
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

NMPA and Center for Drug Evaluation

National Medical Products Administration (國家藥品監督管理局) (formerly the China Food and Drug Administration (國家食品藥品監督管理總局) (the “CFDA”)) (the “NMPA”) is the department in charge of the pharmaceutical industry of China. It is responsible for drawing up the laws and regulations related to pharmaceuticals and medical devices, making policy planning, formulating departmental regulations, organizing the development and issuance of pharmaceutical and medical device standards, classification and management systems, such as national formulary, and supervising the implementation.

Center for Drug Evaluation (the “CDE”) is the technical evaluation unit for drug registration with NMPA. It is mainly responsible for conducting technical evaluation on the drugs applying for registration and verifying the relevant drug registrations.

NHC

The National Health Commission (國家衛生健康委員會) (formerly known as the National Health and Family Planning Commission (國家衛生和計劃生育委員會)) (the “NHC”), is primary national regulator for public health and family planning management. 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.

NHSA

The National Healthcare Security Administration (國家醫療保障局) (the “NHSA”), a new authority established in May 2018, is directly under the State Council and 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; formulating a uniform medical insurance catalog 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.

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Ministry of Commerce

The Ministry of Commerce of the PRC (中華人民共和國商務部) (the “MOFCOM”) is responsible for the overall guidance and management of foreign investment. It formulates, revises and implements the laws, regulations, rules and policies of foreign investment. It also participates in the formulation and promulgation of the Special Management Measures for the Market Entry of Foreign Investment (Negative List) (《外商投資准入特別管理措施(負面清單)》) (the “Negative List”) and Catalog of Industries for Encouraging Foreign Investment (《鼓勵外商投資產業目錄》). The MOFCOM is also responsible for the administration and supervision of the approval and registration of foreign investment in China.

PRINCIPAL REGULATORY PROVISIONS

Laws and Regulations on New Drugs

Research and development of new drugs

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”) in September 1984, last amended on August 26, 2019 and became effective on December 1, 2019, and the Implementation Regulations of the Drug Administration Law of the PRC (《中華人民共和國藥品管理法實施條例》) (the “Implementation Regulations”) promulgated by the State Council in August 2002 and last amended on March 2, 2019, have laid down the legal framework for the establishment and maintenance of pharmaceutical manufacturing and trading enterprises, as well as for the administration of pharmaceutical products including the development and manufacturing of new drugs. According to the Drug Administration Law and the Implementation Regulations, the PRC encourages the research and development of new drugs, and protects the legal rights and interests in the research and development of new drugs. The developer and clinical trial applicant of any new drug shall truthfully submit the new drug’s manufacturing method, quality specifications, results of pharmacological and toxicological tests and the related data, documents and samples to the NMPA for approval before any clinical trial is conducted.

Non-clinical research

The non-clinical safety evaluation study for drugs for the purpose of applying for drug registration shall be conducted in accordance with the Administrative Measures for Good Laboratories Practice (《藥物非臨床研究質量管理規範》), which was promulgated in August 2003 and amended in July 2017 by the CFDA. In April 2007, the CFDA issued the Circular on Measures for Certification of Good Laboratory Practice (《藥物非臨床研究質量管理規範認證管理辦法》), last amended on January 19, 2023 and taking effect on July 1, 2023, which set forth the requirements for an institution to apply for a Certification of Good Laboratory Practice to undertake non-clinical research on drugs.

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Application for clinical trial

According to the Decision on Adjusting the Approval Procedures of Certain Administrative Approval Items for Drugs (《關於調整部分藥品行政審批事項審批程序的決定》) promulgated by the CFDA on March 17, 2017, the decision on the approval of clinical trials of drugs shall be made by the CDE from May 1, 2017. According to the Administrative Measures for Drug Registration (《藥品註冊管理辦法》) (the “Circular 27”), which was promulgated on January 22, 2020 and took effect on July 1, 2020, drug clinical trials shall be divided into Phase I clinical trial, Phase II clinical trial, Phase III clinical trial, Phase IV clinical trial, and bioequivalence trial. In accordance with Circular 27 and the Announcement on Adjusting Evaluation and Approval Procedures for Clinical Trials for Drugs (《關於調整藥物臨床試驗審評審批程序的公告》) issued in July 2018, if a clinical trial applicant does not receive any negative or questioned opinions from the CDE within 60 days after the date when the trial application is accepted and the fees are paid, the applicant can proceed with the clinical trial in accordance with the trial protocol submitted to the CDE.

After obtaining the approval of clinical trial from the NMPA, the applicant must complete the clinical trial registration at the Drug Clinical Trial Information Platform for public disclosure in accordance with the Circular on Drug Clinical Trial Information Platform (《關於藥物臨床試驗信息平台的公告》), which came into effect in September 2013. The applicant shall complete the initial registration of the trial within one month after obtaining the approval of clinical trial to obtain an exclusive trial registration number, and then complete the subsequent information registration before the first patient is enrolled in the trial and submit the registration for public disclosure for the first time.

