REGULATORY OVERVIEW

REGULATIONS RELATING TO CORPORATION

The establishment, operation and management of corporate entities in the PRC are governed by *the PRC Company Law* (《中華人民共和國公司法》) (the "**Company Law**"), which was promulgated by the Standing Committee of the National People's Congress (the "**SCNPC**") in December 1993 and further amended in December 1999, August 2004, October 2005, December 2013, October 2018 and December 2023, respectively. According to the Company Law, companies are generally classified into two categories: limited liability companies and companies limited by shares. The Company Law also applies to foreign-invested limited liability companies and companies limited by shares.

A "joint stock limited company" refers to an enterprise legal person incorporated in China under the Company Law with independent legal person properties and entitlements to such legal person properties and with its registered capital divided into shares. The liability of the company for its own debts is limited to all the properties it owns and the liability of its shareholders for the company is limited to the extent of the shares they subscribe for.

REGULATIONS RELATING TO PHARMACEUTICAL PRODUCT DEVELOPMENT, APPROVAL AND REGISTRATION

Drug Regulatory Regime

The Drug Administration Law of the PRC (《中華人民共和國藥品管理法》) (the "**Drug Administration Law**") was promulgated by the SCNPC in September 1984. The latest amendment to the Drug Administration Law was promulgated in August 2019 and took effect in December 2019. *The Regulations for the Implementation of the Drug Administration Law of the PRC* (《中華人民共和國藥品管理法實施條例》) (the "**Regulations for the Implementation of the Drug Administration Law**") was promulgated by the State Council in August 2002, and was last amended in January 2026 and will take effect in May 2026.

The Drug Administration Law and the Regulations for the Implementation of the Drug Administration Law have laid down the current legal framework for drug development, production, distribution, use, supervision and management within the territory of China. The Drug Administration Law also regulates the packaging, pricing and advertisements of pharmaceutical products in the PRC.

Drug Registration

The Administrative Measures for Drug Registration (《藥品註冊管理辦法》) (the "**Registration Measures**") were promulgated by the State Administration for Market Regulation ("**SAMR**") in January 2020 and took effect in July 2020, which replaced the previous Registration Measures promulgated by the State Food and Drug Administration ("**SFDA**") in July 2007. Pursuant to the Registration Measures, drug marketing registration applications shall be subject to three categories, namely traditional Chinese drugs, chemical drugs and biological products. Among them, the registration applications of biological products shall be categorized by innovative biological products, new modified biological products, already marketed biological products (including biological similar drugs), etc. If all the regulatory requirements are satisfied, a Drug Registration Certificate with a validity period of five years will be issued by the National Medical Products Administration ("**NMPA**"). After obtaining the Drug Registration Certificate, the applicant shall be the marketing authorization holder (the "**MAH**"). The MAH shall continually ensure the safety, efficacy and quality controllability of the drug marketed and shall apply for drug re-registration six months prior to the expiry date of the Drug Registration Certificate.

Clinical Trial

Pursuant to *the Measures for the Administration of Drug Registration* (《藥品註冊管理辦法》), drug clinical trials shall be conducted before a drug is listed for registration. If an applicant submits an application for drug clinical trials after completing the pharmacology, pharmacology toxicology and other studies supporting the drug clinical trial, it shall submit relevant research information in accordance with the requirements of the declaration information.

The relevant authorities should reach a decision on whether to approve the application for drug clinical trials within sixty days from the date of acceptance, and notify the applicant of the approval results through the CDE website. If the notification is not provided within this timeframe, it is deemed that the applicant is permitted to proceed with the drug clinical trials in accordance with the program. Pursuant to *the Administrative Provisions on Drug Clinical Trial Institutions* (《藥物臨床試驗機構管理規定》), promulgated by the NMPA and National Health Commission ("**NHC**") on November 29, 2019 and effective since December 1, 2019, the commencement of clinical trials of drugs should be carried out in drug clinical trial institutions; drug clinical trial institutions should comply with the conditions stipulated in the "Administrative Provisions on Drug Clinical Trial Institutions" and be filed in the State Drug Supervision and Administration Department.

When conducting a clinical trial, all parties involved must comply with *the procedural requirements of the Good Practice for Clinical Trials of Drugs* (《藥物臨床試驗質量管理規範》), which stipulates the requirements for the procedures of conducting clinical trials, including preclinical trial preparations, trial protocols, protection of the rights and interests of the subjects, the duties of the investigators, sponsors and supervisors, as well as the management of data and statistical analyses.

