

REGULATORY OVERVIEW

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

PRINCIPAL REGULATORY AUTHORITIES

The National Medical Products Administration (國家藥品監督管理局) (the “NMPA”) is an authority under the State Administration for Market Regulation (國家市場監督管理總局) (the “SAMR”) and is the primary regulator for medical products. It is primarily responsible for the administrative supervision and technical supervision over the research, production, circulation and usage of drugs, including Traditional Chinese Medicine (“TCM”) in the PRC, organising the formulation and publication of the Chinese Pharmacopeia (《中國藥典》) and the selection, approval, publication and revision of the State Over-the-Counter Medicine Catalogue (《國家非處方藥目錄》). Also the NMPA and its local administrative authorities have a variety of enforcement actions available to enforce its regulations and rules, such as fines and injunctions, recalls or seizure of products, imposition of operating restrictions, partial suspension or complete shutdown of production and transfer to the relevant authorities for criminal investigation. The local administrative authorities at the level of provinces, autonomous regions and municipalities directly under the PRC central government are responsible for the supervision and administration of drugs distribution business within their respective administrative regions.

The National Health Commission of the PRC (中華人民共和國國家衛生健康委員會) (the “NHC”) is the primary national regulator for public health. It is primarily responsible for drafting national health policies, supervising and regulating public health, healthcare services, and health emergency systems, coordinating the reform of medical and health system, organizing the formulation of national drug policies and national essential medicine system, launching an early warning mechanism for the monitoring of the use and clinical comprehensive evaluation of medicine as well as the drug shortage, giving suggestions on the pricing policy of national essential medicine, and regulating the operation of medical institutions and practicing of medical personnel.

The National Administration of TCM of the PRC (中華人民共和國國家中醫藥管理局) (the “SATCM”), a bureau under the governance of the NHC, is responsible for the regulation of TCM industry in the PRC.

The National Healthcare Security Administration (國家醫療保障局) (the “NHSA”). is an authority directly under the State Council of the PRC (中華人民共和國國務院) (the “State Council”) responsible for the management of the healthcare security system. It is primarily responsible for drafting and implementing policies and standards on medical insurance, maternity insurance and medical assistance; supervising and administering the healthcare security funds; organizing the formulation of a uniform medical insurance catalogue and payment standards on drugs, medical disposables and healthcare services; and formulating and supervising the implementation of the bidding and tendering policies for drugs and medical disposables.

LAWS AND REGULATIONS RELATED TO DRUG MANUFACTURING

Drug Manufacturing License

Pursuant to the Drug Administration Law of the PRC (《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 “SCNPC”) lastly amended in August 2019 and came into effect in December 2019, the state adopts an industry entry permit system for drug manufacturers. The conduct of drug manufacturing activities shall be approved and granted with a Drug Manufacturing License (《藥品生產許可證》) by the drug regulatory authority of the people’s government at provincial, autonomous regional or municipal level. According to the Drug Administration Law and Administrative Measures on Supervision of Drug Manufacturing (《藥品生產監督管理辦法》) which was last amended on January 22, 2020 by the SAMR and effective on July 1, 2020, all

REGULATORY OVERVIEW

facilities that manufacture drugs in China must apply for a Drug Manufacturing License which is issued by the drug supervision and administration department of the province, autonomous region or municipality directly under the central government where it is domiciled. The Pharmaceutical Manufacturing Permit is valid for five years and shall be applied for renewal six months before the expiry date.

Good Manufacturing Practice

According to the Drug Administration Law, the enterprises engaging in pharmaceutical production shall abide by the Good Manufacturing Practice for Drugs, establish and improve the quality management system for pharmaceutical production. The Good Manufacturing Practice for Drugs (2010 revised edition) (《藥品生產質量管理規範》(2010年修訂), promulgated on January 17, 2011 by the Ministry of Health of the People’s Republic of China, and became effective on 1 March 2011) (the “2010 GMP”) comprises a set of detailed standard guidelines governing the manufacture of drugs, which includes institution and staff qualifications, production premises and facilities, equipment, hygiene conditions, production management, quality controls, product operation, raw material management, maintenance of sales records and manner of handling customer complaints. The Three Appendixes to the 2010 GMP on TCM Decoction Pieces (《關於發布<藥品生產質量管理規範(2010年修訂)>中藥飲片等3個附錄的公告) promulgated by the China Food and Drug Administration (國家食品藥品監督管理總局) (the “CFDA”) on June 27, 2014 and became effective on July 1, 2014 specifies the requirements on staff qualifications, production premises and facilities, materials and products, equipment, validation, documentation management, production management, as well as quality control for the production of TCM decoction pieces.

Pursuant to the Notice of the CFDA, the Ministry of Health, and the SATCM on Strengthening the Supervision and Administration of TCM Decoction Pieces (《國家食品藥品監督管理局、衛生部、國家中醫藥管理局關於加強中藥飲片監督管理的通知》) issued on January 5, 2011, manufacturers of TCM decoction pieces shall obtain a Drug Manufacturing License and a GMP certificate. Pursuant to the Circular on the Relevant Issues Concerning the Implementation of the Drug Administration Law of the PRC (《關於貫徹實施<中華人民共和國藥品管理法>有關事項的公告》), promulgated by the NMPA on November 29, 2019, and the Drug Administration Law, since December 1, 2019, the GMP and Good Supply Practice (the “GSP”) certifications have been canceled, applications for GMP and GSP certifications are no longer accepted, and GMP and GSP certificates are no longer issued. The legal representative of and principal person in charge of a drug manufacturer are fully responsible for the drug manufacturing activities of the enterprise.

The Administrative Measures for the Inspection of Pharmaceuticals (Trial) (《藥品檢查管理辦法(試行)》) was promulgated by the NMPA on May 24, 2021 and amended on July 19, 2023, and the Certification Measures for Good Manufacturing Practice for Drugs was repealed simultaneously. The Administrative Measures for the Inspection of Pharmaceuticals (Trial) stipulated that if a drug manufacturer applies for a drug manufacturing license for the first time, it will be subject to on-site inspection under relevant contents of the GMP. If a drug manufacturer applies for re-issuance of drug manufacturing license, relevant authorities shall conduct examination pursuant to risk management principle, considering the enterprise’s compliance with pharmaceutical administration laws and regulations, operation status of GMP and quality system, and may conduct GMP compliance inspection, if necessary.

Toxic Decoction-ready Products

According to the Medical Toxic Pharmaceuticals Management Procedure (《醫療用毒性藥品管理辦法》) promulgated by the State Council on December 27, 1988 and effective on the same date, the operation of toxic decoction-ready medicinal materials requires obtaining the corresponding business license. The operation of toxic decoction-ready medicinal materials includes the links of purchase, wholesale, and retail. Pursuant to the Decision of the State Council on the Fifth Batch of Cancellation and Delegation of Administrative Approval Items (Guofa [2010]

REGULATORY OVERVIEW

No.21) (《國務院關於第五批取消和下放管理層級行政審批項目的決定》國發[2010]21號), the business license for toxic decoction-ready medicinal materials is approved by the provincial people's government's food and drug administration department.

Precursor Chemicals

According to the Regulations on the Administration of Precursor Chemicals (《易制毒化學品管理條例》), promulgated by the State Council on August 26, 2005, last amended on September 18, 2018 and became effective on the same date), the precursor chemicals are classified into three categories. Category I includes the major materials that can be used for producing drugs. Categories II and III include the chemical consumable/additives that can be used for producing drugs. An entity purchasing any precursor chemicals in Category II or III shall, prior to the purchase, shall file an information report about the type and quantity in demand for record, with the public security organ of the local people's government at the county level.

Chinese Pharmacopoeia

According to the provisions of the Drug Administration Law (《藥品管理法》), drugs shall comply with the national drug standards. The Chinese Pharmacopoeia is (《中國藥典》) an important part of the national drug standards and is the legal technical standard. All relevant units involved in drug research and development, production (import), operation, use and supervision and management shall follow. All drug marketing authorization holders and drugs produced and marketed shall implement the relevant requirements of the latest edition of the Chinese Pharmacopoeia. The 2020 edition of the Chinese Pharmacopoeia was promulgated by the NMPA and the NHC on June 24, 2020, and came into effect on December 30, 2020. The 2025 edition of the Chinese Pharmacopoeia was promulgated by the National Medical Products Administration and the National Health Commission on March 25, 2025, and has come into effect on October 1, 2025.