Conduct of clinical trial

After obtaining clinical trial approval, the applicant shall conduct clinical trials at qualified clinical trial institutions. The qualified clinical trial institution refers to institutions that have the conditions to conduct clinical trials in accordance with the requirements and technical guidelines set forth in the Regulations for the Administration of Drug Clinical Trial Institutions (《藥物臨床試驗機構管理規定》), which came into effect on December 1, 2019. Such clinical trial institutions shall be subject to filing requirements, with the exception of institutions that only engage in analysis of biological samples which shall not be subject to such filing requirements. The NMPA is responsible for setting up a filing management information platform for the registration, filing and operation management of drug clinical trial institutions, as well as the entry, sharing and disclosure of information from the supervision and inspection activities conducted by the drug regulatory authorities and competent healthcare authorities.

Clinical trials must be conducted in accordance with the Good Clinical Practice for Drug Trials (《藥物臨床試驗質量管理規範》) promulgated by NMPA and NHC on April 23, 2020 and effective on July 1, 2020, which stipulates the requirements for the procedures of conducting clinical trials, including pre-clinical trial preparation, trial protocols, protection of testees’ rights and interests, duties of researchers, sponsors and monitors, as well as data management and statistical analysis.

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According to the Announcement on Adjusting Evaluation and Approval Procedures for Clinical Trials for Drugs (《關於調整藥物臨床試驗審評審批程序的公告》), where the application for clinical trial of new investigational drug has been approved, upon the completion of Phases I and II clinical trials and prior to Phase III clinical trial, the applicant shall submit the application for communication meetings to CDE to discuss with CDE the key technical questions including the design of Phase III clinical trial protocol. According to the Administrative Measures for Communication on the Research, Development and Technical Evaluation of Drugs (《藥物研發與技術審評溝通交流管理辦法》), revised by the NMPA on December 10, 2020, during the research and development periods and in the registration applications of, among others, the innovative new drugs, the applicants may propose to conduct communication meetings with the CDE. The communication meetings can be classified into three types. Type I meetings are convened to address key safety issues in clinical trials of drugs and key technical issues in the research and development of breakthrough therapeutic drugs. Type II meetings are held during the key research and development stages of drugs, mainly including meetings before submitting the clinical trial application, meetings upon the completion of Phase II trials and prior to Phase III trials, meetings before submitting the marketing application for a new drug, and meetings for risk evaluation and control. Type III meetings refer to other meetings not classified as Type I or Type II.

New drug registration

Pursuant to Circular 27, upon completion of clinical trials, determination of quality standards, completion of validation of commercial-scale production processes and completion of other related preparation works, the applicant may apply with the NMPA for the marketing authorization. The NMPA then determines whether to approve the application according to applicable laws and regulations. The applicant must obtain the marketing authorization for a new drug before the drug can be manufactured and sold in the China market. According to Circular 27, the holders of any of the following drugs can apply for conditional approval of such drugs: (1) drugs which are used for the treatment of severe life-threatening diseases currently lacking effective treatment and the data of clinical trials can confirm their efficacy and forecast their clinical value; (2) drugs which are urgently needed for public health and data of clinical trials can demonstrate their efficacy and forecast their clinical value; and (3) vaccines which are urgently needed to deal with major public health emergencies or other vaccines which the NHC deems to be urgently needed, the benefits of both of which are assessed to be outweigh the risk.

Marketing Authorization Holder Mechanism

Pursuant to the Drug Administration Law, China implements the marketing authorization holder mechanism for management of the drug industry. The drug marketing authorization holder refers to an enterprise or a drug research and development institution that has obtained the drug registration certificate. The drug marketing authorization holder shall be responsible for non-clinical research, clinical trials, production and operation, post-marketing research, adverse reaction monitoring, reporting and processing of drugs in accordance with the provisions of the law.

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The marketing authorization holders may manufacture drugs by themselves or entrust a pharmaceutical manufacturing enterprise to manufacture drugs. Likewise, they may sell drugs by themselves or entrust a pharmaceutical distribution enterprise to sell drugs. However, marketing authorization holders may not entrust a pharmaceutical manufacturing enterprise to produce blood products, narcotic drugs, psychotropic drugs, medical-use toxic drugs or pharmaceutical precursor chemicals, except as otherwise stipulated by the drug regulatory department under the State Council.

The drug marketing authorization holder shall establish a drug quality assurance system and be equipped with special personnel to take charge of quality management on drugs independently. The drug marketing authorization holder shall regularly review the quality management system of the drug manufacturer and the drug distributor, and supervise its continuous quality assurance and control capabilities.

Where the marketing authorization holder is an overseas enterprise, its designated domestic enterprise shall perform the obligations of the marketing authorization holder and jointly assume responsibilities of the marketing authorization holder with the overseas enterprise.

