OVERVIEW

This section summarizes the major laws, regulations and rules in China relevant to our business. Such laws and regulations relate to the registration, production, sales, intellectual property rights, foreign exchange, labor, environmental protection, taxation and other fields of medical devices.

Main Regulatory Authorities

The main regulatory authorities of China's medical device industry include the State Administration for Market Regulation (hereinafter "SAMR"), the National Medical Products Administration ("NMPA"), the National Development and Reform Commission ("NDRC"), the National Health Commission ("NHC") and the National Healthcare Security Administration ("NHSA").

SAMR

SAMR is responsible for the comprehensive market regulation, as well as for organizing and guiding the comprehensive law enforcement of market regulation, and promoting the implementation of unified market regulation. SAMR is responsible for regulating the administrative enforcement of market supervision and taking charge of NMPA.

NMPA

NMPA is mainly responsible for the management, safety supervision, standards, registration, quality, post-marketing risks and supervision and inspection of drugs, cosmetics and medical devices. Supervising foreign exchanges and cooperation and guiding the work of local drug administration departments are also within the scope of its official duties. In March 2018, the Institutional Reform Plan of the State Council adopted at the First Session of the 13th National People's Congress decided not to retain the State Food and Drug Administration, and established NMPA to assume the official duties of former State Food and Drug Administration ("former SFDA").

NDRC

NDRC is mainly responsible for the formulation of health development policies, the establishment of technological transformation investment projects, the macro guidance and management of the economic operation of pharmaceutical enterprises and the supervision over the implementation of relevant policies and regulations.

NHC

NHC is the main medical regulatory authority in China. It is responsible for supervising the operations of medical institutions (some of which also act as clinical trial sites).

NHSA

NHSA is mainly responsible for formulating the policies, plans and standards of medical insurance systems in respect of medical insurance, maternity insurance and medical assistance and other things, organizing the formulation and adjustment of prices of drugs and medical services and charging standards, formulating bidding policies for the procurement of drugs and medical consumables, and supervising the implementation of the aforesaid actions.

LAWS AND REGULATIONS ON MEDICAL DEVICES

Supervision over Medical Devices and their Classification

On December 21, 2020, the State Council revised the Regulation on the Supervision and Administration of Medical Devices, which became effective on June 1, 2021. According to the Regulation on the Supervision and Administration of Medical Devices, National Regulatory Authority shall be responsible for the supervision over medical devices in China. All relevant departments of the State Council shall be responsible for the supervision over medical devices within their respective scopes of duties. The drug administration departments of the local People's Governments at the county level and above are responsible for the supervision over the medical devices within their own administrative jurisdictions.

According to the Regulation on the Supervision and Administration of Medical Devices, medical devices are classified into three categories based on their degrees of risks in China, and classified management is implemented. Class I medical devices shall refer to those devices with low risks, and the safety and effectiveness of which can be ensured through routine administration. Class II medical devices shall refer to those devices with medium risks, which are strictly controlled and administered to ensure their safety and effectiveness. Class III medical devices shall refer to those devices with high risks, which are strictly controlled and administered through special measures to ensure their safety and effectiveness.

Registration and Filing of Medical Device Products

On July 30, 2014, former SFDA issued the Administrative Measures for Registration of Medical Devices, which became effective on October 1, 2014 and was repealed on October 1, 2021. According to the Administrative Measures for Registration of Medical Devices, Class I medical devices are subject to filing management, and Class II and Class III medical devices are subject to registration management. For Class I medical devices filing, no clinical trial is required. For the registration application for Class II and Class III medical devices, clinical trials shall be conducted. Under any of the following circumstances, clinical trials can be exempted from: (i) medical devices of the same type with clear mechanism, finalized design, and mature production process on the market that have been applied clinically for years without bad accidents and changes in usage; (ii) the medical devices can be proved to be safe and effective through non-clinical evaluation; (iii) the medical devices can be proved to be safe and effective by analyzing and evaluating the data obtained from clinical trials or clinical applications of medical devices of the same type. The Catalog of Medical Devices Exempted from Clinical Trials was formulated, adjusted and published by former SFDA. For products that are not listed in the Catalog of Medical Devices Exempted from Clinical Trials, the medical devices can be proved to be safe and effective by analyzing and evaluating the data obtained from clinical trials or clinical applications of medical devices of the same type. Applicants may provide explanations and submit relevant supporting materials when applying for registration.

