipulates that the security protection levels of information systems can be divided into five levels, and units operating information systems above the second level shall, within 30 days from the date of determining their security protection levels, go through the filing procedures with the local public security organs.

The SCNPC of the PRC promulgated Personal Information Protection Law of the PRC (《中華人民共和國個人信息保護法》) on August 20, 2021 and came into effect on November 1, 2021. The personal information of natural persons shall be protected by law. No organization or individual may infringe upon natural persons’ rights and interests relating to personal information. Personal information processors shall be responsible for their personal information processing activities, and take necessary measures to guarantee the security of the personal information they process. No organization or individual may illegally collect, use, process, or transmit the personal information of another person or illegally buy or sell, provide, or disclose the personal information of another person; or engage in personal information processing activities compromising national security or public interests.

On May 28, 2020, the National People’s Congress issued the Civil Code of the People’s Republic of China (《中華人民共和國民法典》), or the Civil Code of the PRC, which states that the personal information of natural persons shall be protected by law, and the processing of personal information shall be carried out in accordance with the principles of legality, righteousness and necessity, and no additional processing shall be carried out.

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The SCNPC of the PRC promulgated Data Security Law of the PRC (《中華人民共和國數據安全法》) on June 10, 2021, which came into effect on September 1, 2021. This Law shall apply to data processing activities and the security supervision thereof conducted in the territory of the PRC. When conducting data processing activities, one shall comply with laws and regulations, respect social norms and ethics, observe business and professional ethics, act in good faith, perform data security protection obligations, and undertake social responsibilities, and shall neither compromise national security and public interest nor harm the lawful rights and interests of any organization or individual.

The SCNPC of the PRC promulgated Cybersecurity Law of the PRC (《中華人民共和國網絡安全法》) on November 7, 2016 and came into effect on June 1, 2017. This Law shall apply to the construction, operation, maintenance and use of the network as well as the supervision and administration of cybersecurity within the territory of the PRC. The national cyberspace administration shall be responsible for the overall planning and coordination of cybersecurity work and relevant supervision and administration. The competent telecommunications department of the State Council, public security departments and other relevant authorities shall be responsible for cybersecurity protection, supervision and administration within the scope of their respective functions in accordance with the provisions of this Law and other relevant laws and administrative regulations. Network operators shall, when conducting business operations and providing services, abide by laws and administrative regulations, respect social morality, observe business ethics, have good faith, perform the cybersecurity protection obligation, accept supervision by the government and the public, and undertake social responsibilities.

The Data Security Law of the PRC (《中華人民共和國數據安全法》) was released by the SCNPC on June 10, 2021 and became effective on September 1, 2021. The PRC Data Security Law stipulates the measures to support and promote data security and development, to establish and optimize the national data security management system, and to clarify organizations’ and individuals’ responsibilities in data security. The PRC Data Security Law introduces a data classification and hierarchical protection system based on the materiality 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 entities when such data is tampered with, destroyed, divulged, or illegally acquired or used.

On December 28, 2021, the Cyberspace Administration of China (the “CAC”) and certain other PRC regulatory authorities published the Cybersecurity Review Measures (《網絡安全審查辦法》), which became effective on February 15, 2022. Pursuant to the Cybersecurity Review Measures, critical information infrastructure operators that purchase network products and services and network platform operators engaging in data processing activities that affect or may affect national security must be subject to the Cybersecurity Review.

On September 24, 2024, the State Council released the Regulations on the Administration of Cyber Data Security (《網絡數據安全管理條例》) (the “**Data Security Regulation**”), which came into effect on January 1, 2025. According to the Data Security Regulation, where network data processing activities carried out by a network data processor affect or may affect national security, national security review shall be conducted in accordance with the relevant provisions issued by the state. Furthermore, where it is indeed necessary to provide an overseas party with important data collected and generated by a network data processor during its operation within the territory of the PRC, it shall be subject to the security assessment of outbound data transfer organized by the cyberspace administration of the state. If a network data processor identifies and declares important data according to the relevant provisions of the state, which has not been informed or announced by the relevant region or department to be important data, it is not required to declare such data as important data for security assessment of outbound data transfer.