The Protection of Wildlife and Livestock and Poultry

According to the Law on the Protection of Wildlife of the PRC (《中華人民共和國野生動物保護法》), promulgated by the SCNPC on November 8, 1988, and last amended on December 30 2022 and became effective on May 1, 2023, the sale, purchase or use of the wild animals under the state priority protection and the products thereof, for scientific research, artificial breeding, public display, cultural relics protection or under other special circumstances, shall be subject to the approval of the wildlife protection authorities under the people's governments of the provinces, autonomous regions or municipalities directly under the Central Government, and shall be required to obtain and use designated marks to ensure traceability. In September 30, 2020, the National Forestry and Grassland Administration promulgated Notice on Standardizing the Scope of Classified Management of wild Animals that are Banned for Consumption (關於規範禁食野生動物分類管理範圍的通知) to restrict the use of wild medicinal animal resource. According to the Decision of the Standing Committee of the National People's Congress on a Complete Ban of Illegal Wild Animals Trade and the Elimination of the Unhealthy Habit of Excessive Consumption of Wild Animals for the Protection of Human Life and Health (《全國人民代表大會常務委員會關於全面禁止非法野生動物交易、革除濫食野生動物陋習、切實保障人民群眾生命健康安全的決定》), promulgated on February 24, 2020, animals on the list of livestock and poultry genetic resources shall be classified as livestock and poultry and governed by the Animal Husbandry Law of the PRC (《中華人民共和國畜牧法》).

Under such policies, although prohibited from breeding for the purpose of providing food, certain wild animals are allowed for breeding for medicinal purpose. In March 2023, the National Forestry and Grassland Administration and the Ministry of Agriculture and Rural Affairs promulgated Measures for Quarantine of Wild Animals (《野生動物檢疫辦法》), according to which wild animals that need to be utilized for non-food purposes due to special circumstances such as medicinal use shall be quarantined and qualified in accordance with the relevant provisions before they can be utilized.

REGULATORY OVERVIEW

The Protection of Wild Plants and Wild Medicinal Resources

Pursuant to the Regulations of the People’s Republic of China on the Protection of Wild Plants (《中華人民共和國野生植物保護條例》), promulgated by the State Council on September 30, 1996, and last amended on October 7, 2017 and became effective on the same date, the collection of national first-class protected wild plants is prohibited. For special needs such as scientific research, artificial cultivation, and cultural exchanges, those who wish to collect national first-class protected wild plants shall apply for a collection permit to related forestry administrative department. For the collection of national second-class protected wild plants, approval from the wild plant administrative department of the county-level people’s government at the collection site is required. The sale and purchase of national first-class protected wild plants are prohibited. The sale and purchase of national second-class protected wild plants must be approved by the wild plant administrative department of the people’s government of the province, autonomous region, or municipality directly under the central government, or by its authorized agency.

According to the Regulation on Protection of Wild Medicinal Resources (《野生藥材資源保護管理條例》) promulgated by the State Council on October 30, 1987 and effective on the December 1, 1987, wild medicinal species under first-class shall be prohibited from being gathered, and the hunting and purchasing of wild medicinal plant species under second and third-class protection must be carried out in accordance with the approved plan.

LAWS AND REGULATIONS RELATED TO DRUG OPERATIONS

Drug Business Permit

In September 1984, the SCNPC promulgated the Drug Administration Law (《藥品管理法》), which was amended in 2001, 2013, 2015 and 2019 respectively to regulate all entities or individuals engaging in research, manufacture, operation, use, supervision and management of drugs within the PRC. According to the Drug Administration Law (《藥品管理法》), no pharmaceutical operation, including pharmaceutical wholesale and pharmaceutical retail business, is permitted without obtaining the Pharmaceutical Operation License. Where the trading of drugs is conducted without a Drug Business Permit, the illegal incomes by selling drugs shall be confiscated and the local medical products administrative authorities shall impose the fine ranging from 15 to 30 times of the value of the illegally sold drugs (including sold or unsold drugs). The Implementation Rules for the Drug Administration Law (《藥品管理法實施條例》), was promulgated by the State Council in August 2002 and amended in 2016, 2019 and 2024, which emphasized the detailed implementation rules of drugs administration.

The Administrative Standard of Pharmaceutical Operating Quality (《藥品經營質量管理規範》), promulgated by the CFDA in April 2000 and amended in 2013, 2015 and 2016 respectively, the pharmaceutical operation enterprises shall take effective quality control measures over the process of procurement, storage, transportation and sale of drugs in order to ensure their quality.

As required by the Measures for the Quality Supervision and Management of the Operation and Use of Drugs (《藥品經營和使用質量監督管理辦法》) which was promulgated by the SAMR on September 27, 2023, and effective on the January 1, 2024, operation of drug business, including drug wholesale and drug retail, is prohibited without a Drug Business Permit. A Drug Business Permit shall state the validity period and the scope of business and be subject to review and reissuance upon expiry of the validity period.

Drug Price

In China, governmental pricing controls on drugs (other than narcotic and certain psychiatric drugs) have been lifted since June 2015 when the Opinions on Advancing Drug Price Reform (《推進藥品價格改革意見》) came into effect. Instead of direct governmental controls, the government exercises control over the drugs through establishing a centralized tender process or centralized procurement mechanism, revising the National Reimbursement Drug List (《國家醫療保險藥品目錄》) or provincial medical insurance drug catalogues and strengthening regulation of medical and pricing practices.

REGULATORY OVERVIEW

On October 20, 2019, the Central Committee of the Communist Party of China and the State Council issued the Opinions on Promoting the Inheritance and Innovation of Traditional Chinese Medicine (《關於促進中醫藥傳承創新發展的意見》), proposing to study the cancellation of the markup on TCM decoction-ready products.

According to the Guiding Opinions on Medical Insurance Support for the Inheritance and Innovation of Traditional Chinese Medicine (Document No. 229 [2021] of the Medical Insurance Office) (《關於醫保支持中醫藥傳承創新發展的指導意見》(醫保函(2021)229號)), jointly issued by the NHTA and the National Administration of TCM on December 14, 2021, public medical institutions shall purchase traditional Chinese medicine decoction pieces through regular channels and sell them with a markup not exceeding 25% of the actual purchase price. If public medical institutions are unable to provide actual purchase invoices for TCM decoction-ready products, they may refer to the purchase prices of social pharmacies in their region as the basis for supervision.

LAWS AND REGULATIONS RELATED TO INTERNET DRUG TRANSACTIONS SERVICES AND INFORMATION SERVICES

In August 3 2022, SAMR published the Measures for the Supervision and Administration of Online Pharmaceuticals Sales (“the Online Pharmaceuticals Sales Measures”) (《藥品網絡銷售監督管理辦法》), aiming to enhance the supervision of online drug sales and related platform services. The Measures provides specific and explicit rules for the online sales of TCM decoction-ready products. This Measures stipulates that enterprises producing TCM decoction-ready products must fulfill the relevant obligations of a marketing authorization holder when selling the TCM decoction-ready products they produce. Enterprises engaging in the online sale of pharmaceuticals must operate in accordance with the approved business methods and scope of operations. If an online pharmaceutical sales enterprise is a marketing authorization holder, it is only permitted to sell the drugs for which it has obtained a drug registration certificate. Enterprises without a retail qualification for pharmaceuticals are prohibited from selling drugs to individuals.

According to the Measures Regarding the Administration of Drug Information Service over the Internet (《互聯網藥品信息服務管理辦法》), promulgated by CFDA on July 8, 2004 and amended on November 17, 2017, the operational Internet drug information service refers to the activities of providing medical information (including medical devices) and other services to Internet users through the Internet, and where any website intends to provide Internet drug information services, it shall, prior to applying for an operation permit or record-filing from the State Council’s department in charge of information industry or the telecom administrative authority at the provincial level, file an application with the provincial FDA, and shall be subject to the examination and approval thereof for obtaining the qualifications for providing Internet drug information services. The validity term for a Qualification Certificate for Internet Drug Information Services is five years and may be renewed at least six months prior to its expiration date upon a re-examination by the relevant authority. Pursuant to the Measures Regarding the Administration of Drug Information Service over the Internet, the Internet drug information services are classified into two categories, namely, profit-making services and non-profit-making services. Profit-making services refers to that of providing Internet users with drug information in return for service fees whilst non-profit-making services refers to that of providing Internet users with drug information which is shared and accessible by the public through the Internet free of charge. Furthermore, the information relating to drugs shall be accurate and scientific in nature, and its provision shall comply with the relevant laws and regulations. No product information of narcotic drugs, psychotropic substances, toxic drugs for medical use, radioactive drugs, drugs for external use and over-the-counter drugs made by medical institutes shall be distributed on the website. In addition, advertisements relating to drugs (including medical devices) shall be approved by the NMPA or its competent branches, and shall specify the approval document number.

REGULATORY OVERVIEW

LAWS AND REGULATIONS RELATED TO INTERNET INFORMATION SERVICES

Pursuant to the Administrative Measures on Internet Information Services (《互聯網信息服務管理辦法》) promulgated by the State Council on September 25, 2000 and last amended on December 6, 2024 and the Administration Measures for the Filing of Not-for-profit Internet Information Services (《非經營性互聯網信息服務備案管理辦法》) released on February 8, 2005 by the former Ministry of Information Industry, effective from March 20, 2005 and last revised on January 18, 2024, internet information services are classified into “for-profit internet information services” and “not-for-profit internet information services.” The for-profit internet information service refers to service activities to provide information or website design to online users for profit; the not-for-profit internet information service refers to service activities to provide online users open, shared information on internet free of charge. The national government has installed the filing system for not-for-profit internet information service. Whoever intends to provide not-for-profit internet information service through the websites visited via internet domain names or through the websites which can only be visited via IP address within the territory of the PRC shall go through filing procedures in accordance with law. Such not-for-profit internet information service provider shall, when its website is available, display its filing number at the central part on the bottom of its home page and link the URL of the filing administration system of the Ministry of Industry and Information Technology of the PRC (the “MIIT”), below the filing number for consultation and check by the public. Furthermore, an annual review procedure is required for the not-for-profit internet information service provider to go through on the filing administration system of the MIIT at a specified time each year.

