

REGULATORY OVERVIEW

This section summarizes the principal PRC laws, rules and regulations relevant to our business.

PHARMACEUTICAL REGULATORY SYSTEM

Principal Regulatory Authorities

The major regulatory authorities of pharmaceutical industry in the PRC include the National Medical Products Administration (the “NMPA,” formerly known as the China Food and Drug Administration (“CFDA”)).

The NMPA carries on responsibilities for pharmaceutical supervision of CFDA, its predecessor, as the principal pharmaceutical regulatory authority in charge of the pharmaceutical registration and supervision, including non-clinical research, clinical trial, marketing approval, production and circulation.

LAWS AND REGULATIONS RELATING TO DRUGS

Drugs Administration Laws and Regulation

The PRC Drug Administration Law (《中華人民共和國藥品管理法》) (the “**Drug Administration Law**”) promulgated by the Standing Committee of the National People’s Congress (the “NPCSC”) on September 20, 1984, and amended on February 28, 2001, December 28, 2013, April 24, 2015, and August 26, 2019, as well as the Implementing Rules for the PRC Drug Administration Law (《中華人民共和國藥品管理法實施條例》) (the “**Implementing Rules for the Drug Administration Law**”) issued by the State Council on August 4, 2002, and amended on February 6, 2016, March 2, 2019, December 6, 2024 and January 16, 2026 have together laid down the legal framework for the administration of drugs, including the research, development, manufacturing and business operation for new drugs, and administer the pharmaceutical manufacturing enterprises, pharmaceutical operating enterprises, and medicinal preparations of medical institutions, along with the development, research, production, distribution, packaging, pricing and advertisements of drugs.

In June 2025, the CDE issued the Scope, Classification and Interpretation of Advanced Therapy Medicinal Products (Draft for Comments)(《先進治療藥品的範圍、歸類和釋義（徵求意見稿）》). As of the Latest Practicable Date, this draft regulation has not yet been formally promulgated. Under the draft regulation, both non-genetically modified Cellular and Tissue-based Medicinal Products (non-GMO CTMPs) and *ex vivo* genetically modified Cellular and Tissue-based Medicinal Products (*ex vivo* GMO CTMPs) are categorized as Cellular Therapy Medicinal Products (CTMPs) rather than Gene Therapy Medicinal Products (GTMPs).

Non-Clinical Research

The NMPA requires preclinical data to support registration applications for imported and domestic drugs. According to the Administrative Measures for Drug Registration (《藥品註冊管理辦法》), issued by the SAMR on January 22, 2020, and became effective on July 1, 2020, non-clinical drug safety evaluation studies shall comply with the Good Laboratory Practice for Non-clinical Laboratory Studies (《藥物非臨床研究質量管理規範》) (the “GLP”). The latest GLP has been implemented by the CFDA since September 1, 2017, to improve the quality of non-clinical research.

Pursuant to the Measures for Administration of Certification of the Good Laboratory Practice for Non-clinical Laboratory Studies (《藥物非臨床研究質量管理規範認證管理辦法》) promulgated on January 19, 2023 and implemented since July 1, 2023 by the NMPA, applying for the GLP certification is required for institutions that intend to conduct non-clinical safety evaluation studies in the PRC used for drug registration applications. The NMPA is in charge of the administration of the GLP certification nationwide, while the provincial medical products

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administrative authorities are responsible for the daily supervision and administration of non-clinical safety evaluation studies institutions within the administrative region. The GLP Certificate will be issued by the NMPA with its approval if the relevant requirements for the GLP are satisfied by the applicant. The valid period for the GLP certificate lasts for 5 years. Any entity without such certification must engage a qualified third party to conduct such non-clinical studies regulated under relevant laws and regulations.

Approval of Clinical Trials

Pursuant to the Administrative Measures for Drug Registration, an applicant that applies for a drug clinical trial after completion of the pharmaceutical, pharmacological and toxicological research, etc., which support the drug clinical trial, shall submit relevant research materials according to the requirements for application materials. The application materials shall be accepted if they are deemed acceptable upon formal examination. The Center for Drug Evaluation of the National Medical Products Administration (the “CDE”) shall organize pharmaceutical, medical and other technicians to review the accepted application for the drug clinical trial. A decision on approval or non-approval of the application for clinical trials of drugs shall be made within 60 days from acceptance of application, and the applicant shall be notified of the examination and approval outcome through the CDE website; where the applicant is not notified within the stipulated period, the application shall be deemed approved, and the applicant may conduct clinical trial of drugs in accordance with the submitted scheme.

According to the Circular on Drug Clinical Trial Information Platform (《關於藥物臨床試驗信息平台的公告》) issued by the CFDA on September 6, 2013, all clinical trials approved by the NMPA and conducted in the PRC shall complete clinical trial registration and publish trial information through the Drug Clinical Trial Public Information Platform. The applicant shall complete the initial registration of the trial within one month after obtaining the approval of the drug clinical trial to obtain an exclusive trial registration number and complete the subsequent information registration before the first participant is enrolled in the trial.

