
REGULATORY OVERVIEW

LAWS AND REGULATIONS OF THE PRC

We are subject to a variety of PRC laws, rules and regulations affecting many aspects of our business. This section summarizes the major PRC laws and regulations that we believe are relevant to our business and operations in the PRC.

PRINCIPAL REGULATORY PROVISIONS

Laws and Regulations on Company Establishment and Foreign Investment in the PRC

The establishment, operation and management of corporate entities in China are governed by the Company Law of the People’s Republic of China (《中華人民共和國公司法》) (the “PRC Company Law”), which was latest amended in December 2023. The PRC Company Law applies to foreign-invested limited liability companies and foreign-invested companies limited by shares.

Currently investment activities in the PRC by foreign investors are primarily governed by the Special Administrative Measures for the Access of Foreign Investment (Negative List) (2024 Edition) (《外商投資准入特別管理措施(負面清單)(2024年版)》), which cover 11 industries, and any field not falling in the Negative Lists shall be administered under the principle of equal treatment for domestic and foreign investment. According to 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 was promulgated by the NPC in March 2019, the investment activities of foreign natural persons, enterprises or other organizations directly or indirectly within the territory of China shall comply with and be governed by the Foreign Investment Law.

Laws and Regulations on Drugs

Research and Development of New Drugs

According to the Drug Administration Law of the People’s Republic of China (《中華人民共和國藥品管理法》) (the “Drug Administration Law”) promulgated by the SCNPC in September 1984, latest amended on August 26, 2019, and the Implementation Regulations of the Drug Administration Law of the People’s Republic of China (《中華人民共和國藥品管理法實施條例》) (the “Implementation Regulations”) promulgated by the State Council and latest amended on December 6, 2024, the developer and clinical trial applicant of any new drug shall truthfully submit the new drug’s manufacturing method, quality specifications, results of pharmacological and toxicological tests and the related data, documents and samples to the NMPA for approval before any clinical trial is conducted.

Clinical Trial

According to the Administrative Measures for Drug Registration (《藥品註冊管理辦法》) (the “Circular 27”), which took effect on July 1, 2020, drug clinical trials shall be divided into Phase I clinical trial, Phase II clinical trial, Phase III clinical trial, Phase IV clinical trial, and bioequivalence trial. In accordance with Circular 27 and the Announcement on Adjusting Evaluation and Approval Procedures for Clinical Trials for Drugs (《關於調整藥物臨床試驗審評審批程序的公告》) issued in July 2018, if a clinical trial applicant does not receive any negative or questioned opinions from the CDE within 60 days after the date when the trial application is accepted and the fees are paid, the applicant can proceed with the clinical trial in accordance with the trial protocol submitted to the CDE.

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Classification of Drugs

According to the Administrative Measures for Drug Registration (《藥品註冊管理辦法》), the drug registration administration shall be classified into traditional Chinese drugs, chemical drugs and biological products; among them, the registration of chemical drugs shall be classified into innovative chemical drugs, modified new chemical drugs, generic drugs, etc. the registration of biological products shall be classified into innovative biological products, modified new biological products, and marketed biological products (including biosimilars).

New Drug Application

Pursuant to Circular 27, upon completion of clinical trials, determination of quality standards, completion of validation of commercial-scale production processes and completion of other related preparation works, the applicant may apply to the NMPA for the drug marketing authorization. The NMPA then determines whether to approve the application according to applicable laws and regulations. The applicant must obtain the marketing authorization for a new drug before the drug can be manufactured and sold in the Chinese market.

Administration of Traditional Chinese Medicine Registration

According to the Special Provisions on the Administration of Traditional Chinese Medicine Registration (《中藥註冊管理專門規定》) issued by the NMPA on February 10, 2023, the registration classifications for TCMs include innovative TCMs, modified new drugs of TCMs, compound preparations of TCMs originated from ancient classic prescriptions, and drugs with identical names and formulations. The specific circumstances of TCM registration classifications and corresponding requirements for submission materials shall be implemented in accordance with the relevant provisions concerning TCM registration classifications and submission material requirements.