Gathering, Collection and Filing of Human Genetic Resources

In June 1998, the Ministry of Science and Technology and the Ministry of Health (which was canceled in the institutional reform of the State Council in 2013, its functions were first inherited by the National Health and Family Planning Commission and then by the NHC, which was established in 2018) promulgated the Interim Measures for the Management of Human Genetic Resources (《人類遺傳資源管理暫行辦法》) which sets out rules for the protection and use of human genetic resources in China. Pursuant to the Service Guide for Administrative Licensing of Gathering, Collection, Deal, Export and Exit Approval of Human Genetic Resources of Human genetic resources (《人類遺傳資源採集、收集、買賣、出口、出境審批行政許可事項服務指南》) promulgated by the Ministry of Science and Technology in July 2015 and the Notice on the Implementation of the Administrative License for the Gathering, Collection, Deal, Export and Exit of Human Genetic Resources (《關於實施人類遺傳資源採集、收集、買賣、出口、出境行政許可的通知》) promulgated by the Ministry of Science and Technology in August 2015, the gathering and collection of human genetic resources through clinical trials by a foreign-invested sponsor shall be filed for record with the China Human Genetic Resources Management Office through an online system. The Ministry of Science and Technology promulgated the Notice on Optimizing the Administrative Examination and Approval Process of Human Genetic Resources (《關於優化人類遺傳資源行政審批流程的通知》) in October 2017, which has simplified the approval process for the gathering and collection of human genetic resources for the marketing of drugs in China.

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Pursuant to the Regulations on the Management of Human Genetic Resources of the People’s Republic of China (《中華人民共和國人類遺傳資源管理條例》) promulgated by the State Council in May 2019 and came into effect on July 1, 2019, the state supports the rational use of human genetic resources for scientific research, development of the biomedical industry, improvement of diagnosis and treatment technology, improvement of China’s ability to guarantee biosafety and improvement of the level of people’s health. Foreign organizations, individuals and institutions established or actually controlled by them shall not gather or preserve Chinese genetic resources in China, or provide Chinese genetic resources to foreign countries. In addition, the gathering, preservation, utilization and external provision of Chinese genetic resources shall conform to ethical principles and conduct ethical review in accordance with relevant regulations.

Regulations of Biosimilars

According to the Technical Guideline for the Research, Development and Evaluation Biosimilars (Tentative) (《生物類似藥研發與評價技術指導原則(試行)》) (“the Biosimilar Guidelines”), biosimilars refer to therapeutic biological products that are similar to approved and registered reference drugs in terms of quality, safety and efficacy. The R&D and marketing of biosimilars need to comply with the relevant regulations of the Drug Administration Law and Circular 27. After completion of pre-clinical studies, the applicant is required to propose an application for a clinical trial, and after receiving the approval to conduct a clinical trial, the applicant should complete the clinical trial in accordance with the clinical trial protocol. The applicant shall submit an application for a marketing authorization after completion of the clinical trials and related preparations.

According to Circular 27, drug registration shall be subject to registration and administration by categories, namely Chinese medicine, chemical medicine and biological products etc. Biological product registration shall be categorized in accordance with biological product innovative medicine, biological product improved new medicine, marketed biological products (including biosimilars), etc. In order to cooperate with the implementation of the Circular 27, the NMPA formulated the Registration Classification of Biological Products and Requirements for Application Materials (《生物製品註冊分類及申報資料要求》), and the Registration Classification of Biological Products part came into effect on July 1, 2020 while the Requirements for Application Materials part came into effect on October 1, 2020. According to the Registration Classification of Biological Products and Requirements for Application Materials, biosimilars are classified as category 3.3.

According to the Biosimilar Guidelines, biosimilars shall be filed under the application procedures for new drugs. Application materials for therapeutic biological products shall be submitted following specific requirements in the Biosimilar Guidelines. According to Guidelines on the Acceptance and Review for Registration of Therapeutic Biological Products (Trial) (《治療用生物製品註冊受理審查指南(試行)》), in general, therapeutic biological products under Categories 13 to 15 shall conduct Phase 3 clinical trial only and may submit plans for Phase 3 clinical trial and relevant clinical application materials.

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In February 2015, the CFDA released the Biosimilar Guidelines, which outline the regulatory framework for biosimilars in China and provide the basic principles for the evaluation and management of biosimilars. It sets forth the definition of biosimilars and reference drugs, the requirements in relation to the selection of reference drugs, the basic principles for the technical review, the criteria for comparability, and the conditions under which extrapolations of indications would be permissible. According to the Biosimilar Guidelines, R&D of biosimilar drugs are based on contrast experimental studies to prove their similarities with reference drugs, supporting their safety, efficacy and quality control, a biosimilar drug should in principle have the same amino acid sequence as the reference drug, and the R&D and evaluation of biosimilars should be carried out in accordance with basic principles (i.e. comparison principle, dose-escalation principle, consistency principle and equivalence principle) and should cover pharmaceutical, non-clinical and clinical research and evaluation. For PK contrast experimental studies, equivalence design is usually used to study similarities of absorption/bioavailability. Equivalence thresholds should be set in advance and their reasonableness should be demonstrated, and elimination characteristics (e.g., clearance rate, elimination half-lives) should be analyzed.