According to the Notice of the National Medical Products Administration on Matters Concerning Implementing the Measures for the Administration of Registration and Recordation of Medical Devices and the Measures for the Administration of Registration and Recordation of In-Vitro Diagnostic Reagents issued on September 28, 2021, the Medical Products Administration shall continue to examine and approve registration applications that have been accepted but not yet

approved before the implementation of the Administrative Measures for the Registration and Recordation of Medical Devices in accordance with the original requirements. If the conditions for appearing on the market are met, a medical device registration certificate shall be issued.

On August 26, 2021, the State Administration for Market Regulation issued the Administrative Measures for the Registration and Recordation of Medical Devices, which became effective on October 1, 2021. According to the Administrative Measures for the Registration and Recordation of Medical Devices, Class I medical devices shall be subject to product filing management. Class II and Class III medical devices shall be subject to product registration management. For the filing of domestic Class I medical devices, relevant materials shall be submitted to the drug supervision and administration department at municipal level. Domestic Class II medical devices shall be reviewed by the drug supervision and administration department of provinces, autonomous regions and municipalities, and a medical device registration certificate shall be issued after approval. Domestic Class III medical devices shall be examined by NMPA, and a medical device registration certificate shall be issued after approval. For the import of Class I medical devices, relevant materials shall be submitted to NMPA. The import of Class II and Class III medical devices shall be examined by NMPA, and a medical device registration certificate shall be issued after approval.

The registrant shall take the initiative to carry out post-marketing research on medical devices, further confirm the safety, effectiveness and quality controllability of medical devices, and strengthen the continuous management of medical devices on the market. If there are substantial changes in designs, raw materials, production processes, scopes of application and methods of application of Class II and Class III registered medical devices, which may affect the safety and effectiveness of the medical devices, the registrant shall apply for the changes in the registration at the relevant registration department. If there are other changes, they shall be filed at the relevant registration department within 30 days from the date of change.

According to the Regulation on the Supervision and Administration of Medical Devices and the Administrative Measures for the Registration and Recordation of Medical Devices , the validity period of the medical device registration certificate is 5 years. If it is necessary to renew the registration at the expiration of the validity period, an application for renewal of registration shall be submitted to the relevant registration department within 6 months before the expiration of the validity period. Except for the cases where renewals of registration are not approved, the drug supervision and administration department receiving the application for renewal of registration shall decide to approve the renewal before the expiration of the validity period of the medical device registration certificate. If no decision is made after expiration, it shall be deemed that the renewal is approved. Under any of the following circumstances, the renewal registration shall not be approved: (i) the application for renewal registration is not submitted within the specified period; (ii) the mandatory standards for medical devices have been revised, and the medical devices applying for renewal registration cannot meet the new requirements; and (iii) the medical devices approved with conditions fail to complete the matters specified in the medical device registration certificate within the specified period.

Except for the exemption from clinical evaluation, the registration and filing of medical devices shall be subject to clinical evaluations. Under any of the following circumstances, clinical trials can be exempted from: (i) medical devices of the same type with clear mechanism, finalized design, and mature production process on the market that have been applied clinically for years without bad

accidents and changes in usage; or (ii) the medical devices can be proved to be safe and effective through non-clinical evaluation. The Catalog of Medical Devices Exempted from Clinical Evaluation is formulated, revised and published by NMPA. NMPA issued the Catalog of Medical Devices Exempted from Clinical Evaluation on September 16, 2021, which became effective on October 1, 2021.