The CDE issued the Regulations for *the Assessment and Management of Safety Information During Drug Clinical Trials (Trial)* (《藥物臨床試驗期間安全信息評估與管理規範(試行)》) and *the Management Regulations for Development Safety Update Reports During Research and Development (Trial)* (《研發期間安全性更新報告管理規範(試行)》) on July 1, 2020. After obtaining approval for clinical trials, applicants must submit rapid reports on suspected and unexpected serious adverse reactions (SUSAR) and other potential serious safety risk information during the clinical trial period, as well as DSURs. The CDE issued *the Technical Guideline for Pharmaceutical Research and Change Management During Clinical Trials (Trial)* (《臨床試驗期間生物製品藥學研究和變更技術指導原則(試行)》) on June 14, 2024, which clarified the requirements for pharmaceutical changes and updates during clinical trials to ensure the safety and efficacy of biologics.

REGULATIONS RELATING TO DRUG MANUFACTURER

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

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

Drug manufacturing activities must comply with the GMP Rules, and establish a sound Good Manufacturing Practice ("**GMP**") management system, to ensure that the entire process of drug manufacturing maintains to meet the statutory requirements, and meet the GMP requirements enacted by the drug regulatory authority under the State Council in accordance with the law.

REGULATIONS RELATING TO DRUG SUPPLY

According to the Drug Administration Law, the operation of drug business, including drug wholesale and drug retail, is prohibited without a Drug Supply Permit. A Drug Supply Permit shall state the validity period and the scope of business and be subject to review and reissuance upon expiry of the validity period.

According to *the Measures for the Supervision and Administration of Drug Supply and Usage* (《藥品經營和使用質量監督管理辦法》) that took into effect on January 1, 2024, a Drug Supply Permit is valid for five years. Each holder of the Drug Supply Permit must apply for an extension of its permit six months to two months prior to expiration.

The Good Supply Practice for Pharmaceutical Products (《藥品經營質量管理規範》) (the "**GSP Rules**") was last amended and came into effect on July 13, 2016. The GSP Rules set forth the basic standards in management of drug supply and apply to enterprises engaged in drug supply in the PRC, which require drug suppliers to implement strict controls on its supply of pharmaceutical products, including standards regarding staff qualifications, premises, warehouses, inspection equipment and facilities, management and quality control. Under the Drug Administration Law, the GSP certification is no longer required for drug suppliers, but drug suppliers are still required to comply with the GSP Rules.

REGULATIONS RELATING TO MEDICAL INDUSTRY

Pharmaceutical Representatives

The Measures for the Administration of Pharmaceutical Representatives (《醫藥代表管理辦法》), formulated and issued jointly by the NHC, the NHSA and other competent authorities, shall come into full effect on August 1, 2026. It defines medical representatives, specify their eligibility and filing requirements, and regulate industry conduct. It imposes primary and overall accountability on marketing authorization holders via mandatory filing and stringent rules, requiring them to fully oversee the recruitment, authorization, registration and ongoing management of pharmaceutical representatives.

Basic Medical Insurance Policy

Pursuant to *the Decision on the Establishment of the Urban Employee Basic Medical Insurance Program* (《關於建立城鎮職工基本醫療保險制度的決定》) promulgated by the State Council on December 14, 1998 and *the Tentative Measures for the Administration of the Scope of Medical Insurance Coverage for Pharmaceutical Products for Urban Employee* (《城鎮職工基本醫療保險用藥範圍管理暫行辦法》) promulgated by the National Development and Reform Commission ("**NDRC**"), the SFDA and other authorities, came into effect on May 12, 1999, all employers in cities and towns, including enterprises (state-owned enterprises, collective enterprises, foreign-invested enterprises, private enterprises, etc.), institutions, public institutions, social organizations, private non-enterprise units and their employees are required to participate in basic medical insurance. Pursuant to *the Guiding Opinions on the Pilot of Basic Medical Insurance for Urban Residents* (《關於開展城鎮居民基本醫療保險試點的指導意見》) promulgated by the State Council on July 10, 2007, urban residents (not urban employees) in the pilot areas can voluntarily participate in the basic medical insurance for urban residents. Pursuant to *the Opinions of the State Council on the Integration of the Basic Medical Insurance System for Urban and Rural Residents* (《國務院關於整合城鄉居民基本醫療保險制度的意見》) promulgated by the State Council on January 3, 2016, a unified basic medical insurance system for urban and rural residents was established, including the existing urban residents' medical insurance and all the insured personnel of New Rural Cooperative Medical System, covering all urban and rural residents except those who should be covered by the employee's basic medical insurance.