Phases of Clinical Trials and Communication with the CDE

Pursuant to the Drug Administration Law (《藥品管理法》), drug clinical trials shall be carried out in a clinical trial institution with corresponding conditions. The conditions that clinical trial institution should satisfy shall mainly comply with the relevant requirements of Administrative Regulations for Drug Clinical Trial Institutions (《藥物臨床試驗機構管理規定》), which came into effect on December 1, 2019. Such drug clinical trial institutions shall be subject to filing administration. Institutions that only engage in analysis of biological samples related to drug clinical trials shall not be subject to filing. The NMPA is responsible for setting up a filing management information platform for drug clinical trial institutions for registration, filing and operation management of drug clinical trial institutions, as well as the entry, sharing and disclosure of information on supervision and inspection of the drug regulatory authority and competent healthcare authority.

According to the Administrative Measures for Drug Registration, based on the drug’s characteristics and the purpose of research, clinical trials of drugs consist of Phase I, II, III and IV clinical trials, as well as the bioequivalence trials, contents of which include clinical pharmacology research, exploratory clinical trials, confirmatory clinical trials and post-marketing research. Clinical trials shall be conducted in accordance with the provisions of the PRC GCP, including the preparation for clinical trials, clinical trial protocols, responsibilities of sponsors and investigators, and protection of subjects, etc.

Pursuant to the Administrative Measures for Communication on Drug Development and Technical Reviews (《藥物研發與技術審評溝通交流管理辦法》) issued by the CDE on December 10, 2020, during the research and development, and application for registration stages of innovative drugs, the applicant may propose communication sessions with the CDE. The forms of communication can be face-to-face conference, video conference, telephone conference or written

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replies. The communication sessions are classified into three types. Type I sessions are held to address the material safety issues encountered in the clinical trials of drugs and the significant technical issues in the research and development process of breakthrough therapeutic drugs. Type II sessions are held during the key research and development stages of drugs, mainly including the sessions held prior to the application of IND, the sessions held upon completion of Phase II clinical trials and prior to commencement of Phase III clinical trials of new drugs, the sessions held prior to application for marketing approvals of new drugs, and the risk evaluation and control sessions. Type III sessions are those sessions not falling into the categories of Type I or II sessions.

New drug approvals regulated by the NMPA

According to the Implementing Rules for the Drug Administration Law, which were most recently amended and promulgated by State Council Decree No. 828 on January 16, 2026, and became effective on May 15, 2026, (i) to support the research, development, and innovation of medicinal products based on clinical value, the NMPA may apply breakthrough therapy procedures, conditional approval procedures, priority evaluation and approval procedures, and special approval procedures, among others, to eligible medicinal product registration applications to expedite the marketing of medicinal products; (ii) the undisclosed trial data and other data obtained independently and submitted by MAH of medicinal products containing new chemical ingredients and other qualified medicinal products should be protected, the protection period for the data shall not exceed 6 years from the date of medicinal product registration, during the protection period, any other applicant that uses the data to apply for medicinal product registration without the consent of the MAH shall be denied licensing, unless the other applicant submits data obtained independently, and; (iii) eligible medicinal products for the treatment of rare diseases shall be granted a market exclusivity period of not more than seven years if the MAH undertakes to ensure the supply of such medicinal products, and if the MAH fails to fulfill its undertaking, the market exclusivity period shall terminate.

Medical technologies regulated by NHC

The State Council promulgated the Regulations on the Management of Clinical Research and Clinical Translation of New Biomedical Technologies (《生物醫學新技術臨床研究和臨床轉化應用管理條例》, Decree No. 818) on September 28, 2025, with implementation scheduled for May 1, 2026. Activities involving the manipulation of ex vivo cells, tissues, organs, or similar materials for subsequent implantation or administration into the human body to test new biomedical technologies (“NBT”) shall comply with these Regulations to assess their safety and efficacy and to define their scope of application, operational procedures, and technical requirements. According to Decree No. 818, (i) within 5 working days from the date on which the NBT clinical research passes the academic and ethical reviews, the clinical research institution, which shall be a 3A hospitals, shall undergo recordation with the NHC; (ii) where any NBT is intended for translational clinical application following completion of its clinical research, it shall undergo review and approval by the NHC, and the medical institution using such NBT may charge fees for translational clinical application in compliance with applicable PRC laws and regulations; (iii) applications for the translational clinical application of NBT used to treat life-threatening diseases with no effective treatment methods or urgently needed for public health purposes shall be subject to prioritized review and approval by the NHC.