The CAC promulgated the Security Assessment Measures for Data Provision Abroad (《數據出境安全評估辦法》) (the “**Security Assessment Measures**”), which came into effect on September 1, 2022.

The Security Assessment Measures shall apply to the security assessment of data processors’ provision of important data and personal information collected and generated in their operations within the territory of the PRC to overseas recipients. If it is otherwise provided for in any law or administrative regulation, such provisions shall prevail. The security assessment of outbound data

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transfer shall adhere to the integration of prior assessment and continuous supervision and the integration of risk self-assessment and security assessment, so as to prevent security risks arising from outbound data transfer and ensure the orderly and free flow of data in accordance with the law.

INTERNET SERVICE AND TELECOMMUNICATION BUSINESS QUALIFICATION

The State Council promulgated Telecommunication Regulation of the PRC (2016 Revision) (《中華人民共和國電信條例(2016修訂)》) on February 6, 2016 and came into effect on the same day. Anyone engaged in telecommunications activities or activities in connection with telecommunications within the territory of the PRC shall abide by this Regulation. The competent department of information industry of the State Council is responsible for the nation-wide supervision and administration of telecommunications in accordance with this Regulation. Some of our services are value-added telecommunications services as defined in the Telecommunications Business Classification Catalogue (2015 Edition) (《電信業務分類目錄(2015年版)》). The catalogue was published by the MIIT on December 28, 2015 and was last revised on June 6, 2019.

In July 2017, the MIIT issued the Administrative Measures for the Licensing of Telecommunications Business (《電信業務經營許可管理辦法》), which took effect in September 2017 and complemented the Telecom Regulations. The Administrative Measures for the Licensing of Telecommunications Business stipulate that value-added telecommunications service operators should obtain value-added telecommunications business licenses issued by the MIIT or its authorized provincial, autonomous region, or municipal telecommunications regulatory agencies. The license for value-added telecommunications business shall be valid for a period of 5 years.

The State Council of the PRC promulgated Administrative Measures for Internet Information Services (2024 Revision) (《互聯網信息服務管理辦法(2024修訂)》) on December 6, 2024, and it went into effect on January 20, 2025. Anyone engaged in Internet information service within the territory of the PRC shall abide by this Regulation. The State establishes a licensing system for profitable Internet information service and a filing system for non-profitable Internet information service.

In addition to the above provisions, mobile Internet applications, or apps, are subject to the Mobile Internet Applications Information Services Management Regulations (《移動互聯網應用程序信息服務管理規定》) (the Application Management Regulations) under special supervision. The regulation was promulgated by the Cyberspace Administration of China on June 28, 2016, which was last amended in 2022 and came into force on August 1, 2022. The application information service provider shall obtain the relevant qualifications required by laws and regulations, strictly implement the responsibility of information security management, and fulfill the requirements stipulated in the Application Management Regulations.

COMPLIANCE ON ADVERTISEMENT

The State Administration for Industry and Commerce of the PRC and the Ministry of Health of the PRC promulgated Measures for the Administration of Medical Advertisements (《醫療廣告管理辦法》) on November 10, 2006, which came into effect on January 1, 2007. Medical institutions publishing medical advertisements shall apply for medical advertisement review before publishing. Without obtaining the Certificate of Examination of Medical Advertisements, no medical advertisement shall be published.

REGULATIONS ON INSURANCE BROKERAGE

The SCNPC of the PRC promulgated Insurance Law of the PRC (2015 Amendment) (《中華人民共和國保險法(2015修正)》) on June 30, 1995, which was last amended on April 24, 2015 and came into force on the same day. Whoever carries out insurance activities must abide by the laws and administrative regulations and defer to social ethics, and shall not damage the public interest. Insurance business shall be carried out by insurance companies formed according to this Law or other insurance organizations as prescribed by laws and administrative regulations. No other entity or individual shall carry out insurance business. The insurance, banking, securities and trust sectors shall be segregated in operations and administration, and insurance companies, securities institutions and trust institutions shall be formed separately, except as otherwise specified by the state.