Medical Insurance Catalog

Pursuant to *the Tentative Measures for the Administration of the Scope of Medical Insurance Coverage for Pharmaceutical Products for Urban Employee* (《城鎮職工基本醫療保險用藥範圍管理暫行辦法》), the scope of medical insurance coverage for pharmaceutical products needs to be managed through the formulation of the Medical Insurance Catalog. A pharmaceutical product listed in the Medical Insurance Catalog must be clinically needed, safe, effective, reasonably priced, easy to use, available in sufficient quantity, and must meet the following requirements: it is set forth in *the Pharmacopoeia of the PRC (current edition)* (《中華人民共和國藥典》(現行版)); it meets the standards promulgated by the NMPA; and if imported, it is approved by the NMPA for import. According to *the Opinions of the National Healthcare Security Administration* ("**NHSA**") and the Ministry of Finance on Establishing a List-Based System for Healthcare Security Benefits (《國家醫保局、財政部關於建立醫療保障待遇清單制度的意見》), which came into effect in January 2021, all provinces shall implement the National Reimbursement Drug List in a strict manner, and shall not have the discretion to formulate the catalog or increase the drugs in any form, or adjust the scope of limited payment unless explicitly stipulated. After several adjustments, the currently effective one is *the National Insurance Drug List for Basic Medical Insurance, Work-related Injury Insurance and Maternity Insurance (2024)* (《國家基本醫療保險、工傷保險和生育保險藥品目錄(2024年)》) came into effect since January 6, 2025.

Centralized Procurement Program

The procurement process should be based on the number of pharmaceutical enterprises selected: if three or more pharmaceutical enterprises are selected, the procurement should be conducted through an open tender process; if two enterprises are selected, the procurement should be conducted through a bargaining process; and if only one enterprise is selected, the terms of the procurement should be determined through negotiation.

The NHSA, the NHC, the NMPA, the Ministry of Industry and Information Technology ("**MIIT**") and Logistic Support Department of the Central Military Commission jointly issued *the Circular on Conducting the Second Batch of Centralized Procurement and Use of Drugs Organized by the State* (《關於開展第二批國家組織藥品集中採購和使用工作的通知》) (the "**Circular**"), which became effective on January 13, 2020, and stipulated a number of principles for the implementation of the centralized procurement of drugs by the State in order to comprehensively deepen the reforms and to establish a standardized and regularized centralized purchasing program of drugs nationwide. *The Joint Procurement Office issued the Documents on National Centralized Drug Procurement (GY-YD2020-1)* (《全國藥品集中採購文件(GY-YD2020-1)》) on July 29, 2020 to launch a new batch of centralized procurement of drugs that meet the conditions for centralized procurement.

REGULATIONS RELATING TO INTELLECTUAL PROPERTY

Trademark

According to *the Trademark Law of the PRC* (《中華人民共和國商標法》) (the "**Trademark Law**"), which was promulgated by the SCNPC on August 23, 1982, latest amended on April 23, 2019 and effective on November 1, 2019, the validity period of a registered trademark is 10 years from the date of registration, and can be renewed for additional 10-year periods upon application. In addition, the Trademark Law follows the "first-to-file" principle for trademark registration. The registrant of a trademark enjoys the exclusive right to use the trademark. Any dispute arising from acts infringing upon the exclusive right to use a registered trademark as listed in Article 57 of the Trademark Law shall be resolved through consultation between the relevant parties. If the relevant parties refuse to consult or the consultation fails, the trademark registrant or any interested party may bring a lawsuit to the people's court or request the relevant administrative department for industry and commerce to handle the dispute. In April 2014, the State Council issued the revised *Implementing Regulations of the PRC Trademark Law* (《中華人民共和國商標法實施條例》), which specified the requirements of applying for trademark registration and review.