Mobile internet application is subject to monitoring by the Administrative Provisions on Mobile Internet Application Information Services (《移動互聯網應用程序信息服務管理規定》) promulgated by the Cyberspace Administration of China (the “CAC”) on June 28, 2016 and amended on June 14, 2022 and such amendment took effect on August 1, 2022. Under these provisions, the application providers shall establish sound information content review and management mechanism by erecting and improving measures such as user registration, account management, information review, daily inspection and emergency disposal and be staffed with professionals and technical ability appropriate to the service scale.

Pursuant to the Notice of the Ministry of Industry and Information Technology on the Record-filing of Mobile Internet Apps (《工業和信息化部關於開展移動互聯網應用程序備案工作的通知》), promulgated by the MIIT on July 21, 2023 and took effective on the same day, any APP sponsor that engages in Internet information services within the territory of the PRC shall go through the record-filing formalities in accordance with the Administrative Measures on Internet-based Information Services and other regulations. Any APP sponsor that fails to complete the record-filing formalities shall not engage in APP Internet information services.

LAWS AND REGULATIONS RELATED TO DRUG RECALLS

According to the Measures on Drug Recall (《藥品召回管理辦法》) promulgated on October 2022 and effective from November 1, 2022, a drug manufacturer should establish and improve its recall system by collecting relevant information about drug safety and conducting investigation and evaluation with respect to the drugs with potential safety hazards. If there are any potential safety hazards that endanger human health and life safety in respect of any drugs sold in PRC, such manufacturer must start the drug recall procedures. Where a drug is recalled, the drug operating and using institutions should assist such marketing authorization holder to satisfy its recall obligations by communicating the drug recall information and any feedback, controlling and recovering such drugs according to the recall plan. The recall of TCM decoction-ready products and formula granules shall be implemented by their manufacturing enterprises in accordance with the Measures on Drug Recall.

REGULATORY OVERVIEW

LAWS AND REGULATIONS RELATED TO DRUG ADVERTISEMENT

Pursuant to the Advertisement Law of the PRC (《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. The Advertisement Law further stipulates that advertisements for medical treatment, pharmaceutical products or medical devices shall not contain: (i) any assertion or guarantee for efficacy and safety; (ii) any statement on treatment rate or effectiveness rate; (iii) any comparison with the efficacy and safety of other pharmaceutical products or medical devices or with other healthcare institutions; (iv) recommendation or endorsement of an advertising endorser; or (v) other items as prohibited by laws and regulations.

Pursuant to the Measures for Administration of Medical Advertisement (《醫療廣告管理辦法》), which were jointly promulgated by the State Administration for Industry and Commerce and the Ministry of Health on November 10, 2006 and effective on January 1, 2007, medical advertisements shall be reviewed by relevant health authorities and obtain a Medical Advertisement Examination Certificate shall be obtained before being released. Medical Advertisement Examination Certificate is valid for one year and shall be renewed upon application.

REGULATIONS ON CENTRALIZED PROCUREMENT

On November 15, 2018, the Joint Procurement Office of the State Council published the Papers on Drug Centralized Procurement in “4+7 Cities” (《4+7城市藥品集中採購文件》), which launched the national pilot scheme for centralized volume-based drug procurement in the public medical institutions. The pilot scheme will be carried out in 11 cities, including Beijing, Tianjin, Shanghai, Chongqing, Shenyang, Dalian, Xiamen, Guangzhou, Shenzhen, Chengdu and Xi’an, the 4+7 Cities. On January 1, 2019, the General Office of the State Council also published the Notice of the General Office of the State Council on the Promulgation of the Pilot Program for Centralized Drug Procurement and Use Organized by the State (《國務院辦公廳關於印發〈國家組織藥品集中採購和使用試點方案〉的通知》), which provides detailed measures for the implementation of the national pilot scheme for centralized volume-based drug procurement in the 4+7 Cities.

On the basis of the centralized volume-based drug procurement implemented by 4+7 cities, the Joint Procurement Office issued The Document for Centralized Drug Procurement in the Alliance area (GY-YD2019-1) (《聯盟地區藥品集中採購文件(GY-YD2019-1)》) in September 2019, according to which the alliance area includes the provinces and autonomous regions of Shanxi, Inner Mongolia, Liaoning, Jilin, Heilongjiang, Jiangsu, Zhejiang, Anhui, Jiangxi, Shandong, Henan, Hubei, Hunan, Guangdong, Guangxi, Hainan, Sichuan, Guizhou, Yunnan, Xizang, Shanxi, Gansu, Qinghai, Ningxia and Xinjiang (including Xinjiang Production and Construction Army Unit) other than the 4+7 cities.

On January 22, 2021, the General Office of the State Council issued the Opinions on Promoting the Normalization and Institutionalization of the Centralized Volume-based Procurement 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》), stating that various measures will be taken to promote the normalization and institutionalization of the centralized volume-based procurement of drugs nationwide. All public medical institutions are required to participate in the centralized drug procurement program. The future procurement catalog will include drugs with high market demand or high procurement prices that are included in the NRDL, and is expected to cover, as far as possible, domestically marketed drugs with clinical utility and reliable quality.

REGULATORY OVERVIEW

According to the Notice on Strengthening Regional Collaboration and Improving the Quality and Expanding the Scope of Medical and Pharmaceutical Centralized Procurement in 2024 (Medical Insurance Office [2024] No. 8) (《關於加強區域協同做好2024年醫藥集中採購提質擴面的通知》(醫保辦發(2024)8號)), issued by the Office of the NHTA on May 14, 2024, provinces with conditions are encouraged to take the lead in conducting national joint procurements, focusing on covering chemical drugs that have not passed the consistency evaluation, Chinese patent medicines, and TCM decoction-ready products. The NHTA will provide key guidance, including leading Shandong in carrying out the national joint procurement of TCM decoction-ready products through an alliance procurement.

According to the Centralized Procurement Document of the National TCM Decoction-Ready Products Procurement Alliance (ZYYPLM-2024-1) (《全國中藥飲片採購聯盟集中採購文件(ZYYPLM-2024-1)》) issued by the National TCM decoction-ready products Procurement Alliance Office (the 2024, medical institutions in the alliance regions will carry out centralized volume-based procurement of TCM decoction-ready products. Representatives from each province, autonomous region, municipality directly under the central government, and the Xinjiang Production and Construction Corps have formed the Alliance Office. Under the guidance of the NHTA, the Alliance Office represents the relevant medical institutions in various regions to carry out centralized and bulk procurement of TCM decoction-ready products. The Shandong Provincial Medical Security Administration is responsible for the day-to-day operations and the specific implementation. This centralized volume-based procurement of TCM decoction-ready products in the alliance regions includes 45 varieties, such as Astragalus (黃芪), Codonopsis (黨參), Dwarf lilyturf (麥冬), Angelica Sinensis (當歸), and other types. In addition, the Centralized Procurement Document of the National TCM Decoction-Ready Products Procurement Alliance (ZYYPLM-2024-1) (《全國中藥飲片採購聯盟集中採購文件(ZYYPLM-2024-1)》) has stipulated the centralized procurement process and details related to the procurement of TCM decoction-ready products, including the types of TCM decoction-ready products to be procured, the required procurement quantities, the procurement cycle, the qualifications of the enterprises applying for the procurement, and the determination of the selected medicines.

TWO-INVOICE SYSTEM

In order to further optimize the order of purchasing and selling pharmaceutical products and reduce circulation steps, as required at the executive meeting of the State Council dated April 6, 2016 and under the 2016 List of Major Tasks in Furtherance of the Healthcare and Pharmaceutical Reforms (《深化醫藥衛生體制改革2016年重點工作任務》) issued by the General Office of the State Council on April 21, 2016, the “two-invoice System” (兩票制) will be fully implemented in the PRC. 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 public hospital, and thereby only allows a single level of distributor for the sale of pharmaceutical products from the pharmaceutical manufacturer to the public hospital. According to the Circular, two-invoice system will be promoted in pilot provinces (autonomous regions and municipalities directly under the Central Government) involved in the comprehensive medical reform program and pilot cities for public hospital reform on a priority basis, while other regions are encouraged to implement such system, so that such system can be promoted in full swing nationwide in 2018.

According to the opinions on the implementation of the “two-invoice system” for drug procurement in public medical institutions currently issued by various provinces including Beijing, Hunan, Zhejiang, Anhui, etc., TCM decoction-ready products are temporarily not included within the scope of drugs subject to the “two-invoice system.”