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The China Insurance Regulatory Commission of the PRC promulgated Provisions on the Supervision and Administration of Insurance Brokers (《保險經紀人監管規定》) on February 1, 2018, which came into effect on May 1, 2018. To engage in insurance brokerage business within the territory of the PRC, an insurance brokerage company shall satisfy the requirements prescribed by the China Insurance Regulatory Commission (“CIRC”) and obtain an insurance brokerage business permit. The CIRC shall supervise and administer insurance brokers as authorized by the State Council in accordance with the Insurance Law.

REGULATIONS ON INTELLECTUAL PROPERTY RIGHTS

Patents

According to the Patent Law of the PRC (《中華人民共和國專利法》), or the PRC patent law, promulgated by the SCNPC of the PRC on March 12, 1984 and effected on April 1, 1985 and further amended on September 4, 1992, August 25, 2000, December 27, 2008, October 17, 2020 and came into effect on June 1, 2021 and the Implementing Rules of the Patent Law of the PRC (《中華人民共和國專利法實施細則》), promulgated by the China Patent Bureau Council on January 19, 1985, and last amended on December 11, 2023 and came into effect on January 20, 2024, the term “invention-creations” refers to inventions, utility models and designs. The duration of a patent right shall be 20 years for inventions, 10 years for utility models and 15 years for designs, all commencing from their respective application date.

Trademarks

According to the Trademark Law of the PRC (《中華人民共和國商標法》) promulgated by the SCNPC of the PRC on August 23, 1982, and amended on February 22, 1993, October 27, 2001, August 30, 2013 and April 23, 2019, respectively, the Trademark Law of the PRC has adopted a “first-to-file” principle with respect to trademark registration. Where an application for trademark for which application for registration has been made is identical or similar to another trademark which has already been registered or is under preliminary examination and approval for use on the same kind of or similar commodities or services, the application for registration of such trademark may be rejected. The period of validity for a registered trademark is ten years, commencing on the date of registration. Industrial and commercial administrative authorities have the authority to investigate any behavior that infringes the exclusive right under a registered trademark in accordance with the law.

Domain Names

Domain names are protected under the Administrative Measures on the Internet Domain Names (《互聯網域名管理辦法》), which was promulgated by the MIIT on August 24, 2017, and the Implementing Rules on Registration of National Top-level Domain Names (《國家頂級域名註冊實施細則》), which was promulgated by China Internet Network Information Center on June 18, 2019 and came into effect immediately. The MIIT is the main regulatory body responsible for the administration of PRC internet domain names.

Copyright

The Copyright Law of the PRC (《中華人民共和國著作權法》) (the “**Copyright Law**”), promulgated on September 7, 1990 and last amended on November 11, 2020 and brought into effect on June 1, 2021, specifies that works of Chinese citizens, legal persons or other organizations, namely ingenious intellectual achievements in the fields of literature, art and science that can be presented in a certain form, whether published or not, shall enjoy the copyright. The copyright holder can enjoy multiple rights, including the right of publication, the right of authorship, and the right of reproduction. On May 30, 1991, the State Council promulgated 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 “**Implementation Regulations of the Copyright Law**”), which came into effect on June 1, 1991. It was last amended by the State Council on January 30, 2013 and took effect from March 1, 2013.

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The Computer Software Copyright Registration Measures (《計算機軟件著作權登記辦法》) (the "Software Copyright Measures"), promulgated by the National Copyright Administration and brought into effect on February 20, 2002, regulates the registration of software copyright, exclusive licensing contracts for software copyright and transfer contracts.