To carry out clinical evaluation of medical devices, the safety and effectiveness of medical devices can be proved by carrying out clinical trials according to conditions including product characteristics, clinical risks and existing clinical data, or by analyzing and evaluating the clinical literature and clinical data of medical devices of the same type. According to NMPA, clinical trials of medical devices shall be carried out if the existing clinical literature and clinical data are insufficient to confirm the safety and effectiveness of the medical devices when conducting clinical evaluations on the medical devices. Clinical trials of medical devices shall be carried out in medical device clinical trial institutions with corresponding conditions and filed in accordance with the requirements of Norms on the Quality Management for the Clinical Trials of Medical Devices. Before clinical trials start, sponsors of the clinical trials shall file the clinical trials with the drug supervision and administration department of provinces, autonomous regions or municipalities. If the clinical trials of Class III medical devices have a high risk to human body, approvals shall be obtained from NMPA. The Catalog of Medical Devices of Class III Subject to Approval for Clinical Trials (Revised in 2020) was issued by NMPA and became effective on September 14, 2020.

In addition, the Administrative Measures for the Registration and Recordation of Medical Devices stipulates the details of product development, clinical evaluation, registration system verification, product registration, change of registration, continuation of registration, product filing and other aspects. It also stipulates special registration procedures, e.g. innovative product registration procedures, priority registration procedures and emergency registration procedures.

Special Examination and Approval Procedures for Innovative Medical Devices

On August 9, 2015, the State Council issued the Opinions of the State Council on the Reform of the System of Evaluation, Review and Approval of Drugs and Medical Devices to encourage the R&D and innovation of medical devices. The registration application of innovative medical devices with patented technologies and great clinical value is included in the scope of special examination and approval. Priority shall be given to such application.

On October 8, 2017, the General Office of the CPC Central Committee and the General Office of the State Council issued and implemented the Opinions on Deepening the Reform of the Evaluation and Approval Systems and Encouraging Innovation on Drugs and Medical Devices (hereinafter referred to as "the Opinions"), which aims to encourage the innovation of medical devices. According to the Opinions, priority in examining and approving shall be given to certain innovative medical devices. Not only are these devices supported by the National Science and Technology Major Project and the National Key R&D Program of China, but they also have undergone clinical trials conducted by the National Clinical Research Center and been approved by the Center.

On November 2, 2018, NMPA issued the Special Examination and Approval Procedures for Innovative Medical Devices which became effective on December 1, 2018. According to the Special Examination and Approval Procedures for Innovative Medical Devices, special review procedures are

applicable to the examination of medical devices under any of the following circumstances: (i) through the technological innovation activities led by the applicant, he/she owns the patented technologies in accordance with the laws in China, or obtains the invention patent rights or the right-of-use in China through assignment according to law; the application time of special review for innovative medical devices shall not exceed 5 years from the date of patent authorization announcement; or applications for core technology invention patents have been published by the patent administration department under the State Council, and a search report will be issued by the Patent Search and Consultation Center of State Intellectual Property Office, which states that the core technologies of a product is novel and creative; (ii) the applicant has completed the preliminary research of the products and has a basic model product. The research process is true and controlled, and the research data are complete and traceable; (iii) the main working principle or action mechanism of the product is unprecedented in China; the product has fundamentally improved its performance or safety as compared with those of similar products. The technologies of the product are taking the lead in the world, and the value of their clinical application is significant. The Center for Medical Device Evaluation of NMPA shall give priority to the technical examination of innovative medical devices with accepted registration applications; NMPA gives priority to the administrative examination and approval upon the completion of the technical review.

According to the Administrative Measures for the Registration and Recording of Medical Devices, if the application is applicable to the registration procedures of innovative products, the applicant shall submit an application for the examination of innovative medical devices at NMPA after the product is substantially finalized. NMPA shall assign experts to the examination of the product. If the product is up to the standard of innovation, it can be brought into the registration formalities of innovative products. For the registration applications of medical devices that are applicable to the registration formalities of innovative products, NMPA and the institutions responsible for relevant technical work shall designate special personnel to be responsible for timely communication and provision of guidance in accordance with their respective responsibilities. For medical devices that are included in the registration procedures of innovative products, the Center for Medical Device Evaluation of NMPA can communicate with the applicant on major technical issues, major safety issues, clinical trial schemes, summary and evaluation of phased clinical trial results and other issues before the approval of registration application and during the technical review.