REGULATORY OVERVIEW

REGULATIONS RELATED TO DRUG DIRECTIONS AND LABELS

According to the Drug Administration Law, each piece of drug packaging shall, as required, be printed or affixed with a label with an insert sheet attached. Labels and insert sheets for narcotic drugs, psychotropic substances, toxic drugs for medical use, radioactive drugs, drugs for external use and over-the-counter drugs shall be printed with specified marks as required. Pursuant to the Administrative Provisions on Drug Directions and Labels (《藥品說明書和標籤管理規定》), promulgated on 15 March 2006 and became effective on 1 June 2006), drug directions and labels shall be subject to the ratification of the State Food and Drug Administration. The labels of a drug shall be based on its directions, and the contents thereof shall not exceed the scope of the directions, and may not be printed with any word or mark that implies the curative effect, misleads the use or inappropriately advertises the product. The package of a drug must be printed or affixed with the label according to the provisions, and shall not carry other literal or video materials or other information that advertises the product or the enterprise. The smallest packages produced by a drug manufacturing enterprise for sale on the market must be attached with directions. The drug directions, the interior labels and exterior labels as well as names shall comply with the relevant provisions.

According to the “Regulations on the Label Management of TCM Decoction-Ready Products” (《中藥飲片標籤管理規定》) issued by the NMPA on July 12, 2023, and effective from August 1, 2024, the packaging and labeling of TCM decoction-ready products shall be standardized. The packaging shall be printed with or affixed with labels in accordance with the regulations and shall be accompanied by a quality compliance mark. The label of TCM decoction-ready products shall bear the wording “TCM Decoction-Ready Products” to explicitly indicate the product’s nature. For TCM decoction-ready products that are toxic medicinal products for medical use or anesthetic drugs, their labels shall bear the prescribed special identification marks to avoid errors in medical use. The labels of TCM decoction-ready products involving the use of nationally protected wild animals and their products shall comply with relevant national regulations.

REGULATIONS RELATED TO NATIONAL MEDICAL INSURANCE PROGRAM

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

Pursuant to the Tentative Measures for the Administration of the Scope of Medical Insurance Coverage for Pharmaceutical Products for Urban Employee (《城鎮職工基本醫療保險用藥範圍管理暫行辦法》), the scope of medical insurance coverage for pharmaceutical products needs to be managed through the formulation of the Medical Insurance Catalog. A pharmaceutical product listed in the Medical Insurance Catalog must be clinically needed, safe, effective, reasonably priced, easy to use, available in sufficient quantity, and must meet the following requirements: it is set forth in

REGULATORY OVERVIEW

the Pharmacopoeia of the PRC (current edition) (《中華人民共和國藥典》(現行版)); it meets the standards promulgated by the NMPA; and if imported, it is approved by the NMPA for import. According to the Opinions of the NHSA and the Ministry of Finance on Establishing a List-Based System for Healthcare Security Benefits (《國家醫保局、財政部關於建立醫療保障待遇清單制度的意見》), which came into effect in January 2021, all provinces shall implement the NRDL in a strict manner, and shall not have the discretion to formulate the catalog or increase the drugs in any form, or adjust the scope of limited payment unless explicitly stipulated. On December 14, 2021, the NHSA and the National Administration of TCM jointly issued the Guiding Opinions on Medical Insurance Support for the Inheritance and Innovation of Traditional Chinese Medicine (Document No. 229 [2021] of the Medical Insurance Office) (《關於醫保支持中醫藥傳承創新發展的指導意見》(醫保函(2021)229號)), proposing that qualified TCM decoction-ready products be included in the medical insurance drug directory as stipulated. Localities should, according to the financial capacity of the medical insurance fund and clinical needs, follow procedures to include qualified traditional Chinese medicine decoction pieces within the local medical insurance payment scope, and establish a dynamic adjustment mechanism. After several adjustments, the currently effective one is the National Insurance Drug List for Basic Medical Insurance, Work-related Injury Insurance and Maternity Insurance (2024) (《國家基本醫療保險、工傷保險和生育保險藥品目錄(2024年)》) (the “National Insurance Drug List (2024)”) (“《國家保險藥品目錄(2024)》”), which came into effect on January 1, 2025, and amended and effect on January 6, 2025. According to the National Insurance Drug List (2024), more than 800 types of TCM decoction-ready products have been included in the scope of medical insurance fund coverage, including Rhizoma pinelliae preparatum (法半夏), Ginger processed pinelliae (薑半夏), Rhizoma pinelliae preparata (清半夏), Fritillaria cirrhosa (川貝母), Dwarf lilyturf (麥冬), Astragalus (黃芪), and other types of TCM decoction-ready products.

LAWS AND REGULATIONS RELATED TO PRODUCT LIABILITY

In addition to the strict drug approval process, certain PRC laws have been promulgated to protect the rights of consumers and to strengthen the control of medical products in the PRC. Under current PRC law, manufacturers and vendors of defective products in the PRC may incur liability jointly for loss and injury caused by such products. According to the Civil Code of the PRC (《中華人民共和國民法典》), which was promulgated in May 2020 and became effective in January 2021, a defective product which causes property damage or physical injury to any person may subject the manufacturer or vendor of such product to civil liability for such damage or injury. If a patient suffers damage due to defects in drugs, he may seek compensation from the drug marketing authorization holder or also from the medical institution. Where the patient seeks compensation from the medical institution, the medical institution, after it has made the compensation, shall have the right to recover the compensation from the liable drug marketing authorization holder.

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

The Law of the PRC on the Protection of the Rights and Interests of Consumers (《中華人民共和國消費者權益保護法》), or the Consumer Protection Law, was promulgated in October 1993 and amended in August 2009 and October 2013 to protect consumer rights when they purchase or use goods and services. According to the Consumer Protection Law, all business operators must comply with this law when they manufacture or sell goods and/or provide services to customers. Under the latest amendment, all business operators shall protect the customers’ privacy and keep any consumer information they obtain during the business operation strictly confidential. In addition, in extreme situations, drug manufacturers and operators may be subject to criminal liability if their goods or services lead to the death or injuries of customers or other third parties.

REGULATORY OVERVIEW

LAWS AND REGULATIONS RELATED TO ANTI-UNFAIR COMPETITION

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

According to the Interim Provisions on the Prohibition of Commercial Bribery (《關於禁止商業賄賂行為的暫行規定》), which was promulgated by the State Administration for Industry and Commerce, which was replaced by the SAMR, on November 15, 1996, commercial bribery refers to an act of offering money or property or using other means by an operator to the other entity or individual for the purposes of selling or buying goods, among which "other means" refer to the means used to provide any types of benefits other than money or property, such as offering overseas or domestic travel. According to the Anti-Unfair Competition Law and the Interim Provisions on the Prohibition of Commercial Bribery, regulatory authorities may impose fines depending on the seriousness of the cases and if there is any illegal income, such income shall be confiscated.

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

Besides, according to the Anti-Unfair Competition Law, trade secrets refer to business information that is unknown to the public, have commercial value and is maintained as a secret by its legal owners or holders. Business persons are prohibited from infringing others' trade secrets. If a third party knows or should have known of the infringement but nevertheless obtains, uses or discloses trade secrets of others, the third party may be deemed to have committed a misappropriation of the others' trade secrets.

LAWS AND REGULATIONS RELATING TO ENVIRONMENTAL PROTECTION AND FIRE PREVENTION

Environment Protection

The Environmental Protection Law of the PRC (《中華人民共和國環境保護法》), which was promulgated by the SCNPC on December 26, 1989, came into effect on the same day and last amended on April 24, 2014, outlines the authorities and duties of various environmental protection regulatory agencies. The Ministry of Environmental Protection is authorized to issue national standards for environmental quality and emissions, and to monitor the environmental protection scheme of the PRC. Meanwhile, local environmental 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.

REGULATORY OVERVIEW

Environmental Impact Appraisal

According to the Administration Rules on Environmental Protection of Construction Projects (《建設項目環境保護管理條例》), or the Construction Environmental Protection Rule, which was promulgated by the State Council on November 29, 1998, amended on July 16, 2017 and became effective on October 1, 2017, depending on the impact of the construction project on the environment, a construction entity shall submit an environmental impact report or an environmental impact statement, or file a registration form. As to a construction project, for which an environmental impact report or the environmental impact statement is required, the construction entity shall, before the commencement of construction, submit the environmental impact report or the environmental impact statement to the relevant authority at the environmental protection administrative department for approval. If the environmental impact assessment documents of the construction project have not been examined or approved upon examination by the approval authority in accordance with the law, the construction entity shall not commence the construction.

According to the Environmental Impact Appraisal Law of PRC (《中華人民共和國環境影響評價法》), which was promulgated by the SCNPC on October 28, 2002, amended on July 2, 2016 and December 29, 2018, for any construction projects that have an impact on the environment, an entity is required to produce either a report, or a statement, or a registration form of such environmental impacts depending on the degree of effect that may be exerted on the environment.

The Construction Environmental Protection Rule also requires that upon completion of construction for which an environment impact report or environment impact statement is formulated, the constructor shall conduct acceptance inspection of the environmental protection facilities pursuant to the standards and procedures stipulated by the environmental protection administrative authorities of the State Council, formulate the acceptance inspection report, and announce the acceptance inspection report pursuant to the law except for circumstances where there is a need to keep confidentiality pursuant to the provisions of the State. Where the environmental protection facilities have not undergone acceptance inspection or do not pass acceptance inspection, the construction project shall not be put into production or use.