Drug Marketing Authorization Holder Mechanism

Pursuant to the Drug Administration Law (《藥品管理法》), China implements the drug marketing authorization holder mechanism for the management of the drug industry. The drug marketing authorization holder refers to an enterprise or a drug research and development institution that has obtained the drug registration certificate. The drug marketing authorization holder shall be responsible for non-clinical research, clinical trials, production and operation, post-marketing research, adverse reaction monitoring, reporting and processing of drugs in accordance with the provisions of the law. The drug marketing authorization holder may manufacture drugs by themselves or entrust a pharmaceutical manufacturing enterprise to manufacture drugs. Likewise, they may sell drugs by themselves or entrust a pharmaceutical distribution enterprise to sell drugs.

Regulations of Biosimilars

According to the Technical Guideline for the Research, Development and Evaluation Biosimilars (Trial) (《生物類似藥研發與評價技術指導原則(試行)》) (the “Biosimilar Guidelines”), biosimilars refer to therapeutic biological products that are similar to approved reference drugs in terms of quality, safety and efficacy. The R&D and marketing of biosimilars need to comply with the relevant regulations of the Drug Administration Law (《藥品管理法》) and Circular 27.

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Registration of Generic Drugs

According to the Registration Measures (《註冊管理辦法》), the applicants which apply for registration of generic drugs shall be manufacturers of the same drugs. The applicant’s drugs shall also be within the manufacturing scope specified in the Drug Manufacturing Permit (《藥品生產許可證》). Furthermore, clinical trials are required to be conducted in accordance with the Registration Measures. According to the Circular on Implementation of Notification Management of Bioequivalence Trials of Chemical Drug (《關於化學藥生物等效性試驗實行備案管理的公告》), the management of bioequivalence trials of chemical drug has been changed from examination and approval to notification. With reference to the technical review opinions, the NMPA will either grant a drug registration number or issue a disapproval notice.

Laws and Regulations on Drug Manufacturing

Pursuant to the Drug Administration Law (《藥品管理法》) and the Implementation Regulations of the Drug Administration Law (《藥品管理法實施條例》), a drug manufacturer must obtain a Drug Manufacturing Permit (《藥品生產許可證》) from the drug regulatory authority at provincial, autonomous regional or municipal level before it may start manufacturing drugs in the PRC. The Drug Manufacturing Permit shall indicate the validity period and the scope of production. Each Drug Manufacturing Permit is valid for a period of five years, and the manufacturer is required to apply for renewal of the permit within six months prior to its expiration date.

Laws and Regulations on Drug Supply

National Essential Medicine List

On August 18, 2009, the Ministry of Health (later restructured as the National Health Commission) and eight other state agencies jointly issued the Implementation Opinions on Establishing the National Essential Medicine System (《關於建立國家基本藥物制度的實施意見》). The National Essential Medicine List (2018 Edition) (《國家基本藥物目錄(2018年版)》) (the “National Essential Medicine List”) was promulgated by the NHC on September 30, 2018. Under these regulations, all government-funded primary healthcare institutions are required to fully stock and utilize drugs specified in the National Essential Medicine List. Drugs listed in the National Essential Medicine List used by public hospitals must be procured through centralized public bidding mechanisms and are subject to management by the NDRC, the NHC and other government departments.

National Reimbursement Drug List

Pursuant to the Interim Measures for the Administration of the Use of Medicines Covered by Basic Medical Insurance (《基本醫療保險用藥管理暫行辦法》) promulgated by the NHSA on July 30, 2020 and came into effect since September 1, 2020, the scope of drugs covered under the basic medical insurance system shall be administered through the NRDL. The National Basic Medical Insurance, Work-Related Injury Insurance, and Maternity Insurance (《國家基本醫療保險、工傷保險和生育保險藥品目錄》) (the “NRDL”), jointly issued by the NHSA and the Ministry of Human Resources and Social Security on November 27, 2024 and came into effect since January 1, 2025, establishes reimbursement standards for drugs under the basic medical insurance, work-related injury insurance, and maternity insurance funds. Local governments are mandated to implement the NRDL strictly and are prohibited from making any modifications to its contents. Eligible drugs in the National Essential Medicine List may be incorporated into the NRDL according to the Interim Measures for the Administration of the Use of Medicines Covered by Basic Medical Insurance.