Patent

According to the *Patent Law of the PRC* (《中華人民共和國專利法》), which was promulgated by the SCNPC in 1984, last revised on October 17, 2020 (taking effect on June 1, 2021), this law provides for three types of patents: "invention", "utility model" and "design", with a patentable invention or utility model required to meet the criteria of novelty, inventiveness and practicability. The Patent Office under the State Intellectual Property Office is responsible for receiving, examining and approving patent applications; patent validity periods start from the application date: twenty years for inventions, ten years for utility models, and fifteen years for designs. Except for specific legal circumstances, no entity or person may implement a granted invention or utility model patent (including manufacturing, using, offering to sell, selling or importing patented products for business purposes, or using the patented method/related products) without the patent owner's approval, as such unauthorized implementation constitutes patent right infringement. Disputes over such infringement shall first be resolved through negotiation between relevant parties; if negotiation fails or is refused, the patent owner or stakeholders may file a lawsuit in the people's court or request patent administration authorities to handle the matter.

REGULATIONS RELATING TO PRODUCT QUALITY

China's regulatory framework for product quality is centered on *the Product Quality Law of the PRC* (《中華人民共和國產品質量法》) (the "**Product Quality Law**"), which was originally promulgated by the SCNPC on February 22, 1993, and last amended on December 29, 2018. The market supervision and administration department under the State Council is responsible for nationwide supervision of product quality. Under this law, producers bear primary responsibility for the quality of their products and are prohibited from manufacturing or selling products that fail to meet national or industry standards for protecting human health and ensuring personal and property safety; products must be free from unreasonable risks that threaten personal or property safety. Sellers, in turn, are obligated to adopt measures to maintain the quality of products in the course of circulation to prevent quality deterioration. If a defective product causes personal injury or property damage, the aggrieved party has the right to claim compensation directly from either the producer or the seller. Where a seller makes compensation but the liability is ultimately attributable to the producer, the seller is entitled to recourse against the producer; conversely, if a producer makes compensation but the liability lies with the seller, the producer may also seek recourse from the seller. This clear liability allocation and recourse mechanism ensures efficient compensation for victims while clarifying the ultimate responsibility between producers and sellers. For non-compliant producers and sellers, regulatory authorities may impose administrative penalties including orders to cease production or sales, confiscation of non-compliant products, fines, and seizure of illegal sales proceeds; in severe cases, the business license of the offending party may be revoked to deter violations effectively.

In addition, the Civil Code, adopted by the National People's Congress on May 28, 2020 and effective as of January 1, 2021, further clarifies product defect liability at the civil fundamental law level. Under the Civil Code, producers or commercial sellers shall be liable for personal injury or property damage caused by defective products, and the infringed party may choose to claim compensation from either the producer or the commercial seller. If the infringed party claims compensation from the commercial seller, the seller shall have the right to recourse against the liable producer after making payment. This provision aligns with the recourse rules under the Product Quality Law, together forming a comprehensive legal system governing product quality liability in China.

REGULATIONS RELATING TO ENVIRONMENTAL PROTECTION

Environmental Protection

The Environmental Protection Law of the PRC (《中華人民共和國環境保護法》) was promulgated and effective on 26 December 1989, and most recently amended on 24 April 2014. *The Environmental Protection Law* has been formulated for the purpose of protecting and improving both the living and

the ecological environment, preventing and controlling pollution and other public hazards and safeguarding people's health. According to the provisions of *the Environmental Protection Law*, in addition to other relevant laws and regulations of the PRC, the Ministry of Environmental Protection and its local counterparts are responsible for administering and supervising environmental protection matters. Pursuant to *the Environmental Protection Law*, construction projects that have environmental impact shall be subject to environmental impact assessment.

Environment Impact Assessment

On 28 October 2002, the SCNPC promulgated *the Environmental Impact Assessment Law of PRC* (《中華人民共和國環境影響評價法》), which was latest amended on 29 December 2018. According to *the Environmental Impact Assessment Law*, the State Council implemented the environmental impact assessment to classify construction projects according to the impact of the construction projects on the environment. Pursuant to *the Interim Measures for Environmental Protection Acceptance of Completed Construction Projects* (《建設項目竣工環境保護驗收暫行辦法》) effective as of 20 November, 2017 and the Regulations on *the Administration Construction Project Environmental Protection* (《建設項目環境保護管理條例》), which was revised on 16 July 2017 and implemented on October 1, 2017, after the completion of a construction project for which an environmental impact report or an environmental impact report form is required, the construction entity shall, according to standards and procedures prescribed by the environmental protection administrative authorities, conduct environmental protection completion acceptance check and compile an acceptance check report. A construction project for which an environmental impact report or an environmental impact report form is required shall not be put into production or use until the environmental protection completion acceptance check has been passed. On 30 November 2020, Ministry of Ecology and Environment of the PRC promulgated *the Classified Administration Catalogue of Environmental Impact Assessments for Construction Project (2021 version)* (《建設項目環境影響評價分類管理名錄(2021年版)》), which became effective on 1 January 2021. According to *the Environmental Impact Assessment Law*, where a construction entity commenced construction prior to submission of the environmental impact report and environmental impact statement of the construction project or prior to resubmission of the environmental impact report and environmental impact statement, the ecological environment authorities at the county level or above shall order it to stop the construction, impose a fine of not less than 1% but not more than 5% of the overall investment amount for such construction project according to the seriousness and consequences of such violations, and order it to restore to the original status; and the person-in-charge and responsible personnel of the construction project shall be liable to administrative sanctions in accordance with laws.