OTHER SIGNIFICANT PRC REGULATIONS AFFECTING OUR BUSINESS ACTIVITIES IN THE PRC

Laws and Regulations relating to Company Law and Foreign Investment

Under the Catalogue of Industries Encouraging Foreign Investment (2022 Version) (《鼓勵外商投資產業目錄(2022年版)》) (the “2022 Catalogue”), which was promulgated by the Ministry of Commerce and the NDRC on October 26, 2022 and became effective on January 1, 2023, the Special Administrative Measures Concerning Foreign Investment Access in Free Trade Pilot Zone

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(Negative List) (2021 Version) (《自由貿易試驗區外商投資准入特別管理措施(負面清單)(2021年版)》) and the Negative List (2024 edition) which became effective since November 1, 2024, industries are classified into two categories: encouraged industries and industries put on the negative list. The negative lists further divided them into two subcategories: restricted industries and forbidden industries. Foreign investors shall not invest in forbidden industries. According to the Negative List (2024 edition), the development and application of human stem cells, genetic diagnosis and therapy technologies fall into the industry forbidding foreign investments. Pursuant to the Notice of the Ministry of Commerce, the National Health Commission and the National Medical Products Administration on Launching Pilot Programs for Further Opening-Up in the Medical Field (Letter of Commerce on Foreign Investment No. 568 [2024]) (《商務部國家衛生健康委國家藥監局關於在醫療領域開展擴大開放試點工作的通知》(商資函[2024]568號)), with effect from September 7, 2024, foreign-invested enterprises are permitted to engage in the R&D and application of human stem cell and gene diagnosis & therapy technologies in the China (Beijing) Pilot Free Trade Zone, China (Shanghai) Pilot Free Trade Zone, China (Guangdong) Pilot Free Trade Zone and Hainan Free Trade Port, for the purpose of product registration, listing and manufacturing.

The establishment, operation and management of enterprises in the PRC are governed by the Company Law of the PRC (《中華人民共和國公司法》) (the “**Company Law**”), which was promulgated by the NPCSC on December 29, 1993 and became effective on July 1, 1994. It was subsequently amended on December 25, 1999, August 28, 2004, October 27, 2005, December 28, 2013, October 26, 2018, and December 29, 2023, respectively. Pursuant to the Company Law, companies are classified into two categories, namely limited liability companies and limited companies by shares. The Company Law shall also apply to foreign-invested limited liability companies and companies limited by shares. According to the Company Law, the provisions otherwise prescribed by the laws on foreign investment shall prevail.

On March 15, 2019, the National People’s Congress (the “**NPC**”) issued the Foreign Investment Law of the People’s Republic of China (《中華人民共和國外商投資法》) (the “**Foreign Investment Law**”), which came into effect on January 1, 2020 and the Sino-Foreign Equity Joint Venture Enterprise Law of the People’s Republic of China (《中華人民共和國中外合資經營企業法》), the Wholly Foreign-Invested Enterprise Law of the People’s Republic of China (《中華人民共和國外資企業法》), and the Cooperative Joint Venture Enterprise Law of the People’s Republic of China (《中華人民共和國合作經營企業法》) were simultaneously abolished. Since then, the Foreign Investment Law has become the basic law regulating foreign-invested enterprises wholly or partially invested by foreign investors. According to the Foreign Investment Law and the Implementation Regulations for the Foreign Investment Law of the PRC (《中華人民共和國外商投資法實施條例》) issued by the State Council on December 26, 2019, with effect from January 1, 2020, “foreign investment” refers to the investment activities in the PRC carried out directly or indirectly by foreign individuals, enterprises or other organizations (the “**Foreign Investors**”), including the following: (i) Foreign Investors establishing foreign-invested enterprises in the PRC alone or collectively with other investors; (ii) Foreign Investors obtaining shares, equities, shares of properties or other similar equities of Chinese domestic enterprises; (iii) Foreign Investors investing in new projects in the PRC alone or collectively with other investors; (iv) Foreign Investors investing through other ways prescribed by laws and regulations or the State Council. The provisions of the Company Law, the Partnership Enterprise Law of the People’s Republic of China (《中華人民共和國合夥企業法》) and other laws shall apply to the form of organization of a foreign-invested enterprise, its organizational structure and the rules governing its activities.

The PRC implements a pre-access national treatment plus negative list management system for foreign investment, which means that foreign investors and their investments are given treatment no less favorable than that accorded to domestic investors and their investments at the stage of investment access; while the “negative list” refers to special administrative measures for access of foreign investment in specific fields as stipulated by the PRC. The national treatment shall be granted to foreign investments outside of the negative list. The Measures on Reporting Foreign Investment Information (《外商投資信息報告辦法》) was issued by MOFCOM and State

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Administration for Market Regulation on December 30, 2019 and came into effect on January 1, 2020, pursuant to which, for foreign investors carrying out investment activities directly or indirectly in the PRC, the foreign investors or foreign-invested enterprises shall submit investment information to the commerce authorities pursuant to such measures. When submitting an annual report, a foreign-invested enterprise shall submit the information such as basic enterprise information, the information on investor and actual controller thereof, enterprise business operation, assets and liability, as well as the relevant industry license information, if any special administrative measure for foreign investment access is involved.