Urban Drainage and Sewage Treatment

Enterprises that engage in the activities of industry, construction, catering, and medical treatment, etc. that discharges sewage into urban drainage facilities shall apply to the relevant competent urban drainage department for collecting the permit for discharging urban sewage into drainage pipelines under relevant laws and regulations, including the Regulations on Urban Drainage and Sewage Disposal (《城鎮排水與污水處理條例》), which was promulgated on October 2, 2013 and came into force on January 1, 2014, and the Measures for the Administration of Permits for the Discharge of Urban Sewage into the Drainage Network (《城鎮污水排入排水管道許可管理辦法》), which was promulgated on January 22, 2015 and was amended on December 1, 2022 and became effective on February 1, 2023. Drainage entities covered by urban drainage facilities shall discharge sewage into urban drainage facilities in accordance with the relevant provisions of the state. Where a drainage entity needs to discharge sewage into urban drainage facilities, it shall apply for a drainage license in accordance with the provisions of these Measures. The drainage entity that has not obtained the drainage license shall not discharge sewage into urban drainage facilities.

According to the Administrative Measures on Pollutant Discharge Permit issued by the Ministry of Ecology (《排污許可管理辦法》) and Environment on April 1, 2024 and came into effect on July 1, 2024, enterprises, public institutions and other producers and operators that are subject to the administration of pollutant discharge permits shall apply for pollutant discharge permit and discharge pollutants in accordance with the requirements of the pollutant discharge permit; and those who have not obtained the pollutant discharge permits shall not discharge pollutants. According to the Classification Management List for Fixed Source Pollution Permits (2019 Edition) (《固定污染源排污許可分類管理名錄(2019年版)》), the manufacturing of biological drugs and products falls into the classification management scope for fixed source pollution permits.

REGULATORY OVERVIEW

Fire Prevention Design and Acceptance

The Fire Prevention Law of the PRC (《中華人民共和國消防法》), or the Fire Prevention Law, was adopted on April 29, 1998 and latest amended on April 29, 2021. According to the Fire Prevention Law, for special construction projects stipulated by the housing and urban-rural development authority of the State Council, the developer shall submit the fire safety design documents to the housing and urban-rural development authority for examination, while for construction projects other than those stipulated as special development projects, the developer shall, at the time of applying for the construction permit or approval for work commencement report, provide the fire safety design drawings and technical materials which satisfy the construction needs. According to Interim Regulations on Administration of Examination and Acceptance of Fire Control Design of Construction Projects (《建設工程消防設計審查驗收管理暫行規定》) issued by the Ministry of Housing and Urban-Rural Development of the PRC on April 1, 2020 and amended on August 21, 2023, an examination system for fire prevention design and acceptance only applies to special construction projects, and for other projects, a record-filing and spot check system would be applied.

LAWS AND REGULATIONS RELATED TO HOUSING LEASING

Pursuant to the Urban Real Estate Administration Law of the People's Republic of China (《中華人民共和國城市房地產管理法》) promulgated on July 5, 1994, last amended on August 26, 2019 with effect on January 1, 2020, when leasing a house, the lessor and lessee shall sign a written lease contract, prescribing such provisions as the leasing term, use of the house, rental and repair liabilities, and other rights and obligations of both parties; and go through registration procedures for record with the real estate administration department.

According to the PRC Civil Code, a lessee may, upon the lessor's consent, sublease the leased object to a third person. The lease contract between the lessee and the lessor shall continue to be valid despite the sublease by the lessee, and if the third person causes loss to the leased object, the lessee shall bear the liability for compensation. Where a lessee subleases the leased object without the consent of the lessor, the lessor may rescind the contract. Where a lessee, upon consent of the lessor, subleases the leased object to a third person, if the term of the sublease exceeds the remaining term of the lessee, the sublease in the period in excess of the original term shall not be legally binding on the lessor unless otherwise agreed by the lessor and the lessee.

According to the Administrative Measures for Commodity House Leasing (《商品房屋租賃管理辦法》) promulgated on December 1, 2010 with effect on February 1, 2011, the parties to the house leasing shall sign a lease contract according to laws, and the lease contract shall be registered with the relevant construction or real estate authorities at the city or county level within 30 days after its signing. If the contents of the house lease registration and filing are changed, the lease is renewed or the lease is terminated, the parties concerned shall, within 30 days, go to the original lease registration and filing department to go through the formalities for the modification, renewal or cancelation of the house lease registration and filing. A house falling within any of the following circumstances may not be leased: (i) it is an illegally built house; (ii) it fails to conform to the mandatory standards for project construction with respect to safety and disaster prevention; (iii) the original use of the house has been changed in violation of the relevant provisions; or (iv) it falls within any other circumstance under which it is prohibited by any law or regulation from being leased. If the parties involved in the house leasing fail to go through the registration and filing procedures or violate the above regulations, the parties involved in the house leasing will be ordered to make corrections, and if they fail to make corrections within the time limit, they will be fined.

LAWS AND REGULATIONS RELATED TO IMPORT AND EXPORT OF GOODS

According to the Administrative Provisions on the Record-filing of Customs Declaration Entities of the PRC (中華人民共和國海關報關單位備案管理規定), which was promulgated by the General Administration of Customs of the PRC on November 19, 2021 and came into effect on

REGULATORY OVERVIEW

January 1, 2022, consignors or consignees of imported or exported goods or customs declaration enterprises that apply for record-filing shall obtain market entity qualifications; in the case of consignors or consignees of imported or exported goods applying for record-filing, they shall also complete the record-filing formalities for foreign trade dealers.

LAWS AND REGULATIONS RELATED TO FOREIGN INVESTMENT

The Company Law

On December 29, 1993, the Company Law of the PRC (《中華人民共和國公司法》) (the “Company Law”) promulgated by the SCNPC, which was latest amended on December 29, 2023 and became effective on July 1, 2024, provides that companies established in China may take the form of limited liability company or a company limited by shares. Each company has the status of a legal person and owns its assets in its own name. The Company Law applies to foreign-invested companies unless relevant laws provide otherwise.

Foreign Investment

The Foreign Investment Law of the PRC (《中華人民共和國外商投資法》) (the “FIL”), which was promulgated by the National People’s Congress (the “NPC”) on March 15, 2019, and came into effect on January 1, 2020, provides that the “foreign investment” refers to the investment activities in China carried out directly or indirectly by foreign individuals, enterprises or other organizations (the “Foreign Investors”), including the following: (1) Foreign Investors establishing foreign-invested enterprises in China alone or collectively with other investors; (2) Foreign Investors acquiring shares, equities, properties or other similar rights of Chinese domestic enterprises; (3) Foreign Investors investing in new projects in China alone or collectively with other investors; and (4) Foreign Investors investing through other ways prescribed by laws and regulations or the State Council. The FIL further adopts the management system of pre-establishment national treatment and negative list for foreign investment. The “pre-establishment national treatment” refers to granting to foreign investors and their investments, in the stage of investment access, the treatment no less favorable than that granted to domestic investors and their investments; the “negative list” refers to special administrative measures for access of foreign investment in specific fields as stipulated by the State. The FIL granted national treatment to foreign investments outside the negative list. The negative list will be released by or upon approval of the State Council. In December 2019, the State Council promulgated the Regulations on Implementing the Foreign Investment Law of the PRC (《中華人民共和國外商投資法實施條例》) (the “Implementation Rules”) which came into effect in January 2020. The Implementation Rules further clarified that the state shall encourage and promote foreign investment, protect the lawful rights and interests in foreign investments, regulate foreign investment administration, continue to optimize foreign investment environment, and advance a higher-level opening.

On December 30, 2019, the MOFCOM and the SAMR jointly promulgated the Measures for Information Reporting on Foreign Investment (《外商投資信息報告辦法》), which became effective on January 1, 2020, pursuant to which, where a foreign investor carries out investment activities in the PRC directly or indirectly, the market regulatory authorities shall forward the investment information submitted by foreign investor or the foreign-invested enterprise to the competent commerce administrative authorities. According to the Special Administrative Measures for 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)》) promulgated by the MOFCOM and the NDRC on September 6, 2024 and brought into effect on November 1, 2024, our principal business of R&D, manufacturing and sales of TCM decoction-ready products and online sales through WeChat Mini Program and APP as currently conducted, do not fall under such categories where foreign investment is restricted or prohibited.