The Biosimilar Guidelines set out provisions for the expansion of indications of biosimilars. When similarities are proved in comparative trials, the indications of biosimilars may be expanded to include other indications of reference drugs. The expanded indications shall be those with same pathological mechanisms and/or receptors and the same action mechanisms and targets. In comparative trials, appropriate indications shall be selected and subsequent evaluation shall be made on the safety and immunogenicity of the expanded indications. The expansion of indications shall be considered according to product features on case basis. However, caution shall be taken in expanding indications for groups with combined medication, patients with different combined diseases and different recommended dosage.

On February 10, 2021, the NMPA issued the Technical Guidelines for Similarity Evaluation and Indication Extrapolation of Biosimilars (《生物類似藥相似性評價和適應症外推技術指導原則》) to further standardize the development and evaluation of biosimilars, which came into effect on the same day. According to the Technical Guidelines for similarity evaluation and indication extrapolation of Biosimilars, “similarity” refers to a drug candidate that is overall similar to a reference drug that is approved for registration and that does not present clinically meaningful differences in quality, safety and efficacy, and “Indication Extrapolation” refers to a drug candidate that is overall similar to the reference drug when directly aligned to clinical trials showing that the candidate is clinically similar to the reference drug in at least one indication. It may then be possible to extrapolate scientific arguments for indication related study data and information in support of its use for other indications not directly studied as approved in China for the reference drug. The similarity evaluation of biosimilars should be carried out comprehensively from the perspective of pharmaceutical, non-clinical and clinical studies to determine the overall similarity and should be carried out at different stages of biopharmaceutical studies.

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The Technical Guidance for Clinical Pharmacology Studies of Biosimilars (《生物類似藥臨床藥理學研究技術指導原則》) issued by the CDE in February 2022 provides further guidance recommendations for clinical pharmacology studies of biosimilars in the framework of The Biosimilar Guidelines and the Technical Guidelines for Similarity Evaluation and Indication Extrapolation of Biosimilars, in which it is clear whether the candidate and reference drugs have similarity in clinical pharmacology needs to be evaluated based on statistical methods; currently, the average bioequivalence statistical approach is generally recommended for the comparison of PK and PD parameters.

Laws and Regulations on the Manufacturing of Drugs

Drug Manufacturing Certificate

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

Good Manufacturing Practice

Prior to December 1, 2019, pursuant to the Certification Measures for Good Manufacturing Practice for Drugs (《藥品生產質量管理規範認證管理辦法》) issued by the CFDA in August 2011, when establishing a pharmaceutical manufacturer or a new factory or expanding the production scope, the drug manufacturer is required to submit an application for a good manufacturing practice certification (the “GMP certification”) with the drug regulatory authority. If the Good Manufacturing Practices (the “GMP”) are satisfied, a GMP certificate will be issued. 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 drug manufacturer must conduct the manufacturing process in accordance with the Good Manufacturing Practice for Drugs (《藥品生產質量管理規範》) issued by the Ministry of Health in January 2011, which sets forth a set of detailed standard guidelines governing the manufacture of drugs including 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 management of customer complaints and adverse event reports.

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Contract manufacturing of drugs

Pursuant to the Administrative Regulations for the Contract Manufacturing of Drugs (《藥品委託生產監督管理規定》) (the “Contract Manufacturing Regulations”) issued by the CFDA in August 2014, only when a drug manufacturer temporarily lacks manufacturing conditions due to technology upgrade or is unable to ensure market supply due to insufficient manufacturing capabilities, can such drug manufacturer entrust the manufacturing of the drug to another domestic drug manufacturer. Such contract manufacturing arrangements shall be approved by the provincial branch of the NMPA.

The Administrative Measures on Supervision of Drug Manufacturing (《藥品生產監督管理辦法》) (the “Revised Administrative Measures of Drug Manufacturing”) promulgated by the State Administration for Market Regulation on January 22, 2020 and effective on July 1, 2020 further implements the drug marketing authorization holder system as stipulated in the Drug Administration Law. Drug marketing authorization holders entrusting others to manufacture drugs shall enter into outsourcing agreements and quality agreements with qualified drug manufacturing enterprises and submit the relevant agreements together with the actual manufacturing site application materials to the competent drug administrative authority in order to apply for the Drug Manufacturing Certificate.