Laws and Regulations on Outbound Investment

Pursuant to the Administrative Measures on Outbound Investments (《境外投資管理辦法》) issued by the MOFCOM on March 16, 2009, and amended on September 6, 2014, and the Administrative Measures for the Outbound Investments of Enterprises (《企業境外投資管理辦法》) issued by the NDRC on December 26, 2017, and effective from March 1, 2018, if an enterprise in the PRC intends to make outbound investments, it shall be subject to approval or filing for the project, report relevant information, and cooperate in the supervisory inspections. Non-sensitive projects directly conducted by domestic enterprise in China, involving direct contribution of assets or rights and interests or provision of financing or security, shall be subject to filing.

Laws and Regulations relating to Foreign Exchange

The principal law governing foreign currency exchange in the PRC is the Foreign Exchange Administration Regulations of the PRC (《中華人民共和國外匯管理條例》) (the “**Foreign Exchange Administration Regulations**”). The Foreign Exchange Administration Regulations were enacted by the State Council on January 29, 1996 and implemented on April 1, 1996. On January 14, 1997 and August 5, 2008, the State Council amended the Foreign Exchange Administration Regulations. According to the Foreign Exchange Administration Regulations, international payments in foreign currencies and transfer of foreign currencies under current items shall not be restricted. Foreign currency transactions under the capital account are still subject to limitations and require approvals from, or registration with, the State Administration of Foreign Exchange of the PRC (中華人民共和國外匯管理總局) (the “**SAFE**”) or its local counterpart and other relevant PRC governmental authorities.

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

According to the Circular of SAFE on Reforming and Regulating Policies on the Control over Foreign Exchange Settlement of Capital Accounts (《國家外匯管理局關於改革和規範資本項目結匯管理政策的通知》) (the “**SAFE Circular 16**”) promulgated on June 9, 2016, and revised on December 4, 2023, by the SAFE, the Discretionary Foreign Exchange Settlement shall be unified for all the domestic institutions, while the use of foreign exchange incomes of capital projects by domestic institutions shall follow the principles of authenticity and self-use within the business scope of enterprises. The SAFE Circular 16 stipulates that the foreign exchange proceeds under the capital account of and the Renminbi funds obtained from foreign exchange settlement by a domestic institution may be used for expenditures under the current account within its business scope or the expenditures under the capital account permitted by the laws and regulations. The foreign exchange proceeds under the capital account of and the Renminbi funds obtained from foreign exchange

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settlement by a domestic institution (i) shall not be used directly or indirectly for expenditures beyond the business scope of the domestic institution or as prohibited by the laws and regulations; (ii) unless otherwise provided, shall not be used directly or indirectly for securities investments or other investments (except for wealth management products and structured deposits with risk rating not higher than level 2); (iii) shall not be used for offering loans to non-affiliated enterprises, unless expressly permitted by the business scope; (iv) shall not be used for the purchase of residential real estate not for self-use (except for enterprises engaged in real estate development and real estate leasing).

According to the Circular of SAFE 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 by the SAFE on April 10, 2020, the reform of facilitating the payments of incomes under the capital projects shall be promoted nationwide. Under the prerequisite of ensuring true and compliant use of funds and complying with the prevailing administrative provisions on use of income from capital projects, enterprises which satisfy the criteria are allowed to use income under the capital account, including capital funds, foreign debt and overseas listing, for domestic payment, without the need to provide proof materials for veracity to the bank beforehand for each transaction.

Distribution of Dividends

Pursuant to the provisions of the Company Law, when distributing each year’s profits after taxation, the company shall set aside 10% of its profits for the company’s statutory common reserve fund until the fund has reached more than 50% of the company’s registered capital. When the company’s statutory common reserve fund is not sufficient to make up for the company’s losses for the previous years, the current year’s profits shall first be used to make good the losses before any allocation is set aside for the statutory common reserve fund. After the company has made allocations to the statutory common reserve fund from its profits after taxation, it may, upon the resolution at a shareholders’ general meeting, make further allocations from its profits after taxation to the discretionary common reserve fund. After the company has made good its losses and made allocations to its common reserve fund, the remaining profits after taxation shall be distributed to the shareholders.

On January 26, 2017, the SAFE issued the Notice on Promoting the Reform of Foreign Exchange Administration and Improving the Review of Authenticity and Compliance (《關於進一步推進外匯管理改革完善真實合規性審核的通知》) which provided that when processing the outward remittance of profits of a domestic institution equivalent to more than 50,000 US dollars, the bank shall, in light of the principle of genuine transaction, review the profit distribution resolution made by the board of directors (or by the partners), original tax filing form and audited financial statements relating to the outward remittance of profits, and chop on the original tax filing form to endorse the amount and date of the outward remittance. The domestic institution shall make up for its losses during the previous years according to the laws before remitting the profits.