REGULATIONS ON FOREIGN EXCHANGE AND DIVIDEND DISTRIBUTION

Foreign Exchange regulation

According to the PRC Regulation for the Foreign Exchange (《中華人民共和國外匯管理條例》) promulgated by the State Council on January 29, 1996, which was amended on January 14, 1997 and August 5, 2008, payments of current account items, such as trade and service-related foreign exchange transactions, may be made in foreign currencies without prior approval from SAFE by complying with certain procedural requirements. By contrast, approval from or registration with appropriate government authorities is required where RMB is to be converted into foreign currency and remitted out of China to pay capital expenses.

Circular of the SAFE on Issues Relating to Foreign Exchange Administration of Overseas Investments and Financing and Round-Trip Investments by Domestic Residents via Special Purpose Vehicles (《國家外匯管理局關於境內居民通過特殊目的公司境外投融資及返程投資外匯管理有關問題的通知》), or Circular 37, issued by SAFE and effective on July 4, 2014, regulates foreign exchange matters in relation to the use of special purpose vehicles, or SPVs, by PRC residents or entities to seek offshore investment and financing and conduct round trip investment in China. Under Circular 37, a SPV refers to an offshore entity established or controlled, directly or indirectly, by PRC residents or entities for the purpose of seeking offshore financing or making offshore investment, using legitimate domestic or offshore assets or interests, while "round trip investment" refers to the direct investment in China by PRC residents or entities through SPVs, namely, establishing foreign-invested enterprises to obtain the ownership, control rights and management rights. Circular 37 requires that, before making contribution into a SPV, PRC residents or entities are required to complete foreign exchange registration with SAFE or its local branch. Circular 37 further provides that holders of option or share-based awards granted by a non-listed SPV can exercise the options or share-based awards to become a shareholder of such non-listed SPV, subject to registration with SAFE or its local branch.

The SAFE promulgated the Circular on Further Simplifying and Improving Foreign Exchange Administration Policies in Respect of Direct Investment (《國家外匯管理局關於進一步簡化和改進直接投資外匯管理政策的通知》) on February 13, 2015, which was further amended on December 30, 2019 and prescribed that the bank instead of the SAFE can directly handle the foreign exchange registration and approval under foreign direct investment while the SAFE and its branches indirectly supervise the foreign exchange registration and approval under foreign direct investment through the bank.

REGULATIONS ON LABOR

Labor Law and Labor Contract Law

According to the PRC Labor Law (《中華人民共和國勞動法》), which was promulgated by the SCNPC of the PRC on July 5, 1994 and amended on August 27, 2009 and December 29, 2018, respectively, the PRC Labor Contract Law (《中華人民共和國勞動合同法》), which was promulgated by the SCNPC of the PRC on June 29, 2007 and amended on December 28, 2012 and came into effect on July 1, 2013, and the Implementing Regulations of the Employment Contracts Law of the PRC (《中華人民共和國勞動合同法實施條例》), which was promulgated by the State Council in September 18, 2008, labor contracts in written form shall be executed to establish labor relationships between employers and employees. In addition, wages of employees cannot be lower than the local minimum wage. The employers must establish a system for labor safety and sanitation, strictly abide by State rules and standards, provide education regarding labor safety and sanitation to their employees, provide

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employees with labor safety and sanitation conditions and necessary protection materials in compliance with State rules, and carry out regular health examinations for employees engaged in work involving occupational hazards.

Social Insurance and Housing Provident Funds

According to the Social Insurance 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 Collection and Payment of Social Insurance Premiums (《社會保險費徵繳暫行條例》) recently amended by the State Council and effective 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 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 Administrative Regulations on Housing Provident Funds (《住房公積金管理條例》), which was promulgated on April 3, 1999 and last amended on March 24, 2019, employers are required to make contributions to housing provident funds for their employees. Any entity fails to make payment of housing provident fund within the time limit or has shortfall in payment of housing provident fund will be ordered to make the payment or makeup the shortfall within the prescribed time limit, otherwise, the housing provident management center is entitled to apply for compulsory enforcement with the People’s Court.