Laws and Regulations on Intellectual Properties

Patent

Patents in the PRC are mainly protected by the Patent Law of the PRC (《中華人民共和國專利法》), which was promulgated by the SCNPC on March 12, 1984, last amended on October 17, 2020 and became effective on June 1, 2021, and the Implementation Rules of the Patent Law of the PRC (《中華人民共和國專利法實施細則》), which were promulgated by the State Council on June 15, 2001 and last amended on December 11, 2023 and will become effective on January 20, 2024. The Patent Law of the PRC and its Implementation Rules provide for three types of patents, “invention”, “utility model” and “design.” “Invention” refers to any new technical solution relating to a product, a process or improvement thereof; “utility model” refers to any new technical solution relating to the shape, structure, or their combination, of a product, which is suitable for practical use; and “design” refers to any new design of the shape, pattern, color or the combination of any two of them, of a product, which creates an aesthetic feeling and is suitable for industrial application. The duration of a patent right for “invention” is 20 years, the duration of a patent right for “utility model” is 10 years, and the duration of a patent right for “design” is 15 years, from the date of application. According to the Patent Law of the PRC, for the purpose of public health, the patent administrative department of the State Council may grant mandatory licensing to manufacture and export patented drugs to countries or regions in comply with provisions of the relevant international treaty participated by the PRC.

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Trade Secret

According to the Anti-Unfair Competition Law of the PRC (《中華人民共和國反不正當競爭法》), promulgated by the SCNPC in September 1993 and last amended on April 23, 2019, the term “trade secrets” refers to technical and business information that is unknown to the public, has utility, may create business interests or profits for its legal owners or holders, and is maintained as a secret by its legal owners or holders. Under the Anti-Unfair Competition Law of the PRC, business persons are prohibited from infringing others’ trade secrets by: (1) acquiring a trade secret from the right holder by theft, bribery, fraud, coercion, electronic intrusion, or any other means; (2) disclosing, using, or allowing another person to use a trade secret acquired from the right holder by any means as specified in the item (1) above; (3) disclosing, using, or allowing another person use a trade secret in its possession, in violation of its confidentiality obligation or the requirements of the right holder for keeping the trade secret confidential; (4) abetting a person, or tempting another person into or in acquiring, disclosing, using, or allowing another person to use the trade secret of the right holder in violation of his or her non-disclosure obligation or the requirements of the right holder for keeping the trade secret confidential. If a third party knows or should have known of the above-mentioned illegal conduct 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. The parties whose trade secrets are being misappropriated may petition for administrative corrections, and regulatory authorities may stop any illegal activities and impose fine on the infringing parties.

Trademark

Pursuant to the Trademark Law of the PRC (《中華人民共和國商標法》) promulgated by the SCNPC on August 23, 1982, last amended on April 23, 2019 and became effective on November 1, 2019, the period of validity for a registered trademark is 10 years, commencing from the date of registration. Upon expiry of the period of validity, the registrant shall go through the formalities for renewal within twelve months prior to the date of expiry as required if the registrant needs to continue to use the trademark. Where the registrant fails to do so, a grace period of six months may be granted. The period of validity for each renewal of registration is 10 years, commencing from the day immediately after the expiry of the preceding period of validity for the trademark. In the absence of a renewal upon expiry, the registered trademark shall be canceled. Industrial and commercial administrative authorities have the authority to investigate any behavior in infringement of the exclusive right under a registered trademark in accordance with the law. In case of a suspected criminal offense, the case shall be timely referred to a judicial authority and decided in accordance with applicable laws.

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Copyright

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

Domain Names

In accordance with the Measures for the Administration of Internet Domain Names (《互聯網域名管理辦法》) which was issued by the Ministry of Information Industry on August 24, 2017 and came into effect on November 1, 2017, the Ministry of Industry and Information Technology is responsible for supervision and administration of domain name services in the PRC. Communications 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.” A domain name registrar shall, in the process of providing domain name registration services, ask the applicant for which the registration is made to provide authentic, accurate and complete identity information on the holder of the domain name and other domain name registration related information.

Laws and Regulations on Labor and Employee Incentives

Labor, Social Insurance and Housing Provident Funds

According to the Labor Law of the PRC (《中華人民共和國勞動法》), which was promulgated by the SCNPC in July 1994 and last amended and came into effect in December 2018, the Labor Contract Law of the PRC (《中華人民共和國勞動合同法》), which was promulgated by the SCNPC in June 2007 and amended in December 2012 and came into effect in July 2013, and the Implementing Regulations of the Labor Contracts Law of the PRC (《中華人民共和國勞動合同法實施條例》), which was promulgated by the State Council and came into effect in September 2008, labor contracts in written form shall be executed to establish labor relationships between employers and employees. In addition, wages shall not be lower than local minimum wages. The employers must establish a system for labor safety and sanitation, strictly comply with national rules and standards, provide education regarding labor safety and sanitation to its employees, provide employees with labor safety and sanitation conditions and necessary protection materials in compliance with national rules, and carry out regular health examinations for employees engaged in work involving occupational hazards.