Pollutant Discharges Permitting Administration

Pursuant to the provisions of *the Regulation on the Administration of Permitting of Pollutant Discharges* (《排污許可管理條例》) promulgated on 24 January 2021, and *the Measures for Pollutant Discharge Permitting Administration* (《排污許可管理辦法》) promulgated on April 1, 2024 and became effective on July1, 2024, the PRC implements the classified pollutant discharge permit management (i.e., key management, simplified management and registration management) on pollutant discharges of enterprises based on factors such as the volume of pollutants generated, the amount of pollutant discharged and the degree of impact on the environment. Enterprises and other producers that are included in *the Classification Administration List of Pollutant Discharge Permits for Fixed Pollution Sources* (《固定污染源排污許可分類管理名錄》) shall apply for and obtain a pollutant discharge permit or fill in a pollutant discharge registration form within the prescribed time limit, and shall not discharge pollutants without a pollutant discharge permit or filling in a pollutant discharge registration form. For any violation of the Regulation on the Administration of Permitting of Pollutant Discharges and the Measures for Pollutant Discharge Permitting Administration, in accordance with *the Environmental Protection Law of the PRC*, *the Atmospheric Pollution Prevention and Control Law of the PRC*, *the Water Pollution Prevention and Control Law of the PRC* and other laws and regulations, the environmental protection authorities have the right to order to make corrections, restrict production, suspend production for

rectification, and suspend business and close down, and impose a fine. If a violation of the public security provisions is constituted, it shall be punished for public security violation in accordance with the law. If a crime is constituted, it shall be investigated for criminal liabilities in accordance with the law.

REGULATIONS RELATING TO LABOR

Employment

The Labor Law of the PRC (《中華人民共和國勞動法》) (promulgated on July 5, 1994, last amended on December 29, 2018) imposes multiple obligations: for workplace safety and sanitation, enterprises must establish and improve relevant systems, adhere to state rules and standards, conduct employee training on these matters, ensure facilities meet statutory standards, and (along with institutions) provide employees with safe conditions compliant with labor protection laws and regulations; additionally, under the Labor Law (as revised in 2018) and *the Labor Contract Law of the PRC* (《中華人民共和國勞動合同法》) (promulgated June 29, 2007, revised December 28, 2012), employers and employees must conclude a written labor contract (which may be fixed-term, open-ended, or task-based) to establish their relationship, with wages no lower than the local minimum and paid timely, and both parties required to fully fulfill their contractual obligations.

Social Securities

Under Chinese laws and regulations (including the *Social Insurance Law of the PRC* (《中華人民共和國社會保險法》) — promulgated October 28, 2010, last revised December 29, 2018 — the *Interim Regulations on the Collection and Payment of Social Insurance Premiums* (《社會保險費徵繳暫行條例》) — promulgated January 22, 1999, amended March 24, 2019 — and the *Regulations on Work-related Injury Insurance* (《工傷保險條例》) — promulgated April 27, 2003), PRC employers (including enterprises and institutions) are required to participate in employee welfare programs: specifically, contributing to social insurance funds (covering basic old-age, medical, unemployment, work-related injury, and maternity insurance) and the housing provident fund on behalf of employees. Contributions are calculated as a percentage of employees' salaries (including bonuses and allowances), with rates set by the local government where the employer operates or is based.

Additionally, employers must complete social insurance registration with the local social insurance agency within 30 days of their own establishment, and within 30 days of an employee's hiring. Violations of these rules trigger penalties: non-compliant employers are ordered to correct issues within a specified timeframe, with fines imposed on the employer and its responsible personnel if corrections are not made; failure to pay premiums in full and on time results in a demand for full payment plus a daily late surcharge of 0.05%, and if payment remains overdue, a fine of 1–3 times the overdue amount may be levied.