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Drug Procurement by Hospitals

According to the Guidance Opinion of the General Office of the State Council on the Improvement of the Drug Centralized Procurement Work of Public Hospitals (《國務院辦公廳關於完善公立醫院藥品集中採購工作的指導意見》) promulgated and came into effect on February 9, 2015, the centralized procurement work of public hospitals will be improved through the classification purchase of drugs. All drugs used by public hospitals (with the exception of traditional Chinese medicine decoction pieces) should be procured through a provincial centralized pharmaceutical procurement platform. The provincial procurement agency should work out a summary of the procurement plans and budget submitted by hospitals and compile reasonably a drug procurement catalog of the hospitals with its own administration region, listing by classification the drugs to be procured through bids, negotiations, direct purchases by hospitals or to be manufactured by appointed manufacturers.

Volume-based Procurement of Drugs

On January 22, 2021, the General Office of the State Council issued the Opinions on Promoting the Normalization and Institutionalization of the VBP of Drugs (《關於推動藥品集中帶量採購工作常態化制度化開展的意見》, the “Normalization Opinions”), which stated that various measures would be adopted to promote the normalization and institutionalization of nationwide VBP. All public medical institutions are required to participate in the VBP program. The procurement program will focus on drugs with high demand and high procurement costs in the National Essential Medicines List, gradually covering clinically necessary, reliable quality drugs available on the domestic market. Future procurement lists are expected to include widely demanded or high-priced drugs in the National Medical Insurance List, aiming to encompass as many clinically necessary and high-quality drugs as possible.

Drug Price

Pursuant to the Drug Administration Law (《藥品管理法》), for drug products with market-regulated prices in accordance with the law, the drug marketing authorization holder, the drug manufacturer, the drug distributor and medical institution shall determine the price pursuant to the principles of fairness, reasonableness, integrity and trustworthiness as well as quality for value in order to supply drug users with reasonably priced drug products; and shall comply with the requirements relating to drug price administration promulgated by the State Council’s pricing authorities, determine and clearly mark the retail prices of drug products. Pursuant to the Notice on Issuing Opinions on Promoting Drug Price Reform (《關於印發<推進藥品價格改革意見>的通知》) jointly promulgated by the NDRC, the NHC, the Ministry of Human Resources and Social Security, the Ministry of Industry and Information Technology of the People’s Republic of China (“MIIT”), the MOF, the MOFCOM and the CFDA on May 4, 2015 and came into effect since June 1, 2015. From June 1, 2015, except for narcotic drugs and first-class psychotropic drugs, the price of drugs set by the government will be cancelled.

Two-invoice System

According to the Circular on Issuing the Implementing Opinions on Carrying out the Two-invoice System for Drug Procurement among Public Medical Institutions (for Trial Implementation) 《印發<關於在公立醫療機構藥品採購中推行“兩票制”的實施意見(試行)>的通知》) (the “Circular”), which was effective from December 26, 2016, the two-invoice system means one invoice between the pharmaceutical manufacturer and the pharmaceutical distributor, and one invoice between the pharmaceutical distributor and the hospital, and thereby only allows a single level of distributor for the sale of pharmaceutical products from the pharmaceutical manufacturer to the hospital.

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Export of Drugs

Pursuant to the Reply by the NMPA on Certain Issues of Pharmaceutical Products Export (《國家藥品監督管理局關於藥品出口有關問題的批覆》), both promulgated on and effective from September 20, 1999, enterprise’s right to operate import and export of pharmaceutical products and the qualification shall be decided by the foreign trade authority. Export of pharmaceutical products shall mainly comply with the requirements of the importing country, so long as there is no special requirement by the importation country, the NMPA would support the export in principle based on the national policy of encouraging exports. However, pursuant to the PRC Drug Administration Law, the export license issued by the NMPA is required for the export of narcotics and psychotropic drugs prescribed by the PRC.