REGULATORY OVERVIEW

LAWS AND REGULATIONS RELATED TO EMPLOYMENT AND SOCIAL SECURITY

Employment

The major PRC laws and regulations that govern employment relationships are the Labor Law of the PRC (《中華人民共和國勞動法》) (the “Labor Law”), issued by the SCNPC on July 5, 1994, effective on January 1, 1995 and revised on August 27, 2009 and December 29, 2018, the Labor Contract Law of the PRC (《中華人民共和國勞動合同法》), or the Labor Contract Law, which was promulgated by the SCNPC on June 29, 2007 and became effective on January 1, 2008, and then amended on December 28, 2012, and the Implementation Rules of the Labor Contract Law of the PRC (《中華人民共和國勞動合同法實施條例》), which was issued by the State Council on September 18, 2008 and came into effect on the same day. According to the aforementioned laws and regulations, labor relationships between employers and employees must be executed in written form. The laws and regulations above impose stringent requirements on the employers in relation to entering into fixed-term employment contracts, hiring of temporary employees and dismissal of employees. As prescribed under the laws and regulations, employers shall ensure their employees have the right to rest and the right to receive wages no lower than the local minimum wages. Employers must establish a system for labor safety and sanitation that strictly abide by state standards and provide relevant education to its employees. Violations of the Labor Contract Law and the Labor Law may result in the imposition of fines and other administrative liabilities and/or incur criminal liabilities in the case of serious violations.

Social Insurance

According to the Social Insurance Law of PRC (《中華人民共和國社會保險法》), which issued by the SCNPC on October 28, 2010 and came into effect on July 1, 2011 and was newly revised on December 29, 2018, enterprises and institutions in the PRC shall provide their employees with welfare schemes covering basic pension insurance, unemployment insurance, maternity insurance, work-related injury insurance and basic medical insurance. The employer shall apply to the local social insurance agency for social insurance registration within 30 days from the date of its formation. And it shall, within 30 days from the date of employment, apply to the social insurance agency for social insurance registration for the employee. Any employer who violates the regulations above shall be ordered to rectify within a prescribed time limit; if the employer fails to rectify within the time limit, the employer and its directly liable person will be fined. If the employer fails to pay social insurance contributions on time and in full, the social insurance agency shall place an order with the employer demanding full payment within a prescribed period, and an overdue payment at the rate of 0.05% per day shall be levied as of the date of indebtedness. When the payment is not made at the expiry of the prescribed period, a fine above the overdue amount but less than its triple shall be demanded by the authoritative administrative department. Meanwhile, the Interim Regulation on 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 came into effect on the same day and was recently revised on March 24, 2019) prescribes the details concerning the social securities.

Apart from the general provisions about social insurance, specific provisions on various types of insurance are set out in the Regulations on Work-Related Injury Insurance (《工傷保險條例》) (issued by the State Council on April 27, 2003, came into effect on January 1, 2004 and revised on December 20, 2010), the Regulations on Unemployment Insurance (《失業保險條例》) (issued by the State Council on January 22, 1999 and came into effect on the same day), the Trial Measures on Employee Maternity Insurance of Enterprises (《企業職工生育保險試行辦法》) (issued by the Ministry of Labor on December 14, 1994 and came into effect on January 1, 1995). Enterprises subject to these regulations shall provide their employees with the corresponding insurance.

On July 31, 2025, the Supreme People’s Court promulgated the Supreme People’s Court’s Interpretation (II) on Several Issues Concerning the Application of Law in 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)》) (the “Judicial

REGULATORY OVERVIEW

Interpretation (II)”), which took effect on September 1, 2025. Article 19(1) of the Juridical Interpretation(II) stipulates that if an employer and an employee agree or the employee undertakes that social insurance contributions need not be paid, the People’s Court shall deem such agreement or undertaking invalid. Further, the relevant employee has the right to terminate the labor contract and claim economic compensation from the employer pursuant to Article 38(3) of the Labor Contract Law.

According to the confirmation of our Group and our Directors, during the Track Record Period and as of the Latest Practicable Date, (i) we had not signed any written document that stipulate exemption from social insurance contributions with any employee; (ii) there had been no dispute between us and our employees arising from the payment of social insurance contributions; (iii) no administrative action or penalty had been imposed by the relevant regulatory authorities with respect to our social insurance contributions. Based on legal provisions and the aforementioned confirmations, our PRC Legal Advisors are of the view that the Judicial Interpretation (II) would not have a material adverse effect on our compliance with applicable labor laws in this regard.

Housing Provident Fund

According to the Regulations Concerning the Administration of Housing Provident Fund (《住房公積金管理條例》), implemented since April 3, 1999 and amended on March 24, 2002 and March 24, 2019, any newly established entity shall make deposit registration at the housing accumulation fund management center within 30 days as of its establishment. After that, the entity shall open a housing accumulation fund account for its employees in an entrusted bank. Within 30 days as of the date an employee is recruited, the entity shall make deposit registration at the housing accumulation fund management center.

Any entity that fails to make deposit registration of the housing accumulation fund or fails to open a housing accumulation fund account for its employees shall be ordered to complete the relevant procedures within a prescribed time limit. Any entity failing to complete the relevant procedure within the time limit will be fined RMB10,000 to RMB50,000. Any entity fails to make payment of housing provident fund within the time limit or has a shortfall in payment of housing provident fund will be ordered to make the payment or make up the shortfall within the prescribed time limit, otherwise, the housing provident management center is entitled to apply for compulsory enforcement with the People’s Court.

LAWS AND REGULATIONS RELATED TO INTELLECTUAL PROPERTY

Patents

According to the Patent Law of the PRC (《中華人民共和國專利法》), or the PRC Patent Law, promulgated by the SCNPC on March 12, 1984 and effected on April 1, 1985 and further amended on September 4, 1992, August 25, 2000, December 27, 2008, October 17, 2020 and came into effect on June 1, 2021 and the Implementing Rules of the Patent Law of the PRC (《中華人民共和國專利法實施細則》), promulgated by the China Patent Bureau on January 19, 1985 and last amended on December 11, 2023 by the State Council and came into effect on January 20, 2024, the term “invention-creations” refers to inventions, utility models and designs. The duration of a patent right shall be 20 years for inventions, 10 years for utility models and 15 years for designs, all commencing from their respective application date. According to the PRC Patent Law, for public health purposes, the patent administrative department under the State Council of the PRC may grant a compulsory license for manufacturing patented drugs and exporting them to countries or regions covered under relevant international treaties to which PRC has acceded.

According to the PRC Patent Law, any entity or individual that seeks to exploit a patent owned by another party shall enter into a patent license contract with the patent owner and pay patent royalties to the patent owner. Pursuant to the Measures for the Filling of Patent Exploitation License

REGULATORY OVERVIEW

Contracts (《專利實施許可合同備案辦法》) promulgated by the State Intellectual Property Office on June 27, 2011 and became effective on August 1, 2011, the parties under the license shall complete filing formalities within three months from the effective date of a patent licensing contract.

Trademarks

Pursuant to the Trademark Law of the PRC (《中華人民共和國商標法》) which was promulgated on August 23, 1982 and last amended on April 23, 2019 and came into effect on November 1, 2019, the Implementation Regulations of the Trademark Law of PRC (《中華人民共和國商標法實施條例》) which was issued on August 3, 2002 and amended on April 29, 2014, the Trademark Office under the State Administration for Industry and Commerce of the PRC, or the Trademark Office, shall handle trademark registrations and grant a term of ten-years to registered trademarks, which may be renewed for an additional ten-year period upon request from the trademark owner. The Trademark Law of the PRC has adopted a “first-to-file” principle with respect to trademark registration. Where an application for a trademark for which application for registration has been made is identical or similar to another trademark that has already been registered or is under preliminary examination and approval for use on the same kind of or similar commodities or services, the application for registration of such trademark may be rejected. Any person applying for the registration of a trademark may not prejudice the existing right of others, nor may any person register in advance a trademark that has already been used by another party and has already gained a “sufficient degree of reputation” through such party’s use. A trademark registrant may, by entering into a trademark licensing contract, license another party to use its registered trademark. Where another party is licensed to use a registered trademark, the licensor shall report the license to the Trademark Office for recordation, and the Trademark Office shall publish it. An unrecorded license may not be used as a defense against a third party in good faith.

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 Industry and Information Technology on August 24, 2017 and came into effect on November 1, 2017, the Ministry of Industry and Information Technology is responsible for supervision and administration of domain name services in the PRC. Communication administrative bureaus at provincial levels shall conduct supervision and administration of the domain name services within their respective administrative jurisdictions. Domain name registration services shall, in principle, be subject to the principle of “first apply, first register.”

Copyright

The SCNPC adopted PRC Copyright Law (《中華人民共和國著作權法》) in 1990 and most recently amended in 2020, with its implementing rules adopted in 1991 and most recently amended in 2013 by PRC State Council. In addition, there is a voluntary registration system administered by the China Copyright Protection Center. According to the aforementioned law and regulation, the term of protection for the right of publication of a work is fifty years. The Regulation on the Protection of the Right to Communicate Works to the Public over Information Networks (《信息網絡傳播權保護條例》), which was most recently amended on January 30, 2013, provides specific rules on fair use, statutory license, and a safe harbor for use of copyrights and copyright management technology and specifies the liabilities of various entities for violations, including copyright holders, libraries and Internet service providers. In order to further implement the Regulations for the Protection of Computer Software (《計算機軟件保護條例》) promulgated by the State Council on December 20, 2001 and last amended on January 30, 2013, the National Copyright Administration issued the Registration of Computer Software Copyright Procedures (《計算機軟件著作權登記辦法》) on February 20, 2002, which applies to software copyright registration, license contract registration and transfer contract registration with respect to software copyright.