Housing Fund

The *Regulations on the Administration of Housing Provident Fund* (《住房公積金管理條例》) (promulgated and effective April 3, 1999, last amended March 24, 2019 by the State Council) mandates that employers register with the competent housing provident fund managing center; upon the center's approval, enterprises must open a bank account to deposit employees' housing provident funds, and are required to contribute these funds on employees' behalf fully and timely, with a contribution ratio of no less than 5% of each employee's previous year's average monthly salary.

Violations of these rules incur penalties: employers who fail to register for contributions or open accounts are ordered to complete these procedures within a prescribed timeframe, with a fine of RMB10,000 to RMB50,000 if they fail to comply; those who make overdue or insufficient contributions are ordered to rectify the issue within a set period, and if they still fail to do so, the managing center may apply to a people's court for compulsory enforcement.

REGULATIONS RELATING TO DATA SECURITY

Enacted by the SCNPC on June 10, 2021 and taking effect on September 1 of the same year, *the Data Security Law of the PRC* (《中華人民共和國數據安全法》) (the "**Data Security Law**") outlines key provisions for data-related activities: it imposes data security and privacy obligations on entities and individuals engaged in such activities, establishes a data classification and hierarchical protection system (where data is categorized by its significance to economic/public development and the potential harm to national security, social interests, or individual/organizational rights if compromised, with corresponding protection measures required for each category — for example, important data handlers must assign dedicated personnel and a management body for data security, conduct risk assessments of their processing activities, and submit assessment reports to competent authorities), and additionally sets out a national security review procedure for data processing activities affecting or potentially affecting national security, while imposing restrictions on the export of certain data.

On September 24, 2024, *the Regulations on Network Data Security Management* (《網絡數據安全管理條例》) was issued by the State Council, which took effect on January 1, 2025. According to the Regulations on Network Data Security Management, network data handlers shall, in accordance with the provisions of laws and administrative regulations and the mandatory requirements of national standards, and on the basis of classified protection of cyber security, strengthen the protection of network data security, establish and perfect the system of network data security management, take technical measures to protect network data, and prevent illegal and criminal activities aiming at and using network data.

REGULATIONS RELATING TO PERSONAL INFORMATION SECURITY

The Civil Code stipulates that the personal information of a natural person shall be protected by the law. Any organization and individual shall legally obtain the personal information of others when necessary and ensure the safety of such personal information, and shall not illegally collect, use, process or transmit the personal information of others, or illegally buy or sell, provide or make public the personal information of others. The processing of personal information shall be subject to the principle of legitimacy, rightfulness and necessity.

In the *Personal Information Protection Law of the PRC* (《中華人民共和國個人信息保護法》) (the "**Personal Information Protection Law**"), enacted by the SCNPC on August 20, 2021, and entering into force on November 1, 2021, "personal information" is defined as any data (recorded electronically or through other means) associated with identified or identifiable natural persons — with the exception of information that has been fully anonymized.

This legislation establishes a comprehensive regulatory framework for personal information protection. A core mandate of this framework is that prior consent from the individual must be obtained for any processing of personal information, unless the law explicitly specifies alternative permissible circumstances. For processing activities involving sensitive personal information, additional constraints apply: such activities are only authorized if they are limited to specific, clearly defined purposes, deemed strictly necessary, and subject to enhanced protective safeguards. Cross-border transfers of personal information are further restricted, permissible only if the requirements outlined in the Personal Information Protection Law are met. These requirements include completion of a security review overseen by the national cyberspace authority, as well as compliance with other conditions prescribed by relevant laws, regulations, and directives from the national cyberspace authority.

The Regulations on the Administration of Network Data Security also sets forth requirements for the processing of network-based data, encompassing (but not limited to) the development of rules for personal information processing, overarching standards for such processing, and procedures for addressing individuals' requests regarding their personal information; notably, network data processors that handle the personal information of 10 million or more individuals must additionally adhere to the provisions outlined in Articles 30 and 32 of the Regulations. For network

data processors engaged in the handling of important data, the Regulations mandate the designation of a dedicated data security officer and the establishment of a formal network data security management structure — entities tasked with overseeing the protection of network data security. Finally, in the event of organizational changes (such as mergers, divisions, dissolution, or bankruptcy) or other circumstances that could compromise data security, network data processors are required to implement safeguards to preserve network data security and notify the relevant competent regulatory authorities of such developments.