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According to the Social Insurance Law of PRC (《中華人民共和國社會保險法》), which was promulgated by the SCNPC in October 2010 and last amended and came into effect in December 2018, and the Interim Regulations on the Collection and Payment of Social Security Funds (《社會保險費徵繳暫行條例》), which was promulgated by the State Council in January 1999 and last amended in March 2019, and the Regulations on the Administration of Housing Provident Funds (《住房公積金管理條例》), which was promulgated by the State Council in April 1999 and last amended in March 2019, employers are required to contribute, on behalf of their employees, to a number of social security funds, including funds for basic pension insurance, unemployment insurance, basic medical insurance, occupational injury insurance and maternity insurance and to housing provident funds. Any employer who fails to make the required contributions may be fined and ordered to compensate the deficit within a stipulated time limit.

The Prevention and Control of Occupational Diseases Law of the PRC (《中華人民共和國職業病防治法》), which was promulgated by the SCNPC on October 27, 2001 and latest amended on December 29, 2018 (the “Prevention and Control of Occupational Diseases Law”), is the basic law for the prevention and control of occupational diseases. According to the Prevention and Control of Occupational Diseases Law, budget for facilities for the prevention and control of occupational diseases of a construction project shall be included in the budget of the project and those facilities shall be designed, constructed and put into operation simultaneously with the main body of the project. The entity that takes charge of the project should carry out the assessment of the effectiveness of measures for the prevention and control of occupational diseases before the final acceptance of the construction project. In addition, employers shall take required administrative measures to prevent and control occupational diseases in work.

Employee Stock Incentive Plans

On February 15, 2012, SAFE issued the Circular on Issues concerning the Foreign Exchange Administration for Domestic Individuals Participating in Share Incentive Plans of Overseas Publicly Listed Companies (《關於境內個人參與境外上市公司股權激勵計劃外匯管理有關問題的通知》) (the “Share Incentive Rules”). Under the Share Incentive Rules and relevant rules and regulations, PRC citizens or non-PRC citizens residing in China for a continuous period of not less than one year, who participate in any stock incentive plan of an overseas publicly listed company, subject to a few exceptions, are required to register with SAFE through a domestic qualified agent, which could be a PRC domestic company participating in such stock incentive plan, and complete certain procedures. In addition, the STA has issued circulars concerning employee share options or restricted shares. Under these circulars, employees working in the PRC who exercise share options, or whose restricted shares vest, will be subject to PRC individual income tax. The domestic qualified agent have obligations to file documents related to employee share options or restricted shares with relevant tax authorities and to withhold individual income tax of those employees related to their share options or restricted shares. If the employees fail to pay, or the PRC domestic companies fail to withhold, their individual income tax according to relevant laws, rules and regulations, the PRC domestic companies may face sanctions imposed by the tax authorities or other relevant PRC government authorities.

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Laws and Regulations on Environmental Protection

Environment Protection

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

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》), 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 employer 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 employer 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 employer 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》) (“the Environmental Impact Appraisal Law”), 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 seriousness of effect that may be exerted on the environment.

Laws and Regulations on Foreign Investment

Since January 1, 2020, the Foreign Investment Law of the PRC (《中華人民共和國外商投資法》) (“the Foreign Investment Law”), promulgated by the NPC has come into effect. The Sino-Foreign Equity Joint Ventures Law of the PRC, the Wholly Foreign-Owned Enterprises Law of the PRC and the Sino-Foreign Cooperative Joint Ventures Law of the PRC abolished at the same time. Since then, the Foreign Investment Law has become the basic law regulating foreign-invested enterprises wholly or partially invested by foreign investors. While the organization form, institutional framework and standard of conduct of foreign-invested enterprises shall be subject to the provisions of the Company Law of the PRC and other laws.

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The PRC government will implement the management system of pre-entry national treatment and the Negative List for foreign investment abolished the original approval and filing administration system for the establishment and change of foreign-invested enterprises. Pre-entry national treatment refers to the treatment accorded to foreign investors and their investments at the stage of investment entry which is no less favorable than the treatment accorded to domestic investors and their investments. Negative List refers to a special administrative measure for the entry of foreign investment in specific sectors as imposed by the PRC. The PRC accords national treatment to foreign investment outside of the Negative List. The Negative List lists the special management measures for foreign investment access for industries regulated by the Negative List, such as equity requirements and senior management requirements.

While strengthening investment promotion and protection, the Foreign Investment Law further regulates foreign investment management and proposes the establishment of a foreign investment information reporting system that replaces the original foreign investment enterprise approval and filing system of the Ministry of Commerce. The foreign investment information reporting is subject to the Foreign Investment Information Reporting Method (《外商投資信息報告辦法》) jointly developed by the MOFCOM and the SAMR, which came into effect on January 1, 2020. According to the Foreign Investment Information Reporting Method, foreign investors who directly or indirectly carry out investment activities in China shall submit investment information to the competent commercial department through the enterprise registration system and the National Enterprise Credit Information Publicity System and the reporting methods include initial reports, change reports, cancelation reports, and annual reports.