REGULATORY OVERVIEW

LAWS AND REGULATIONS RELATED TO INFORMATION SECURITY AND DATA PRIVACY

Data Security and Export

The SCNPC promulgated the Data Security Law of the PRC (《中華人民共和國數據安全法》) on June 10, 2021, which became 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.

On December 28, 2021, the CAC and other twelve PRC regulatory authorities jointly revised and promulgated the Measures for Cybersecurity Review (《網絡安全審查辦法》) (the “Cyber Review Measures”), which came into effect on February 15, 2022. The Cyber Review Measures stipulate that, among others, (i) when the purchase of network products and services by a critical information infrastructures operator (the “CIIO”) (關鍵信息基礎設施運營者) or the data processing activities conducted by a network platform operator (網絡平台運營者) affect or may affect national security, a cybersecurity review shall be conducted pursuant to the Cyber Review Measures; (ii) an application for cybersecurity review shall be made by an issuer who is a network platform operator holding personal information of more than one million users before such issuer applies to list its securities abroad; and (iii) the relevant PRC governmental authorities may initiate cybersecurity review if such governmental authorities determine that the issuer’s network products or services, or data processing activities affect or may affect national security.

According to the Measures on Security Assessment of Cross-border Data Transfer (《數據出境安全評估辦法》) issued by the CAC on July 7, 2022 and effective on September 1, 2022, a data processor that provides data overseas under any of the following circumstances shall apply to the national cyberspace administration for the security assessment of the outbound data transfer through local provincial cyberspace administration: (i) a data processor provides important data abroad; (ii) the CIIO or the data processor that has processed the personal information of more than 1 million people provides personal information abroad; (iii) the data processor that has provided the personal information of over 100,000 people or the sensitive personal information of over 10,000 people cumulatively since January 1 of the previous year provides personal information abroad; and (iv) any other circumstance where an application for the security assessment of outbound data transfer is required by the national cyberspace administration.

Personal Information Protection

According to the Civil Code of the PRC (《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, ensure the security of the information, and must not illegally collect, use, process, or transmit other people’s personal information or illegally buy, sell, provide, or disclose the information. The Personal Information Protection Law of the PRC (《中華人民共和國個人信息保護法》) promulgated by the SCNPC 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 PRC (《中華人民共和國網絡安全法》) promulgated by the SCNPC 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, 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

REGULATORY OVERVIEW

provide. Network operators are not allowed to leak, tamper with, or damage the personal information they collect, and are not allowed to provide personal information to others without the consent of the person whose data is being collected. However, this does not apply to cases where a specific individual cannot be identified, and the identity cannot be recovered after processing. Network operators should take technical measures and other necessary measures to ensure the security of the personal information they collect and prevent leakage, damage and loss of information.

LAWS AND REGULATIONS RELATED TO FOREIGN EXCHANGE AND OVERSEAS INVESTMENT AND DIVIDEND DISTRIBUTION

Foreign Exchange and Overseas Investment

On January 29, 1996, the State Council promulgated the Administrative Regulations on Foreign Exchange of the PRC (《中華人民共和國外匯管理條例》) which became effective on April 1, 1996 and was amended on January 14, 1997 and 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.

On November 19, 2012, the SAFE issued the Circular of Further Improving and Adjusting Foreign Exchange Administration Policies on Foreign Direct Investment (《國家外匯管理局關於進一步改進和調整直接投資外匯管理政策的通知》), or the SAFE Circular 59, which came into effect on December 17, 2012 and was revised on May 4, 2015, October 10, 2018 and partially abolished on December 30, 2019. The SAFE Circular 59 aims to simplify the foreign exchange procedure and promote the facilitation of investment and trade. According to the SAFE Circular 59, the opening of various special purpose foreign exchange accounts, such as pre-establishment expenses accounts, foreign exchange capital accounts and guarantee accounts, the reinvestment of RMB proceeds derived by foreign investors in the PRC, and remittance of foreign exchange profits and dividends by a foreign-invested enterprise to its foreign shareholders no longer require the approval or verification of SAFE, as well multiple capital accounts for the same entity may be opened in different provinces. Later, the SAFE promulgated the Circular on Further Simplifying and Improving Foreign Exchange Administration Policies in Respect of Direct Investment (《關於進一步簡化和改進直接投資外匯管理政策的通知》) in February 2015, which was partially abolished in December 2019 and prescribed that the bank instead of SAFE can directly handle the foreign exchange registration and approval under foreign direct investment while SAFE and its branches indirectly supervise the foreign exchange registration and approval under foreign direct investment through the bank.

On May 10, 2013, the SAFE issued the Administrative Provisions on Foreign Exchange in Domestic Direct Investment by Foreign Investors (《外國投資者境內直接投資外匯管理規定》), or the SAFE Circular 21, which became effective on May 13, 2013, amended on October 10, 2018 and partially abolished on December 30, 2019. The SAFE Circular 21 specifies that the administration by SAFE or its local branches over direct investment by foreign investors in the PRC must be conducted by way of registration and banks must process foreign exchange business relating to the direct investment in the PRC based on the registration information provided by SAFE and its branches.

REGULATORY OVERVIEW

According to the Notice of the State Administration of Foreign Exchange on Reforming the Management Mode of Foreign Exchange Capital Settlement of Foreign Investment Enterprises (《國家外匯管理局關於改革外商投資企業外匯資本金結匯管理方式的通知》), or the SAFE Circular 19 promulgated on March 30, 2015, coming into effect on June 1, 2015 and partially abolished on December 30, 2019 and March 23, 2023, foreign-invested enterprises could settle their foreign exchange capital on a discretionary basis according to the actual needs of their business operations. Whilst, foreign-invested enterprises are prohibited to use the foreign exchange capital settled in RMB (a) for any expenditures beyond the business scope of the foreign invested enterprises or forbidden by laws and regulations; (b) for direct or indirect securities investment; (c) to directly or indirectly provide entrusted loans (unless permitted in the business scope), repay loans between enterprises (including advances by third parties) or repay RMB bank loans that have been relented to a third party; and (d) to purchase real estates not for self-use purposes (save for real estate enterprises).

On June 9, 2016, SAFE issued the Notice of the State Administration of Foreign Exchange on Reforming and Standardizing the Foreign Exchange Settlement Management Policy of Capital Account (《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》), or the SAFE Circular 16, which was amended on December 4, 2023. The SAFE Circular 16 provides that discretionary foreign exchange settlement applies to foreign exchange capital, foreign debt offering proceeds and remitted foreign listing proceeds, and the corresponding RMB capital converted from the foreign exchange may not be used to extend loans in RMB or repay inter-company loans (including advances by third parties).

On October 23, 2019, SAFE promulgated the Notice on Further Facilitating Cross-Board Trade and Investment (《國家外匯管理局關於進一步促進跨境貿易投資便利化的通知》), which was amended on December 4, 2023. The notice cancelled restrictions on domestic equity investments made with capital funds by non-investing foreign-funded enterprises. In addition, restrictions on the use of funds for foreign exchange settlement of domestic accounts for the realization of assets have been removed and restrictions on the use and foreign exchange settlement of foreign investors' security deposits have been relaxed. Eligible enterprises in the pilot area are also allowed to use revenues under capital accounts, such as capital funds, foreign debts and overseas listing revenues for domestic payments without providing materials to the bank in advance for authenticity verification on an item-by-item basis, while the use of funds should be true, in compliance with applicable rules and conforming to the current capital revenue management regulations.

LAWS AND REGULATIONS RELATED TO TAXATION

Enterprise Income Tax

The Enterprise Income Tax Law of the PRC (《中華人民共和國企業所得稅法》), or the EIT Law, promulgated by the NPC on March 16, 2007, came into effect on January 1, 2008 and was amended on February 24, 2017 and December 29, 2018, as well as the Implementation Rules of the EIT Law (《中華人民共和國企業所得稅法實施條例》), or the EIT Implementation Rules, promulgated by the State Council on December 6, 2007, came into force on January 1, 2008 and last amended on December 6, 2024, are the principal law and regulation governing enterprise income tax in the PRC. According to the EIT Law and the EIT Implementation Rules, enterprises are classified into resident enterprises and non-resident enterprises. Resident enterprises refer to enterprises that are legally established in the PRC, or are established under foreign laws but whose actual management bodies are located in the PRC. And non-resident enterprises refer to enterprises that are legally established under foreign laws and have set up institutions or sites in the PRC but with no actual management body in the PRC, or enterprises that have not set up institutions or sites in the PRC but have derived incomes from the PRC. 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 income are obtained outside the PRC but have an actual connection with the set-up institutions or

REGULATORY OVERVIEW

sites. And non-resident enterprises that have not set up institutions or sites in the PRC or have set up institutions or sites but the incomes obtained by the said enterprises have no actual connection with the set-up institutions or sites, shall pay enterprise income tax at the rate of 10% in relation to their income sources from the PRC.