Laws and Regulations Related to Intellectual Property Rights

Patents

Pursuant to the Patent Law of the PRC (《中華人民共和國專利法》) (the “**Patent Law**”) promulgated by the NPCSC on March 12, 1984, and amended on September 4, 1992, August 25, 2000, December 27, 2008, and October 17, 2020, respectively, with the latest amendments effective from June 1, 2021, and the Implementation Rules of the Patent Law of the PRC (《中華人民共和國專利法實施細則》) promulgated by the State Council on June 15, 2001, with the latest amendments on December 11, 2023, effective from January 20, 2024, the patents in the PRC refer to invention, utility model and design. An invention or a utility model to be granted as a patent shall have novelty, creativity and practicality. The Patent Office under the State Intellectual Property Office is responsible for receiving, examining, and approving patent applications. A patent is valid for a twenty-year term for an invention, a ten-year term for a utility model, or a fifteen-year term for a design, commencing from their respective application dates.

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According to the provisions of the Patent Law and the Implementation Rules of the Patent Law of the PRC, for the purpose of compensating for the time taken to examine and approve a new drug to be marketed, the patent administrative department under the State Council shall grant compensation to the validity period of patent rights for the invention patents of new drugs approved to be marketed in the PRC upon request of the patentee. The compensation period shall not exceed five years, and the total validity period of patent rights after a new drug is approved to be marketed shall not exceed fourteen years. During the validity compensation period of patent rights, the scope of protection of the invention patent of a new drug is limited to the new drug and its approved indications-related technical solutions; within the scope of protection, the patentee enjoys the same rights and undertakes the same obligations as those before the validity compensation period.

Trademark

Pursuant to the Trademark Law of the PRC (《中華人民共和國商標法》) promulgated by the NPCSC on August 23, 1982, and amended on February 22, 1993, October 27, 2001 and August 30, 2013 respectively, and last amended on April 23, 2019 with the latest amendment effective on November 1, 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》) promulgated by the State Council on August 3, 2002 which became effective on September 15, 2002 and was revised on April 29, 2014 and the latest amendment became effective on May 1, 2014, the period of validity for a registered trademark is 10 years, commencing from the date of registration. Upon expiry of the period of validity, the registrant shall go through the formalities for renewal within 12 months prior to the date of expiry as required if the registrant needs to continue to use the trademark. Where the registrant fails to do so, a grace period of six months may be granted. The period of validity for each renewal of registration is 10 years, commencing from the day immediately after the expiry of the preceding period of validity for the trademark. In the absence of a renewal upon expiry, the registered trademark shall be canceled.

Copyright

Copyright is protected by the Copyright Law of the PRC (《中華人民共和國著作權法》) promulgated by the NPCSC on September 7, 1990 and last amended on November 11, 2020 with the latest amendment effective on June 1, 2021 and the Implementation Regulations of the Copyright Law of PRC (《中華人民共和國著作權法實施條例》) issued by the State Council on August 2, 2002 and last amended on January 30, 2013 with the latest amendment effective on March 1, 2013, which provided provisions on the classification of works and the obtaining and protection of copyright and the related rights.

Domain Names

Domain names are protected by the Administrative Measures of Internet Domain Names (《互聯網域名管理辦法》) issued by the Ministry of Industry and Information Technology (the “MIIT”) on August 24, 2017 and effective from November 1, 2017 and the Implementing Rules on Registration of China Country Code Top-level Domain Names (《國家頂級域名註冊實施細則》) issued by China Internet Network Information Center on June 18, 2019. The MIIT is the regulatory body responsible for the administration of PRC internet domain names. The China Internet Network Information Center is responsible for the administration of registration of China country code top-level domain names. Domain name registrations are processed by the domain name registration service agencies established pursuant to the relevant provisions. The applicants become domain name holders upon successful registration.

Trade Secrets

According to the Anti-Unfair Competition Law of the PRC (《中華人民共和國反不正當競爭法》) promulgated by the NPCSC on September 2, 1993 and amended on November 4, 2017 and April 23, 2019 respectively and the Provisions of the Supreme People’s Court on Several Issues Concerning the Application of Law in the Trial of Civil Cases Involving Trade Secret Infringement

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(《最高人民法院關於審理侵犯商業秘密民事案件適用法律若干問題的規定》) issued by the Supreme People’s Court on September 10, 2020 and effective from September 12, 2020, the term “trade secrets” refers to technical, operational and other business information that is unknown to the public, has business value, may create business interests or profits for its legal owners or holders, and is maintained as a secret with relevant security measures taken by its right holders. According to the Anti-Unfair Competition Law of the PRC, business operators 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 illicit means; (ii) disclosing, using or allowing other person to use a trade secret acquired from the right holder by any means as specified in the preceding subparagraph; (iii) disclosing, using or allowing other person to 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, tempting or aiding a person into or in acquiring, disclosing, using or allowing other person to use the trade secret of the right holder in violation of its confidentiality obligation or the requirements of the right holder for keeping the trade secret confidential. If a third party knows or should have known the above mentioned illegal conducts but nevertheless acquires, uses or allows other persons to use such trade secrets, the third party shall be deemed to have infringed others’ trade secrets. The right holders whose trade secrets are infringed may apply for administrative corrections, and the regulatory authorities shall order to stop any illegal activities and impose fine penalties on the infringers.