Drug Advertisement

Pursuant to the Advertisement Law of the People’s Republic of China (《中華人民共和國廣告法》), which was promulgated by Standing Committee of the NPC on October 27, 1994 and effective from February 1, 1995 and latest amended and effective from April 29, 2021, advertisements shall not contain false statements or be deceitful or misleading to consumers. Advertisements relating to pharmaceuticals and medical devices, shall be reviewed by relevant authorities in accordance with applicable rules before being distributed by broadcasting, movies, television, newspapers, journals or otherwise.

Laws and Regulations on Intellectual Properties

Patent

Patents in the PRC are mainly protected by the Patent Law of the People’s Republic of China (《中華人民共和國專利法》), which was latest amended on October 17, 2020 and became effective on June 1, 2021, and the Implementation Rules of the Patent Law of the People’s Republic of China (《中華人民共和國專利法實施細則》), which were latest amended on December 11, 2023. The Patent Law of the People’s Republic of China and its Implementation Rules provide for three types of patents, “invention”, “utility model” and “design.” The duration of a patent right for “invention” is twenty years, the duration of a patent right for “utility model” is ten years, and the duration of a patent right for “design” is fifteen years, from the date of application. For the purpose of making up the time required for the assessment and approval of the marketing of a new drug, the patent administrative department of the State Council may, at the request of the patentee, provide patent term extension for an invention patent relating to the new drug approved for marketing in China. The extension may not exceed five years, and the total effective term of the patent after the new drug is approved for marketing shall not exceed 14 years.

Trade Secret

According to the Anti-Unfair Competition Law of the People’s Republic of China (《中華人民共和國反不正當競爭法》), promulgated by the SCNPC in September 1993 and latest amended on April 23, 2019, the term “trade secret” refers to technical and business information that is unknown to the public, has utility, may create business interests or profits for its legal owners or holders, and is maintained as a secret by its legal owners or holders. Under the Anti-Unfair Competition Law of the People’s Republic of China, business persons are prohibited from infringing others’ trade secrets. The parties whose trade secrets are being misappropriated may petition for administrative corrections, and regulatory authorities may stop any illegal activities and impose fines on the infringing parties.

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Trademark

Pursuant to the Trademark Law of the People’s Republic of China (《中華人民共和國商標法》) promulgated by the SCNPC on August 23, 1982, latest amended on April 23, 2019 and became effective on November 1, 2019, the period of validity for a registered trademark is ten years, commencing from the date of registration. Upon expiry of the period of validity, the registrant shall go through the formalities for renewal within twelve 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 ten 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. Industrial and commercial administrative authorities have the authority to investigate any behavior in infringement of the exclusive right under a registered trademark in accordance with the law. In case of a suspected criminal offense, the case shall be timely referred to a judicial authority and decided in accordance with applicable laws.

Copyright

Copyright in the PRC is primarily protected by the Copyright Law of the People’s Republic of China (《中華人民共和國著作權法》), which was promulgated by the SCNPC on September 7, 1990, latest amended on November 11, 2020 and became effective on June 1, 2021, and Implementation Regulations of the Copyright Law of People’s Republic of China (《中華人民共和國著作權法實施條例》), which was promulgated by the State Council on August 2, 2002 and latest amended on January 30, 2013. These laws and regulations provide provisions on the classification of works and the obtaining and protection of copyright.

Domain Names

In accordance with the Measures for the Administration of Internet Domain Names (《互聯網域名管理辦法》) which was issued by the Ministry of Information Industry on August 24, 2017 and came into effect on November 1, 2017, domain name registration services shall, in principle, be subject to the principle of “first apply, first register.”