According to Article 27 of the EIT Law and Article 86 of the EIT Implementation Rules, the income derived from the preliminary processing of agricultural products by enterprises is exempt from enterprise income tax.

On November 20, 2008, the Ministry of Finance and the State Administration of Taxation issued the Notice on Issuing the Scope of Agricultural Product Preliminary Processing Eligible for Enterprise Income Tax Preferences (Trial) or Circular 149, which further clarifies the scope of agricultural product preliminary processing eligible for the enterprise income tax exemption, including, amongst others, the preliminary processing of medicinal plants under the category of crop cultivation. This involves simple processing treatments such as selecting, sorting, bundling, washing, air-drying, cutting, steaming, and stir-frying the roots, stems, barks, leaves, flowers, fruits, and seeds of various medicinal plants to produce slices, shreds, chunks, and sections of traditional Chinese medicinal materials. However, the processing of various traditional Chinese patent medicines is not considered preliminary processing.

Withholding Tax

Pursuant to the EIT Law and the EIT Implementation Rules, if a non-resident enterprise has not set up an organization or establishment in the PRC, or has set up an organization or establishment but the income derived has no actual connection with such organization or establishment, it will be subject to a withholding tax on its PRC-sourced income at a rate of 10%. According to the Arrangement between Chinese Mainland and the Hong Kong Special Administrative Region for the Avoidance of Double Taxation and Tax Evasion on Income (《內地和香港特別行政區關於對所得避免雙重徵稅和防止偷漏稅的安排》) effective from December 8, 2006, dividends repatriated from a PRC entity to its Hong Kong shareholder owning more than 25% of capital would be entitled to a reduced withholding tax rate of 5% subject to certain conditions.

The State Taxation Administration, or the SAT, issued the Administrative Measures on Entitlement of Non-residents to Treatment under Treaties (《非居民納稅人享受協定待遇管理辦法》) on October 14, 2019 and effective on January 1, 2020, which applies to non-resident taxpayers who have tax liability in China and need to claim treaty benefits. Non-resident taxpayers enjoying their tax treaty benefits shall adopt the method of "self-assessment, claims by declaration and retention of the relevant materials for future inspection." Non-resident taxpayers who make their own declaration shall make a self-assessment regarding whether they are entitled to tax treaty benefits and submit the relevant reports, statements and materials as required, and simultaneously collect and retain the relevant materials for future inspection. Also, tax authorities at any level shall, through strengthening follow-up administration for non-resident taxpayers' entitlement to tax treaty benefits, implement tax treaties accurately and prevent risks of indiscriminately application of tax treaties, tax evasion and tax avoidance.

Value-Added Tax

According to the Value-added Tax Law of the PRC (《中華人民共和國增值稅法》), which became effective on January 1, 2026, and the Regulation on the Implementation of the Value-added Tax Law of the PRC (《中華人民共和國增值稅法實施條例》), the VAT rate for general VAT taxpayers engaging in sale of goods, services, lease of tangible and movable goods or importation of goods shall be 13%, the VAT rate for general VAT taxpayers engaging in sale of transportation services, postal services, basic telecommunications services, construction services, the lease and sale of real properties, and the transfer of land use rights shall be 9%, unless otherwise provided.

REGULATORY OVERVIEW

REGULATIONS RELATED TO DIRECT INVESTMENT

Pursuant to the Regulations on the Foreign Exchange Administration of the Overseas Direct Investment of Domestic Institutions (《境內機構境外直接投資外匯管理規定》) issued by the SAFE on July 13, 2009 and came into effect on August 1, 2009, upon obtaining approval for overseas investment, an enterprise in Chinese Mainland shall apply for foreign exchange registration for its overseas direct investments. According to the Notice of the State Administration of Foreign Exchange on Further Simplifying and Improving the Foreign Exchange Management Policies for Direct Investment, the administrative approval for foreign exchange registration approval under overseas direct investment has been canceled, and the banks are entitled to review and carry out foreign exchange registration under overseas direct investment directly.

Pursuant to the Measures for the Administration of Overseas Investment (《境外投資管理辦法》) which was issued by the MOFCOM on September 6, 2014 and came into effect on October 6, 2014, the MOFCOM and the commerce departments at provincial levels shall subject the overseas investment of enterprises to recordation or confirmation management, depending on the actual circumstances of investment. Overseas investment involving any sensitive country or region, or any sensitive industry shall be subject to confirmation management. Overseas investment under other circumstances shall be subject to recordation management.

Pursuant to the Administrative Measures for Outbound Investment by Enterprises (《企業境外投資管理辦法》) promulgated by the NDRC on December 26, 2017 and came into effect on March 1, 2018, the investing activities of enterprises in Chinese Mainland such as acquiring overseas ownerships, controlling rights, operating and management rights and other relevant interests by way of investing assets and interests or providing financing and guarantees to control its overseas enterprises, either directly or indirectly, are required to obtain approval or filing with the NDRC in accordance with the relevant conditions of the overseas investment projects. Outbound investment projects that involve sensitive countries and regions or sensitive industries shall be subject to administration of verification and approval by the NDRC and non-sensitive outbound investment projects shall be subject to administration by record-filing. For non-sensitive projects of US\$300 million or above invested by local enterprise in Chinese Mainland or carried out by overseas enterprises controlled by them, the investors shall file with the NDRC and non-sensitive outbound investment projects, of which the investment amount of investors in Chinese Mainland of less than US\$300 million (exclusive) shall file with the provincial counterpart of the NDRC.

REGULATIONS RELATED TO OVERSEAS SECURITIES OFFERING AND LISTING

The CSRC promulgated the Trial Administrative Measures of Overseas Securities Offering and Listing by Domestic Companies (《境內企業境外發行證券和上市管理試行辦法》), or the Overseas Listing Trial Measures, and five relevant guidelines on February 17, 2023, which took effect on March 31, 2023. The Overseas Listing Trial Measures comprehensively reformed the regulatory regime for overseas offering and listing of PRC domestic companies' securities, either directly or indirectly, into a filing-based system.

According to the Overseas Listing Trial Measures, the PRC domestic companies that seek to offer and list securities in overseas markets, either in direct or indirect means, are required to fulfill the filing procedure with the CSRC and report relevant information. The Overseas Listing Trial Measures provides that an overseas listing or offering is explicitly prohibited, if any of the following applies: (i) such securities offering or listing is explicitly prohibited by provisions in PRC laws, administrative regulations or relevant state rules; (ii) the proposed securities offering or listing may endanger national security as reviewed and determined by competent authorities under the State Council in accordance with laws; (iii) the domestic company intending to be listed or offer securities in overseas markets, or its controlling shareholder(s) and the actual controller, have committed crimes such as corruption, bribery, embezzlement, misappropriation of property or undermining the order of the socialist market economy during the latest three years; (iv) the domestic company intending to be listed or offer securities in overseas markets is currently under

REGULATORY OVERVIEW

investigations for suspicion of criminal offenses or major violations of laws and regulations, and no conclusion has yet been made thereof; or (v) there are material ownership disputes over equity held by the domestic company’s controlling shareholder(s) or by other shareholder(s) that are controlled by the controlling shareholder(s) and/or actual controller.

Where an issuer submits an application for initial public offering to competent overseas regulators, filing application with the CSRC shall be submitted within three business days thereafter. Subsequent securities offering of an issuer in the same overseas market where it has previously offered and listed securities shall be filed with the CSRC within three business days after the offering is completed. Subsequent securities offering and listing of an issuer in other overseas markets shall be filed as initial public offering.

Moreover, upon the occurrence of any of the material events specified below after an issuer has offered and listed securities in an overseas market, the issuer shall submit a report thereof to CSRC within 3 working days after the occurrence and public disclosure of the event: (i) change of control; (ii) investigations or sanctions imposed by overseas securities regulatory agencies or other competent authorities; (iii) change of listing status or transfer of listing segment; (iv) voluntary or mandatory delisting. Where an issuer’s main business undergoes material changes after overseas offering and listing, and is therefore beyond the scope of business stated in the filing documents, such issuer shall submit to the CSRC an ad hoc report and a relevant legal opinion issued by a domestic law firm within 3 working days after occurrence of the changes.

On February 24, 2023, the CSRC and other relevant government authorities promulgated the Provisions on Strengthening the Confidentiality and Archives Administration of Overseas Securities Issuance and Listing by Domestic Enterprises (《關於加強境內企業境外發行證券和上市相關保密和檔案管理工作的規定》), or the Provision on Confidentiality, which took effect on March 31, 2023. Pursuant to the Provision on Confidentiality, where a domestic enterprise provides or publicly discloses to the relevant securities companies, securities service institutions, overseas regulatory authorities and other entities and individuals, or provides or publicly discloses through its overseas listing subjects, documents and materials involving state secrets and working secrets of state organs, it shall report the same to the competent department with the examination and approval authority for approval in accordance with the law, and submit the same to the secrecy administration department of the same level for filing. Domestic enterprises providing accounting archives or copies thereof to entities and individuals concerned such as securities companies, securities service institutions and overseas regulatory authorities shall perform the corresponding procedures pursuant to the relevant national provisions.