Regulations Relating to Enterprise Income Tax and Value-added Tax

Enterprise Income Tax

Pursuant 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**”) promulgated by the NPCSC on March 16, 2007, which became effective from January 1, 2008, and last amended on December 29, 2018, enterprises shall be classified into resident enterprises and non-resident enterprises. The income tax rate of resident enterprises is 25%, while the income tax rate of non-resident enterprises is 20%. According to the EIT Law and the Implementation Regulations for 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 for EIT Law**”) issued by the State Council on December 6, 2007, which became effective from January 1, 2008, and last amended on December 6, 2024, enterprise income tax shall be payable by a resident enterprise for the income derived from or accruing in or outside the PRC. Enterprise income tax shall be payable by a non-resident enterprise with office or premises within the territory of the PRC for the income derived from or accruing in the PRC by its office or premises, and the income derived from or accruing outside the PRC for which its office or premises has a de facto relationship. Where the non-resident enterprise has no office or premises within the territory of the PRC or the income derived or accrued has no de facto relationship with its office or premises, enterprise income tax shall be payable by the non-resident enterprise for the income derived from or accruing in the PRC at a reduced rate of 10%.

Value-Added Tax

According to the Interim Regulations of the PRC on Value-added Tax (《中華人民共和國增值稅暫行條例》), which was promulgated by the State Council on December 13, 1993 and amended on November 10, 2008, February 6, 2016 and November 19, 2017 respectively, and the Detailed Rules for the Implementation of the Interim Regulations of the PRC on Value-added Tax (《中華人民共和國增值稅暫行條例實施細則》), which was promulgated by the Ministry of Finance on December 25, 1993 and last amended on October 28, 2011 with the last amendment effective on November 1, 2011, entities and individuals selling goods or processing, repair and fitting-out services, selling services, intangible assets, immovable property and importing goods within the territory of the PRC shall be subject to VAT. The applicable VAT rates, depending on the nature of the taxable acts of the general taxpayer, are 17%, 11%, 6% and 0%, respectively. According to the Circular of the MOF and the SAT on Adjusting Value-added Tax Rate (《財政部、稅務總局關於調整增值稅稅率的通知》), which was jointly issued by the MOF and the SAT on April 4, 2018 and

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took effective on May 1, 2018, the VAT rates of 17% and 11% originally applicable to general taxpayers’ relevant taxable acts are adjusted to 16% and 10%, respectively. According to the Announcement on Improving the Value-Added Tax Ending Input Tax Credit Refund Policy (Caishui [2025] No. 7) (《財政部稅務總局關於完善增值稅期末留抵退稅政策的公告》), which was jointly issued by the Ministry of Finance and the State Taxation Administration on August 22, 2025, and became effective on September 1, 2025, the VAT rates of 16% and 10% originally applicable to general taxpayers’ relevant taxable acts are further adjusted to 13% and 9%, respectively.

Laws and Regulations Relating to Product Quality

The Product Quality Law of the PRC (《中華人民共和國產品質量法》) promulgated on February 22, 1993 by the NPCSC and amended on July 8, 2000, August 27, 2009 and December 29, 2018 respectively, is the main law regulating the supervision and management of quality of products in China. According to the Product Quality Law of the PRC, producers shall be responsible for the quality of the products they produce, and sellers shall take measures to maintain the quality of the products they sell. If a defect in a product causes physical injury or damage to property other than the defective product, the producer shall bear the liability for compensation, unless the producer can prove any of the following circumstances: (i) the product has not been put into circulation; (ii) the defect causing the damage did not exist when the product was put into circulation; (iii) when the product was put into circulation, the level of science and technology at the time was not sufficient to detect the existence of the defect.

Pursuant to the Civil Code of the PRC (《中華人民共和國民法典》) promulgated by the NPC on May 28, 2020 and coming into effective on January 1, 2021, where a patient suffers damage due to defects in drugs, he/she may seek compensation from the drug marketing authorization holder, producer 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 or the producer.

Laws and Regulations Relating to Safety Production

Pursuant to the Safety Production Law of the PRC (《中華人民共和國安全生產法》) promulgated by the NPCSC on June 29, 2002 and amended on August 31, 2014 and June 10, 2021 respectively with the latest amendment taking effect on September 1, 2021, production and operation units shall abide by the Safety Production Law of the PRC and other laws and regulations related to production safety, strengthen production safety management, and establish a sound production safety responsibility system and formulate a set of production safety rules and regulations for all employees; increase the efforts to guarantee the input of funds, supplies, technology and personnel to production safety, improve production safety conditions, and strengthen standardization and informatization of production safety; construct a “dual-prevention” mechanism consisting of graded management and control of safety risks and examination and control of potential risks, improve the risk prevention and resolution mechanism, enhance production safety levels and ensure production safety.