REGULATIONS RELATING TO BRIBERY AND CORRUPTION

In accordance with *the Anti-Unfair Competition Law of the PRC* (《中華人民共和國反不正當競爭法》) and *the Interim Regulations of the State Administration for Industry and Commerce on Prohibition of Commercial Bribery* (《關於禁止商業賄賂行為的暫行規定》), the business operator shall not provide or promise to provide economic benefits (including cash, other property or by other means) to a counter-party in a transaction or a third party that may be able to influence the transaction, in order to entice such party to secure a transactional opportunity or competitive advantages for the business operator. Any business operator breaching the relevant anti-bribery rules above mentioned may be subject to administrative punishment or criminal liability depending on the seriousness of the cases.

In accordance with *the Notice on Promulgation of the Key Points for the Work of Correcting Malpractice in the Medicine Purchase and Sales Field and Medical Services in 2023* (《關於印發2023年糾正醫藥購銷領域和醫療服務中不正之風工作要點的通知》), it demands(i) rectifying the problems of malpractice in industrial organizations, especially the disguised apportionment in the name of donation, academic activities, holding or participation in conferences, etc., providing platforms for illegal tunneling, and illegal receipt of donations and funding; (ii) rectifying the malpractice in the purchase and sales of medical products, especially giving rebates to the practitioners of medical institutions, and tunneling to relevant institutions in the guise of various forms.

REGULATIONS RELATING TO TAXATION

Enterprise Tax

According to *the Enterprise Income Tax Law of the PRC* (《中華人民共和國企業所得稅法》) (the "**EIT Law**"), originally promulgated by the SCNPC on March 16, 2007 and most recently amended and effective 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稅法實施條例》) (the "**Implementation Regulations**"), issued by the State Council on December 6, 2007, with amendments effective on April 23, 2019 and the latest revision promulgated on December 6, 2024 (effective January 20, 2025), enterprises are categorized as resident enterprises and non-resident enterprises. A resident enterprise refers to an enterprise established within the PRC in accordance with PRC laws, or an enterprise established under the laws of a foreign country (region) but with its actual management institution located in the PRC. Such enterprises are subject to a uniform enterprise income tax ("**EIT**") rate of 25% on their worldwide income, whether generated inside or outside the PRC. Non-resident enterprises are those established under the laws of a foreign country (region) with their actual management institution not in the PRC, but which have set up establishments or premises in the PRC, or those which have no establishments or premises in the PRC but derive income from sources within the PRC. The PRC government provides preferential EIT treatment to key industries and projects that are supported and encouraged by the state: qualifying small and low-profit enterprises are eligible for a reduced EIT rate of 20%, while high and new technology enterprises in need of key state support may enjoy a preferential EIT rate of 15%.

The Notice on the Issues Concerning Withholding the Enterprise Income Tax on Dividends Paid by Chinese Resident Enterprises to H-Share Holders Which Are Overseas Non-resident Enterprises (Guo Shui Han [2008] No. 897) (《關於中國居民企業向境外H股非居民企業股東派發股息代扣代繳企業所得稅有關問題的通知》(國稅函 [2008] 897號)), which was issued and implemented by the SAT on November 6, 2008, further clarifies that a PRC-resident enterprise must withhold enterprise income tax at a rate of 10% on the dividends that it distributes to overseas non-resident enterprise shareholders of H Shares.

Value-added Tax

According to the *Rules for the Implementation of the Provisional Regulations on Value-Added Tax of the PRC* (《中華人民共和國增值稅暫行條例實施細則》) (the "**Implementation Rules**"), issued by the Ministry of Finance ("**MOF**") on December 25, 1993, entering into force on the same date, and last amended on October 28, 2011 with effect from November 1, 2011, all enterprises, entities and individuals engaging in the sale of goods, provision of processing, repair and replacement services ("**labor services**"), sales of services, intangible assets, real estate, or the importation of goods within the territory of the PRC are taxpayers of value-added tax ("**VAT**") and shall pay VAT in accordance with the law. Under the regulations, taxpayers providing sales of goods, labor services, or tangible personal property leasing services, or importing goods, are subject to a VAT rate of 17% unless otherwise specified; those providing transportation, postal services, basic telecommunications, construction, real estate leasing services, sales of real estate, transfer of land use rights, or the sale or import of certain goods are subject to a 11% rate; those providing sales of services or intangible assets are subject to a 6% rate, except as otherwise specified; and taxpayers exporting goods are generally subject to a 0% VAT rate, unless otherwise provided by the State Council. Pursuant to the Notice of the MOF and the State Taxation Administration ("**STA**") on *the Adjustment to VAT Rates* (《關於調整增值稅稅率的通知》), promulgated on April 4, 2018 and effective May 1, 2018, the original 17% and 11% VAT rates applicable to taxable sales or imports of goods were adjusted to 16% and 10%, respectively. Further, under *the Announcement on Policies for Deepening the VAT Reform* (《關於深化增值稅改革有關政策的公告》), jointly issued by the MOF, STA and the General Administration of Customs on March 20, 2019 and effective April 1, 2019, the 16% and 10% rates were further adjusted to 13% and 9%, respectively.