Laws and Regulations on Labor and Employee Incentives

Labor, Social Insurance and Housing Provident Funds

According to the Labor Law of the People’s Republic of China (《中華人民共和國勞動法》), which was promulgated by the SCNPC and latest amended and came into effect in December 2018, the Labor Contract Law of the People’s Republic of China (《中華人民共和國勞動合同法》), which was promulgated by the SCNPC and amended in December 2012 and came into effect in July 2013, and the Implementing Regulations of the Labor Contracts Law of the People’s Republic of China (《中華人民共和國勞動合同法實施條例》), which was promulgated by the State Council and came into effect in September 2008, labor contracts in written form shall be executed to establish labor relationships between employers and employees. In addition, wages shall not be lower than local minimum wages. The employers must establish a system for labor safety and sanitation, strictly comply with national rules and standards, provide education regarding labor safety and sanitation to its employees, provide employees with labor safety and sanitation conditions and necessary protection materials in compliance with national rules, and carry out regular health examinations for employees engaged at work involving occupational hazards.

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According to the Social Insurance Law of People’s Republic of China (《中華人民共和國社會保險法》), which was promulgated by the SCNPC and latest amended in December 2018, and the Interim Regulations on the Collection and Payment of Social Security Funds (《社會保險費徵繳暫行條例》), which was promulgated by the State Council and latest amended in March 2019, and the Regulations on the Administration of Housing Provident Funds (《住房公積金管理條例》), which was promulgated by the State Council and latest amended in March 2019, employers are required to contribute, on behalf of their employees, to a number of social security funds, including funds for basic pension insurance, unemployment insurance, basic medical insurance, occupational injury insurance and maternity insurance and to housing provident funds. Any employer who fails to make the required contributions may be fined and ordered to compensate the deficit within a stipulated time limit.

On July 31, 2025, the Supreme People’s Court issued Interpretation (II) of the Supreme People’s Court on Issues Concerning the Application of Law in the Trial of Labor Dispute Cases (最高人民法院關於審理勞動爭議案件適用法律問題的解釋(二)), which took effect on September 1, 2025. It stipulates that where an employer and a worker agree or a worker undertakes to an employer that there is no need to pay social insurance premiums, the people’s court shall determine that such an agreement or undertaking is invalid. If the employer fails to pay social insurance premiums in accordance with the law, and the worker files a claim for rescission of the labor contract and payment of economic compensation by the employer in accordance with Article 38(3) of the Labor Contract Law, the people’s court shall support such a claim in accordance with the law.

Laws and Regulations on Environmental Protection

The Environmental Protection Law of the People’s Republic of China (《中華人民共和國環境保護法》) (the “Environmental Protection Law”), which was promulgated by the SCNPC on December 26, 1989, came into effect on the same day and latest amended on April 24, 2014, outlines the authorities and duties of various environmental protection regulatory agencies. The Ministry of Ecology and Environment of the People’s Republic of China is authorized to issue national standards for environmental quality and emissions, and to monitor the environmental protection scheme of the PRC. Meanwhile, local environment protection authorities may formulate local standards which are more rigorous than the national standards, in which case, the concerned enterprises must comply with both the national standards and the local standards.

Regulations on Information Security and Data Privacy

Data security and data export

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》), on June 10, 2021 (effective from September 1, 2021), for the establishment of a data classification and grading protection system to conduct classified and hierarchical protection of data. Entities engaged in data processing activities shall, in accordance with laws and regulations, establish a sound full-process data security management system, organize data security education and training, and take corresponding technical measures and other necessary measures to ensure data security. To clarify the data outbound transfer regulatory mechanism established by the Cybersecurity Law, the Data Security Law, and the Personal Information Protection Law, on July 7, 2022, the Cyberspace Administration of China (the “CAC”) issued the Measures for the Security Assessment of Data Outbound Transfers (《數據出境安全評估辦法》), which took effect on September 1, 2022. The Measures set out the provisions and procedures for the security assessment of the outbound transfer of important data or personal information collected and generated within China. On February 22, 2023, the CAC introduced the Measures for Standard Contract for Outbound Transfer of Personal Information (《個人信息出境標準合同辦法》), which took effect on June 1, 2023, clarifying that personal information processors conducting outbound transfers of personal information through standard contracts must meet certain conditions and file the signed standard contracts with the provincial-level cyberspace administration departments in their locations. On March 22, 2024, the CAC issued the Provisions