Labor, Social Insurance and Housing Fund

The Labor Law of the PRC (《中華人民共和國勞動法》) promulgated by the NPCSC on July 5, 1994 and last amended on December 29, 2018 and the Labor Contract Law of the PRC (《中華人民共和國勞動合同法》) promulgated on June 29, 2007, effective from January 1, 2008, and last amended on December 28, 2012 and effective on July 1, 2013 stipulate the relationship between the employers and the employees, and specifies the terms and conditions of the labor contracts.

Pursuant to the Social Insurance Law of the PRC (《中華人民共和國社會保險法》) promulgated by the NPCSC on October 28, 2010, effective from July 1, 2011, and last amended on December 29, 2018, the Provisional Regulations for the Collection and Payment of Social Insurance Premiums (《社會保險費徵繳暫行條例》) issued by the State Council on January 22, 1999 and last amended on March 24, 2019, and the Regulations on the Administration of Housing Provident Fund

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(《住房公積金管理條例》) issued by the State Council on April 3, 1994, and amended on March 24, 2002 and March 24, 2019, respectively, employers are required to pay social insurance premiums such as basic pension insurance, unemployment insurance, basic medical insurance, work-related injury insurance and maternity insurance for their employees, and contribute to housing provident funds.

According to the Supreme People’s Court’s Interpretation (II) on Issues Concerning the Application of Law in the Trial of Labour Dispute Cases, promulgated on 31 July 2025 and effective from 1 September 2025, where an employer and employee agree, or an employee undertakes to the employer, that social insurance contributions need not be paid, the People’s Court shall deem such agreement or undertaking invalid. Where an employer fails to pay social insurance contributions in accordance with the law, and an employee requests termination of the labour contract pursuant to Article 38(1)(3) of the Labour Contract Law, seeking payment of economic compensation from the employer, the People’s Court shall support such request in accordance with the law. Where the aforementioned circumstances exist, and the employer subsequently makes supplementary payments of social insurance contributions in accordance with the law, the People’s Court shall support the employer’s request for the employee to return the social insurance contribution compensation already paid, in accordance with the law.

As advised by the PRC Legal Advisor, the new judicial interpretation codifies a consensus view by providing uniform standards for applying the existing legal provisions and is consistent with the currently effective Article 38(3) and Article 46(1) of the PRC Labor Contract Law. Furthermore, the new judicial interpretation contains no provisions on the payment of housing fund contributions. Therefore, the above interpretation does not affect the assessment of whether an employer’s social insurance and housing fund contributions are compliant, nor does it change the substantive standards for determining compliance. As advised by the PRC Legal Advisor, this interpretation does not affect the compliance status of the Company’s social insurance and housing fund contributions.

Regulations Relating to Information Security and Data Privacy

Data Security

On June 10, 2021, the NPCSC promulgated the Data Security Law of the People’s Republic of China (《中華人民共和國數據安全法》), with effect on September 1, 2021, which establishes a classified and tiered system for data protection. Entities engaged in data processing activities shall, in accordance with laws and regulations, establish a sound data security management system that covers the whole process of data processing, organize data security education and training, and take corresponding technological measures and other necessary measures to protect data security.

Protection of Personal Information

Pursuant to the Civil Code, the personal information of a natural person shall be protected by the law. Any organization or individual that needs to obtain personal information of others shall obtain such information legally and ensure the security of such information, and shall not illegally collect, use, process or transmit personal information of others, or illegally purchase, sell, provide or make public the personal information of others. On August 20, 2021, the Standing Committee of the National People’s Congress promulgated the Personal Information Protection Law of the People’s Republic of China (《中華人民共和國個人信息保護法》), which took effect on November 1, 2021. The Personal Information Protection Law further emphasizes the obligation and responsibility of personal information processors on personal information and implements stricter protection measures on processing sensitive personal information.

On September 24, 2024, the State Council promulgated the Administrative Regulations on Network Data Security Management (《網絡數據安全管理條例》) (the “Data Security Regulations”), which became effective on 1 January 2025. The Data Security Regulations establish the basic framework for the purposes of regulating network data (including personal information)

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processing activities, ensuring the security of network data, promoting the reasonable and effective use of network data in accordance with the law, protecting the lawful rights and interests of individuals and organizations, and safeguarding national security and public interest.

Regulations Relating to Overseas Listing

According to the Trial Administrative Measures of Overseas Securities Offering and Listing by Domestic Companies (“**Trial Administrative Measures**”) released by the China Securities Regulatory Commission (“**CSRC**”) on February 17, 2023 and come into effect on March 31, 2023, domestic enterprise in the PRC that directly issues securities outside the PRC shall file with the CSRC in accordance with the Trial Administrative Measures. For the overseas initial public offering or listing, issuers shall file with the CSRC within three working days after the submission of its application for listing in overseas region. If the filing materials are complete and comply with regulations, the CSRC will complete the filing within 20 working days from the date of receipt of the filing materials and will announce the filing information through its website publicly.