Laws and Regulations on Foreign Exchange and Taxation

Foreign Exchange

On January 29, 1996, the State Council promulgated the Administrative Regulations on Foreign Exchange of the 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.

REGULATORY OVERVIEW

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》) (“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》) on February 13, 2015, which was partially abolished on December 30, 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 11, 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》) (“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.

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

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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》) (“the SAFE Circular 19”) promulgated on March 30, 2015, coming effective on June 1, 2015 and partially abolished on December 30, 2019, 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 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 on lent to a third party; and (d) to purchase real estate 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》) (“the SAFE Circular 16”), which came into effect on the same day and was partly amended according to Notice of the State Administration of Foreign Exchange on Further Deepening Reforming to Facilitate Cross-border Trade and Investment (《國家外匯管理局關於進一步深化改革促進跨境貿易投資便利化的通知》). 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 foreign exchange may be used to extend loans to related parties or repay inter-company loans (including advances by third parties). However, there remain substantial uncertainties with respect to SAFE Circular 16’s interpretation and implementation in practice.

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 became effective on the same date (except for Article 8.2, which became effective on January 1, 2020) and was partly amended according to Notice of the State Administration of Foreign Exchange on Further Deepening Reforming to Facilitate Cross-border Trade and Investment (《國家外匯管理局關於進一步深化改革促進跨境貿易投資便利化的通知》). This notice canceled 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.

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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》) (“the EIT Law”), promulgated by the NPC on March 16, 2007, came into effect on January 1, 2008 and 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》) (“the Implementation Rules”), promulgated by the State Council on December 6, 2007, came into force on January 1, 2008 and amended on April 23, 2019, are the principal law and regulation governing enterprise income tax in the PRC. According to the EIT Law and its 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 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.

Value-Added Tax (the “VAT”)

The major PRC law and regulation governing value-added tax are the Interim Regulations on Value-added Tax of the PRC (《中華人民共和國增值稅暫行條例》) issued on December 13, 1993 by the State Council, came into effect on January 1, 1994, and revised on November 10, 2008, February 6, 2016 and November 19, 2017, as well as the Implementation Rules for the Interim Regulations on Value-Added Tax of the PRC (《中華人民共和國增值稅暫行條例實施細則》) issued on December 25, 1993 by the Ministry of Finance (中華人民共和國財政部) (the “MOF”), came into effect on the same day and revised on December 15, 2008 and October 28, 2011, any entities and individuals engaged in the sale of goods, supply of processing, repair and replacement services, and import of goods within the territory of the PRC are taxpayers of VAT and shall pay the VAT in accordance with the law and regulation. The rate of VAT for sale of goods is 17% unless otherwise specified, such as the rate of VAT for sale of transportation is 11%. With the VAT reforms in the PRC, the rate of VAT has been changed several times. The MOF and the STA issued the Notice of on Adjusting VAT Rates (《財政部、國家稅務總局關於調整增值稅稅率的通知》) on April 4, 2018 to adjust the tax rates of 17% and 11% applicable to any taxpayer’s VAT taxable sale or import of goods to 16% and 10%, respectively, this adjustment became effect on May 1, 2018. Subsequently, the MOF, the STA and the General Administration of Customs jointly issued the Announcement on

REGULATORY OVERVIEW

Relevant Policies for Deepening the VAT Reform (《財政部、國家稅務總局關於深化增值稅改革有關政策的公告》) on March 20, 2019 to make a further adjustment, which came into effect on April 1, 2019. The tax rate of 16% applicable to the VAT taxable sale or import of goods shall be adjusted to 13%, and the tax rate of 10% applicable thereto shall be adjusted to 9%.

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

On February 17, 2023, the CSRC promulgated the Trial Administrative Measures of Overseas Securities Offering and Listing by Domestic Companies (《境內企業境外發行證券和上市管理試行辦法》) (“the Overseas Listing Trial Measures”) and relevant supporting guidelines, which came into effect on March 31, 2023. The Overseas Listing Trial Measures comprehensively improves and reforms the existing regulatory regime for overseas offering and listing of PRC domestic companies’ securities and regulates both direct and indirect overseas offering and listing of PRC domestic companies’ securities. Any domestic company that is deemed to conduct overseas offering and listing activities shall file with the CSRC in accordance with the Overseas Listing Trial Measures.