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on Promoting and Regulating Cross-order Data Flow (《促進和規範數據跨境流動規定》) (the “Promotion Provisions”), further adjusting the scope, exemptions and procedures applicable to the security assessment of data outbound transfers and the filing mechanism for standard contracts for the outbound transfer of personal information. By this point, China’s regulatory framework for data outbound transfers had largely taken shape. According to the aforementioned measures and provisions, data processors providing data overseas that meet any of the following conditions shall apply for a security assessment of data outbound transfers through the provincial-level cyberspace administration departments in their locations to the national cyberspace administration department: (1) operators of critical information infrastructure providing personal information or important data overseas; and (2) data processors other than operators of critical information infrastructure providing important data overseas, or cumulatively providing personal information (excluding sensitive personal information) of more than 1 million individuals or sensitive personal information of more than 10,000 individuals overseas since January 1 of the current year, unless exempt under the circumstances specified in Articles 3 to 6 of the Promotion Provisions. Data processors other than operators of critical information infrastructure shall file standard contracts for the outbound transfer of personal information with overseas recipients or obtain personal information protection certification in the following scenarios: (1) cumulatively providing personal information (excluding sensitive personal information) of more than 100,000 individuals but less than 1 million individuals overseas since January 1 of the current year; (2) cumulatively providing sensitive personal information of less than 10,000 individuals overseas since January 1 of the current year, unless exempt under the circumstances specified in Articles 3 to 6 of the Promotion Provisions. Our business operations do not involve cross-border data transfer or exchange for overseas data. All the data we collected and generated during our business operations in the PRC is stored in the PRC. Furthermore, the data we process has not been identified or publicly announced as important data by the relevant departments or local regulatory authorities and our business operations do not involve the transfer of important data, personal information, or clinical data cross-border transfer of personal information or important data outside of the PRC. Based on the foregoing, our PRC Legal Advisor is of the view that the likelihood that such measures required by the aforementioned regulations concerning cross-border data transfer apply to our business operations is remote.

Personal information protection

According to the Civil Code of the People’s Republic of China (《中華人民共和國民法典》), personal information of natural persons is protected by law. If any organization or individual needs to obtain other people’s personal information, they should obtain it in accordance with the law and ensure the security of the information. They must not illegally collect, use, process, or transmit other people’s personal information, and must not illegally buy, sell, provide, or disclose the information. 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》) promulgated by the NPCSC on August 20, 2021 and implemented on November 1, 2021, further emphasizes the obligations and responsibilities of processors for the protection of personal information, and requests higher level of protective measures on the processing of sensitive personal information. According to the Cybersecurity Law of the People’s Republic of China (《中華人民共和國網絡安全法》) promulgated by the NPCSC on November 7, 2016 and effective on June 1, 2017, network operators must follow the principles of legality, legitimacy and necessity when collecting and using personal information, and publicly disclose the rules for collection and use, clearly state the purpose, method and scope of collecting and using information, and obtain the consent of the person whose data is being collected. Network operators shall not collect personal information unrelated to the services they provide.

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Laws and Regulations on Anti-corruption and Anti-bribery

Laws and Regulations on Anti-corruption

According to the Criminal Law of the People’s Republic of China (《中華人民共和國刑法》), latest amended by the SCNPC on December 29, 2023, the crime of job appropriation means that an employee of any company, enterprise or any other organization unlawfully takes possession of the money or property of the organization by taking advantage of office, if the amount is relatively large, he shall be sentenced to fixed-term imprisonment of not more than three years or criminal detention and shall be fined concurrently; if the amount is huge, he shall be sentenced to fixed-term imprisonment of not less than three years but not more than ten years and shall be fined concurrently; or if the amount is extremely huge, he shall be sentenced to fixed-term imprisonment of not less than ten years or life imprisonment and shall be fined concurrently.

Laws and Regulations on Anti-bribery

According to the Anti-Unfair Competition Law of the People’s Republic of China (《中華人民共和國反不正當競爭法》) promulgated by the SCNPC, as amended and effective on October 15, 2025, and the Interim Provisions on the Prohibition of Commercial Bribery (《關於禁止商業賄賂行為的暫行規定》) promulgated by the SAIC on November 15, 1996, any 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.