According to the Trial Administrative Measures, an overseas offering and listing are prohibited under any of the following circumstances: (i) financing through listing is explicitly prohibited by laws, administrative regulations or relevant national regulations; (ii) the overseas offering and listing may endanger national security as determined by the relevant competent department under the State Council after examination according to the law; (iii) a domestic enterprise or its controlling shareholder or actual controller has committed a criminal crime of corruption, bribery, embezzlement, misappropriation of property or disrupting the order of the socialist market economy in the last three years; (iv) a domestic enterprise is under formal investigation according to the law for being suspected of any crime or major violation of laws and regulations, but no clear conclusions have been made; or (v) there is a major dispute over ownership of the equity held by the controlling shareholder or a shareholder controlled by the controlling shareholder or the actual controller.

Confidentiality and Archives Administration Concerning Overseas Listing

Pursuant to the Provisions on Strengthening Confidentiality and Archives Administration Concerning Overseas Securities Offerings and Listings 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》), which was jointly announced by numerous departments including CSRC on February 24, 2023 and came into effect since March 31, 2023, during the overseas issuance and listing activities of domestic enterprises, such enterprises and securities companies, securities service institutions which provide corresponding services shall strictly comply with the relevant laws and regulations of PRC and the requirements of these Provisions, in order to strengthen the legal awareness on safeguarding national secret and strengthening archives administration, establish a sound system on confidentiality and archives administration, and adopt necessary measures for fulfilling its obligations on confidentiality and archives administration, They shall not leak any national secrets and work secrets of national authorities, and shall not jeopardize the national and public interests. A domestic enterprise, which provides or publicly discloses documents and information about the national secrets and the work secrets of national authorities to entities or individuals such as securities companies, securities service institutions and overseas regulatory authorities, or provides such documents and information through its overseas listed entity, shall report to, and obtain approval from competent authority with approval authorizations in accordance with law, and shall report to the administrative department of confidentiality at the same level for filing. A domestic company that provides or publicly discloses documents and information that may pose adverse effects to national security or public interests to relevant entities or individuals including securities companies, securities service institutions, and overseas regulators, or provides or publicly discloses such documents and information through its overseas listed entity, shall strictly fulfill relevant procedures stipulated by applicable national regulations.

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Regulations Relating to “Full Circulation” of H Shares

According to the Trial Administrative Measures, if a domestic enterprise is directly listed overseas, when its shareholders of its domestic unlisted shares apply to convert their domestic unlisted shares held to overseas listed shares and to be circulated in overseas exchanges, it shall comply with the relevant regulations of CSRC and entrust the domestic enterprises to file with the CSRC.

According to 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》) announced by the CSRC on November 14, 2019 and amended on August 10, 2023, shareholders of domestic unlisted shares may, under the premise of complying with the relevant laws and regulations and the requirements of the policies on management of state-owned assets, foreign investment, and industry regulation, among others, determine the amount and proportion of shares whose circulation is applied for on their own through consultation, and entrust H-share companies with undergoing the filing formalities with the CSRC. Domestic companies with limited liability which have not been listed in any exchanges, may file with the “full circulation” of its H-shares with the CSRC along with its overseas initial public offering. Shareholders of domestic unlisted shares shall, according to the relevant business rules of China Securities Depository and Clearing Corporation Limited (the “CSDC”), handle registration of transfer of shares, undergo the formalities of registration of shares, and quotation and listing of shares, among others, according to the relevant provisions of the Hong Kong market, and conduct information disclosure according to the laws and regulations. H-share companies shall submit relevant status report to the CSRC within 15 days after the shares involved in the application are transferred to the CSDC.

On December 31, 2019, the 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》), which are applicable to businesses of cross-border share transfer registration, maintenance of deposit and holding details, transaction entrustment and instruction transmission, settlement, management of settlement participants, nominal holder services and other related operations in relation to the H-share “full circulation business.”

On June 27, 2025, the Shenzhen Branch of China Securities Depository and Clearing Corporation Limited (CSDC) revised the “Guidelines for the ‘Full Circulation’ Business of H-Shares of 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》), which are applicable to the business preparation, cross-border share transfer registration and overseas centralized custody, the initial maintenance of details of domestic shareholding and the maintenance of its changes, corporate actions, clearing, settlement and risk management measures. On the same day, China Securities Depository and Clearing (Hong Kong) Company Limited issued the H-Share Full Circulation Business Guide of China Securities Depository and Clearing (Hong Kong) Limited (《中國證券登記結算(香港)有限公司H股“全流通”業務指南》), which is applicable to businesses such as share custody and depository, agent service, arrangement for settlement and delivery, and risk management measures.