On July 31, 2025, the Supreme People’s Court promulgated the Supreme People’s Court’s Interpretation (II) on Several Issues Concerning the Application of Law in Labour 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)》) (the “**New Judicial Interpretation**”), which stipulated, among others, that any agreement between an employer and an employee or any commitment made by an employee to the employer stating that social insurance premiums need not be paid shall be deemed invalid.

Our PRC Legal Advisor is of the view that the New Judicial Interpretation will not have a material adverse effect on our business, financial condition or results of operations, based on the following considerations: (i) upon its implementation, the New Judicial Interpretation did not affect the compliance status of our contributions to social insurance; (ii) during the Track Record Period and up to the Latest Practicable Date, we have not entered into any agreement with our employees, nor required our employees to make commitments to exempt us from paying social insurance contributions.

REGULATIONS ON PRODUCT LIABILITY

In addition to the strict drug approval process, certain PRC laws have been promulgated to protect the rights of consumers and to strengthen the control of medical products in the PRC. Under current PRC law, manufacturers and vendors of defective products in the PRC may incur liability jointly for loss and injury caused by such products. According to the Civil Code of the PRC, a defective product which causes property damage or physical injury to any person may subject the manufacturer or vendor of such product to civil liability for such damage or injury. If a patient suffers damage due to defects in drugs, he may seek compensation from the drug marketing authorization holder or also from the medical institution. Where the patient seeks compensation from the medical institution, the medical institution, after it has made the compensation, shall have the right to recover the compensation from the liable drug marketing authorization holder.

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In February 1993, the Product Quality Law of the PRC (《中華人民共和國產品品質法》), or the Product Quality Law, was promulgated aiming to protect the legitimate rights and interests of the end-users and consumers and to strengthen the supervision and control of the quality of products. The Product Quality Law was latest revised in December 2018. According to the revised Product Quality Law, manufacturers who produce defective products may be subject to civil or criminal liability and have their business licenses revoked.

REGULATIONS ON ANTI-UNFAIR COMPETITION

Since the early 1990s, the legislative authorities at different levels in China have promulgated certain laws and regulations in respect of commercial bribery. According to the PRC Anti-Unfair Competition Law, or the Anti-Unfair Competition Law (《中華人民共和國反不正當競爭法》), which was most recently amended on June 27, 2025, operators shall abide by the principle of voluntariness, equality, impartiality, integrity, and adhere to laws and business ethics during market transactions. Operators in violation of the Anti-unfair Competition Law shall bear corresponding civil, administrative or criminal liabilities depending on the specific circumstances.

Pursuant to the Regulations on the Establishment of Adverse Records with Respect to Commercial Briberies in the Medicine Purchase and Sales Industry (《關於建立醫藥購銷領域商業賄賂不良記錄的規定》) (2013 revision) enforced on March 1, 2014 by the NHFPC, the enterprises manufacturing and operating drugs, medical equipment and medical supplies, and the agencies as well as individuals thereof, which bribe the employee(s) of the medical and health institutions procuring and using their drugs, medical equipment or medical supplies with property or other benefits, shall be included into the Adverse Records of Commercial Bribery if they satisfy any of the circumstances as described the above-mentioned regulation. If medical production and operation enterprises be listed into the Adverse Records of Commercial Bribery more than once in five years, their products shall not be purchased by all public medical institutions and medical and health institutions receiving financial subsidies nationwide for two years since publication of the record.

REGULATIONS ON TAXATION

Enterprise Income Tax

According to the Enterprise Income Tax Law (《中華人民共和國企業所得稅法》) promulgated by the NPC on March 16, 2007 and amended by the SCNPC of the PRC in February 24, 2017 and December 29, 2018, and the Implementation Rules of the Enterprise Income Tax Law of the PRC (《中華人民共和國企業所得稅法實施條例》) promulgated by the State Council on December 6, 2007 and last amended in December 6, 2024, other than a few exceptions, the income tax rate for both domestic enterprises and foreign-invested enterprises is 25%. Enterprises are classified as either “resident enterprises” or “non-resident enterprises.” Besides enterprises established within the PRC, enterprises established outside China whose “de facto management bodies” are located in China are considered “resident enterprises” and subject to the uniform 25% enterprise income tax rate for their global income. A non-resident enterprise refers to an entity established under foreign law whose “de facto management bodies” are not within the PRC but have an establishment or place of business in the PRC, or who do not have an establishment or place of business in the PRC but have income sourced within the PRC. An income tax rate of 20% will normally be applicable to dividends declared to non-PRC resident enterprise investors that do not have an establishment or place of business in the PRC, or that have such establishment or place of business, but the relevant income is not effectively connected with the establishment or place of business, to the extent such dividends are derived from sources within the PRC.