Laws and Regulations on Foreign Exchange and Taxation

Foreign Exchange

On January 29, 1996, the State Council promulgated the Administrative Regulations on Foreign Exchange of the People’s Republic of China (《中華人民共和國外匯管理條例》) which became effective on April 1, 1996 and latest amended on August 5, 2008. Foreign exchange payments under current account items shall, pursuant to the administrative provisions of the foreign exchange control department of the State Council on payments of foreign currencies and purchase of foreign currencies, be made using self-owned foreign currency or foreign currency purchased from financial institutions engaging in conversion and sale of foreign currencies by presenting the valid document. Domestic entities and domestic individuals making overseas direct investments or engaging in issuance and trading of overseas securities and derivatives shall process registration formalities pursuant to the provisions of the foreign exchange control department of the State Council.

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 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 branch office of state administration of foreign exchange 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 document and other disclosure documents.

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Taxation

Enterprise Income Tax

According to the Enterprise Income Tax Law of the People’s Republic of China (《中華人民共和國企業所得稅法》) (the “EIT Law”), promulgated by the NPC and latest amended on December 29, 2018, as well as the Implementation Rules of the EIT Law of the People’s Republic of China (《中華人民共和國企業所得稅法實施條例》) (the “Implementation Rules”), promulgated by the State Council and latest amended on December 6, 2024, enterprises are classified into resident enterprises and non-resident enterprises. A uniform income tax rate of 25% applies to all resident enterprises and non-resident enterprises that have set up institutions or sites in the PRC to the extent that such incomes are derived from their set-up institutions or sites in the PRC, or such incomes are obtained outside the PRC but have an actual connection with the set-up institutions or sites.

Value-Added Tax

Pursuant to the Value-added Tax Law of the PRC, which took effective on January 1, 2026, entities and individuals engaged in sale of goods, services, intangible assets and immovables and importation of goods within the territory of the PRC are VAT payers of VAT and shall pay the VAT in accordance with the law and regulation. The MOF and the STA issued the Notice of on Adjusting VAT Rates (《財政部、國家稅務總局關於調整增值稅稅率的通知》) on April 4, 2018 to adjust the tax rates of 17% and 11% applicable to any taxpayer’s VAT taxable sale or import of goods to 16% and 10%, respectively, this adjustment became effect on May 1, 2018. Subsequently, the MOF, the STA and the General Administration of Customs jointly issued the Announcement on Relevant Policies for Deepening the VAT Reform (《財政部、國家稅務總局關於深化增值稅改革有關政策的公告》) on March 20, 2019 to make a further adjustment, which came into effect on April 1, 2019. The tax rate of 16% applicable to the VAT taxable sale or import of goods shall be adjusted to 13%, and the tax rate of 10% applicable thereto shall be adjusted to 9%.

Laws and Regulations on Overseas Securities Offering and Listing by Domestic Companies

On February 17, 2023, the CSRC promulgated the Overseas Listing Trial Measures and relevant supporting guidelines, which came into effect on March 31, 2023. Any domestic company that is deemed to conduct overseas offering and listing activities shall file with the CSRC in accordance with the Overseas Listing Trial Measures. The Overseas Listing Trial Measures provide that the overseas securities offering and listing will be considered a direct overseas offering by a PRC domestic company if the issuer is a company limited by shares registered and established in Chinese Mainland. Pursuant to the Overseas Listing Trial Measures, an issuer shall file with the CSRC within three business days after its application for initial public offering is submitted to competent overseas securities regulators.

U.S. Outbound Investment Rule

On October 28, 2024, the U.S. Department of the Treasury issued a final rule on outbound investment (“**Outbound Investment Rule**”), which implements Executive Order 14105, *Addressing United States Investments in Certain National Security Technologies and Products in Countries of Concern*. The Outbound Investment Rule became effective on January 2, 2025.

The Outbound Investment Rule aims to mitigate U.S. national security risks associated with investments in sensitive technologies such as semiconductors, artificial intelligence (“**AI**”), quantum computing, and supercomputing in identified “countries of concern”.