Dividend Withholding Tax

According to 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* (《內地和香港特別行政區關於對所得避免雙重徵稅和防止偷漏稅的安排》), promulgated by the State Taxation Administration on August 21, 2006 and effective from December 8, 2006 (together with relevant protocols), a withholding tax rate of no more than 5% applies to dividends paid by a PRC company to a Hong Kong company that directly holds at least 25% of the equity interests (or capital) in the PRC company. If the Hong Kong company holds less than 25% of the equity interests (or capital) in the PRC company, a withholding tax rate of no more than 10% applies. The application of the dividend clause of tax agreements is subject to the requirements of PRC tax laws and regulations, such as *the Notice of the SAT on the Issues Concerning the Application of the Dividend Clauses of Tax Agreements (Guo Shui Han [2009] No. 81)* (《國家稅務總局關於執行稅收協定股息條款有關問題的通知》(國稅函 [2009] 81號)).

Individual Share Transfer Tax

According to *the Notice Concerning Continuing Temporary Exemption From Individual Income Tax on The Income From Stocks Transfer (Cai Shui Zi [1998] No. 61)* (《關於個人轉讓股票所得繼續暫免徵收個人所得税的通知》(財税字 [1998] 61號)) promulgated by the MOF and the SAT and became effective on March 30, 1998, since January 1, 1997, the individual income tax levied on the individual income from transfer of stocks of listed companies will continue to be temporarily exempted. In the newly revised Individual Income Tax Law of the PRC, the SAT did not clearly stipulate whether to continue to exempt individuals from tax on the income from transfer of stocks of listed companies.

REGULATIONS RELATING TO OVERSEAS LISTING

On February 17, 2023, the China Securities Regulatory Commission ("**CSRC**") promulgated the *Trial Administrative Measures of Overseas Securities Offering and Listing by Domestic Companies* (《境內企業境外發行證券和上市管理試行辦法》) (the "**Trial Administrative Measures**"), which took effect on March 31, 2023 — on the same date, the CSRC also released supporting documents (collectively called the Guidance Rules and Notice), including Supporting Guidance Rules No. 1 through No. 5, notes on the Trial Administrative Measures, a notice on overseas listing filing arrangements, and answers to reporter questions. Under these rules, domestic companies (whether conducting overseas securities offerings/listings directly or indirectly) must file with the CSRC within three working days after submitting an **[REDACTED]** or **[REDACTED]**. Non-compliance — such as failing to complete filings, concealing material facts, or falsifying filing documents — may result in administrative penalties (including rectification orders, warnings, and fines) for the company, as well as its controlling shareholders, actual controllers, and directly responsible personnel.

In addition, the CSRC, the Ministry of Finance, National Administration of State Secrets Protection and National Archives Administration of China promulgated *the Provisions on Strengthening the Confidentiality and Archives Administration of Overseas Securities Issuance and Listing by Domestic Companies* (《關於加強境內企業境外發行證券和上市相關保密和檔案管理工作的規定》) (CSRC Announcement [2023] No. 44) (the "**Provisions on Confidentiality and Archives Administration**") on February 24, 2023 to further strengthen the confidentiality and archives administration in connection with the overseas securities issuance and listing by domestic companies, clarify the information security responsibilities of listed companies, safeguard national information security and promote cross-border regulatory cooperation. To align with the Overseas Listing Trial Measures, "domestic companies" in the Provisions on Confidentiality and Archives Administration are defined as either one of the following entities: a joint stock company incorporated domestically that conducts overseas offering and listing, or a domestic operating entity of a company that conducts indirect overseas offering and listing. In addition, procedural requirements have been added to the Provisions on Confidentiality and Archives Administration which also clarifies the requirements of companies' confidentiality responsibilities and accounting archives administration.