REGULATORY OVERVIEW

Value Added Tax

The SCNPC promulgated PRC Value-added Tax Law (《中華人民共和國增值稅法》) on December 25, 2024, which came into effect on January 1, 2026. The State Council promulgated Implementation Regulations of the Value-Added Tax Law of the PRC (《中華人民共和國增值稅法實施條例》) on December 25, 2025, which came into effect on January 1, 2026. According to the PRC Value-added Tax Law and Implementation Regulations of the Value-Added Tax Law of the PRC, the VAT rate for general VAT taxpayers engaging in sale of goods, services, lease of tangible and movable goods or importation of goods was adjusted to 13% and 6%, the VAT rate for general VAT taxpayers engaging in, among others, the sale of transportation services, postal services, basic telecommunications services, construction services, the lease and sale of real properties, and the transfer of land use rights was adjusted to 9%. From January 1, 2026, the Interim Regulations of the PRC on Value-added Tax (《中華人民共和國增值稅暫行條例》) has been repealed.

REGULATIONS ON SECURITIES OFFERING AND LISTING OUTSIDE OF THE PRC

On February 17, 2023, the CSRC issued the Trial Administrative Measures of the Overseas Securities Offering and Listing by Domestic Companies (《境內企業境外發行證券和上市管理試行辦法》) (the “**Overseas Listing Trial Measures**”), which came into force on March 31, 2023. The Trial Measures regulates overseas securities offering and listing activities by domestic companies in direct or indirect form. The Trial Measures provides that (i) Chinese companies that seek to offer and list securities in overseas markets shall fulfill the filing procedures with the CSRC and report relevant information to the CSRC, and the filing shall be submitted within three working days after the application for an initial public offering is submitted, and (ii) in the event that Chinese companies that have directly or indirectly listed securities in overseas markets intend to conduct follow-on offerings in overseas markets, such companies shall fulfill the filing procedures with and report relevant information to the CSRC, and such filing shall be submitted within three working days after such follow-on offering is completed. Moreover, an overseas offering and listing is prohibited if (i) it is prohibited by PRC laws, (ii) it may endanger national security as reviewed and determined by competent PRC authorities under the State Council in accordance with law, (iii) in recent three years, the Chinese operating entities or their controlling shareholders or actual controllers have committed relevant prescribed criminal offenses, (iv) domestic companies that are suspected of committing crimes or major violations of laws and regulations are under investigation according to law, and no conclusion has yet been made thereof, or (v) there are material ownership disputes over equity held by the controlling shareholders or by other shareholders that are controlled by the controlling shareholders or actual controllers.

On February 24, 2023, the CSRC jointly with other authorities, promulgated the Provisions on Strengthening Confidentiality and File Management Related to Overseas Issuance and Listing of Securities by Domestic Enterprises or the Confidentiality Provisions (《關於加強境內企業境外發行證券和上市相關保密和檔案管理工作的規定》), which came into effect on March 31, 2023. Pursuant to the Confidentiality Provisions, domestic joint stock companies that directly issue shares to be listed overseas and domestic operating organizations of enterprises listed overseas through indirect share issuance shall submit for approval and comply with other regulations, before filing prior to publicly disclosing or providing to securities companies, securities service providers, overseas regulatory bodies and other entities and individuals any documents or information that involves state secrets, the working secrets of state organs, or documents and information that, if divulged, would jeopardize national security or public interests.