Currently, “countries of concern” under the Outbound Investment Rule are limited to the PRC, the Special Administrative Region of Hong Kong, and the Special Administrative Region of Macau.

REGULATORY OVERVIEW

As of January 2, 2025, “U.S. persons” are subject to certain compliance obligations when engaging in certain transactions with “covered foreign persons” from “countries of concern”, which may include a prohibition on the transaction or a notification requirement to the U.S. government within 30 days of completing the transaction.

- The term “**U.S. person**” means any United States citizen, lawful permanent resident, entity organized under the laws of the United States or any jurisdiction within the United States (including any foreign branch of any such entity), or any person in the United States.
- A “**person of a country of concern**” is defined to include individuals and entities with a principal place of business in, who are headquartered in, or organized under the laws of PRC, Hong Kong, and/or Macau, as well as entities majority-owned by individuals from the above jurisdictions.
- “**Covered foreign persons**” are defined to include (1) a “person of a country of concern” that engages in a “covered activity”, and (2) a person that holds ownership or governance over a person identified in (1), if that person derives more than 50% of revenue, net income, capital expenditures, or operating expenses from that entity.
- The term “**covered activities**” means, in the context of a particular transaction, any activities covered by the prohibited transactions and notifiable transactions set forth under the Outbound Investment Rule.
- A “**covered transaction**” means a U.S. person’s direct or indirect:
 - (1) Acquisition of an equity interest or contingent equity interest in a person that the U.S. person knows at the time of the acquisition is a covered foreign person;
 - (2) Provision of a loan or a similar debt financing arrangement to a person that the U.S. person knows at the time of the provision is a covered foreign person, where such debt financing affords or will afford the U.S. person an interest in profits of the covered foreign person, the right to appoint members of the board of directors (or equivalent) of the covered foreign person, or other comparable financial or governance rights characteristic of an equity investment but not typical of a loan;
 - (3) Conversion of a contingent equity interest into an equity interest in a person that the U.S. person knows at the time of the conversion is a covered foreign person, where the contingent equity interest was acquired by the U.S. person on or after January 2, 2025;
 - (4) Acquisition, leasing, or other development of operations, land, property, or other assets in a country of concern that the U.S. person knows at the time of such acquisition, leasing, or other development will result in, or that the U.S. person plans to result in (i) the establishment of a covered foreign person, or (ii) the engagement of a person of a country of concern in a covered activity;
 - (5) Entrance into a joint venture, wherever located, that is formed with a person of a country of concern, and that the subject U.S. person knows at the time of entrance into the joint venture that the joint venture will engage, or plans to engage, in a covered activity; or
 - (6) Acquisition of a limited partner or equivalent interest in a venture capital fund, private equity fund, fund of funds, or other pooled investment fund (in each case where the fund is not a U.S. person) that a U.S. person knows at the time of the acquisition likely will invest in a person of a country of concern that is in the

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semiconductors and microelectronics, quantum information technologies, or artificial intelligence sectors, and such fund undertakes a transaction that would be a covered transaction if undertaken by a U.S. person.

Based on consultation with our legal advisor, the Company’s business activities do not fall under the definition of “covered activities”, and as a result, the Company is not considered a “covered foreign person.” As such, an investment by a “U.S. person” in the H shares of the Company is not a “covered transaction”, and neither prohibited nor subject to the notification requirements under the Outbound Investment Rule.

In addition, on December 18, 2025, U.S. President Trump signed into law the Fiscal Year 2026 National Defense Authorization Act, which includes the Comprehensive Outbound Investment National Security Act of 2025 (“**COINS Act**”). The COINS Act largely codifies the core of the current Outbound Investment Rule while making certain modifications. The COINS Act requires the U.S. Treasury Department to, within 450 days from passage, promulgate new or amended regulations to implement the law. Based on consultation with our legal advisor, the COINS Act does not change our view that the Company’s business activities do not fall under the definition of “covered activities”, and as a result, the Company is not considered a “covered foreign person.”