The Overseas Listing Trial Measures provide that the overseas securities offering and listing will be considered a direct overseas offering by a PRC domestic company if the issuer is a company limited by shares registered and established in mainland China. In addition, the overseas securities offering and listing will be considered an indirect overseas offering by a PRC domestic company if the issuer meets both of the following criteria: (i) 50% or more of any of the issuer’s operating revenue, total profit, total assets or net assets as documented in its audited consolidated financial statements for the most recent fiscal year is accounted for by a domestic company; and (ii) the main parts of the issuer’s business activities are conducted in mainland China, or its main place(s) of business are located in mainland China, or the majority of senior management staff in charge of its business operations and management are PRC citizens or have their usual place(s) of residence located in mainland China.

Pursuant to the Overseas Listing Trial Measures, an issuer shall file with the CSRC within three business days after its application for initial public offering is submitted to competent overseas securities regulators.

H-share Full Circulation

“Full circulation” means listing and circulating on the stock exchange of the domestic unlisted shares of an H-share listed company, including unlisted domestic shares held by domestic shareholders prior to overseas listing, unlisted domestic shares additionally issued after overseas listing, and unlisted shares held by foreign shareholders. On November 14, 2019, the CSRC issued the Guidelines for the “Full Circulation” Program for Domestic Unlisted Shares of H-share Listed Companies (《H股公司境內未上市股份申請“全流通”業務指引》)

REGULATORY OVERVIEW

(the “Guidelines for the Full Circulation”), which was partly revised on August 10, 2023 according to the Decision on Revising and Abolishing Part of Securities and Futures Policy Documents by CSRC (《中國證券監督管理委員會關於修改、廢止部分證券期貨制度文件的決定》).

According to the Guidelines for the Full Circulation, shareholders of domestic unlisted shares may determine by themselves through consultation the amount and proportion of shares, for which an application will be filed for circulation, provided that the requirements laid down in the relevant laws and regulations and set out in the policies for state-owned asset administration, foreign investment and industry regulation are met, and the corresponding H-share listed company may be entrusted to file the said application for full circulation. To apply for full circulation, an H-share listed company shall file the application with the CSRC according to the administrative filing procedures necessary for the Overseas Listing Trial Measures. After the filing with the CSRC for full circulation has been completed, the H-share listed company shall submit a report on the relevant situation to the CSRC within 15 days after the registration with CSDCC of the shares related to the application has been completed.

On December 31, 2019, CSDCC and the Shenzhen Stock Exchange (“SZSE”) jointly announced the Measures for Implementation of H-share Full Circulation Business (《H股“全流通”業務實施細則》) (the “Measures for Implementation”). The businesses in relation to the H-share full circulation business, such as cross-border transfer registration, maintenance of deposit and holding details, transaction entrustment and instruction transmission, settlement, management of settlement participants, services of nominal holders, etc. are subject to the Measures for Implementation.

In order to fully promote the reform of H-share full circulation and clarify the business arrangement and procedures for the relevant shares’ registration, custody, settlement and delivery, CSDCC promulgated the Guide to the Program for Full Circulation of H-shares (《H股“全流通”業務指南》) on February 7, 2020, which specifies the business preparation, account arrangement, cross-border share transfer registration and overseas centralized custody, and other relevant matters. In February 2020, China Securities Depository and Clearing (Hong Kong) Limited (“CSDC (Hong Kong)”) also promulgated the Guide of China Securities Depository and Clearing (Hong Kong) Limited to the Program for Full Circulation of H-shares to specify the relevant escrow, custody, agent service, arrangement for settlement and delivery, risk management measures and other relevant matters.

According to the Measures for Implementation and the Guide to the Program for Full Circulation of H-shares, shareholders who apply for H Share Full Circulation (“Participating Shareholders”) shall complete the cross-border transfer registration for conversion of relevant domestic unlisted shares into H Shares before dealing in the shares, i.e., CSDCC as the nominal shareholder, deposits the relevant securities held by Participating Shareholders at CSDC (Hong Kong), and CSDC (Hong Kong) will then deposit the securities at HKSCC in its own name, and exercise the rights to the securities issuer through HKSCC, while HKSCC Nominees as the ultimate nominal shareholder is listed on the register of shareholders of H-share listed companies.

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According to the Guide to the Program for Full Circulation of H-shares, H-share listed companies shall be authorized by Participating Shareholders to designate the only domestic securities company (“Domestic Securities Company”) to participate in the transaction of converted H shares. The specific procedure is as follows:

Participating Shareholders submit trading orders of the converted H Shares through the Domestic Securities Company, which transmits the orders to the Hong Kong Securities Company designated by the Domestic Securities Company through Shenzhen Securities Communications Co., Ltd.; and Hong Kong Securities Company conducts corresponding securities transactions in the Hong Kong market in accordance with the aforementioned trading orders and the rules of the Stock Exchange.

According to the Guide to the Program for Full Circulation of H-shares, upon the completion of the transaction, settlements between each of the Hong Kong Securities Company and CSDC (Hong Kong), CSDC (Hong Kong) and CSDCC, CSDCC and the Domestic Securities Company, and the Domestic Securities Company and the Participating Shareholders, will all be conducted separately.