MEDICAL DEVICE PRODUCTION LICENSE

According to the Regulation on the Supervision and Administration of Medical Devices, in addition to the medical device registration certificate, the medical device manufacturer shall also be filed with the drug regulatory department of the people's government at the corresponding level or apply for a production license before engaging in the production of medical devices. The validity period of the medical device production license is 5 years. If the medical device production license needs to be renewed at the expiration of its validity period, the renewal formalities shall be handled in accordance with the relevant statutory requirements on administrative licensing.

Former SFDA amended the Measures for Supervision and Administration of Medical Device Production, which became effective on November 17, 2017. According to the Measures for Supervision and Administration of Medical Device Production, enterprises engaging in the production of medical devices shall possess production sites, environmental conditions, production equipment

and professional technicians commensurate with the medical devices produced; they shall possess institutions or full-time inspectors and inspection equipment for the quality inspection of the medical devices produced; they shall possess a management system to ensure the quality of medical devices; they shall possess after-sales service capabilities commensurate with the medical devices produced; and they shall meet the requirements as prescribed in the product research and development and production process documents. The enterprises engaging in the production of the medical devices of Class I shall undergo the recordation formalities with the drug supervision and administration department of the local people's governments at the districted city level. The enterprises engaging in the production of the medical devices of Class II and Class III shall apply for production licenses of the medical devices to the drug supervision and administration department of the local people's governments of the provinces, autonomous regions or municipalities directly under the Central Government. In case of any changes of the content as specified in the production license, the recordation shall be modified at the original recordation department. In case of any changes of the contents as specified in the production filing certificate of Class I medical devices, the recordation shall be modified for filing.

According to the Measures for Supervision and Administration of Medical Device Production, enterprises engaging in the production of Class I medical devices shall complete filing with former SFDA departments under the people's government of the city with districts where it is located and submit supporting materials evidencing its compliance with the criteria specified in the Regulations on Supervision and Administration of Medical Devices for engaging in the production of such medical devices; enterprises engaging in the production of Class II and Class III medical devices shall apply for a production license from former SFDA departments under the people's government of the province, autonomous region or municipality where it is located and submit supporting materials evidencing its compliance with the criteria specified in the Regulations on Supervision and Administration of Medical Devices for engaging in the production and the product registration certificates of such medical devices.

Medical Devices Production and Quality Management

On December 29, 2014, former SFDA promulgated the Good Manufacturing Practice for Medical Devices, which became effective on March 1, 2015. According to the Good Manufacturing Practice for Medical Devices, an enterprise engaging in the production of medical devices shall establish and effectively maintain a sound quality control system that are suitable for such medical devices produced, in accordance with the requirements of the Good Manufacturing Practice for Medical Devices with consistent product characteristics. The enterprise shall establish its procurement control procedure to ensure the purchased products are in compliance with the relevant requirements, which shall not be lower than the relevant requirements of laws, regulations and national mandatory standards. The enterprise shall establish an examination system and conduct review and evaluation on the suppliers. The enterprise shall record the procurement, production and inspection of raw materials. Such records shall be true, accurate, complete and traceable. The enterprise shall apply risk management to the whole process of design and development, production, sales and after-sale services. The measures being adopted shall be applicable to risks associated with the related products.

Former SFDA promulgated the Notice of Four Guidelines including the On-site Inspection Guidelines for the Standards on Production and Quality Management of Medical Devices, which

became effective on September 25, 2015. According to the On-site Inspection Guidelines for the Standards on Production and Quality Management of Medical Devices, during the course of on-site verification of the registration of medical devices and on-site inspection of production permit (including changing production permit), the inspection team shall, in accordance with the guidelines, issue recommended conclusions for on-site inspections, which shall be divided into "Passed," "Failed" and "Reassessment after rectification." If it is found that the requirements of the key items or ordinary items that may have direct impact on product quality are not satisfied during the supervision and inspection, the enterprise shall suspend production and go through rectification. If it is found that the requirements of the ordinary items are not satisfied, and it does not directly affect product quality, the enterprise shall rectify in a prescribed time. The regulatory authorities will examine and verify the recommended conclusions and on-site inspection materials submitted by the inspection group, and issue the final inspection results.

Norms on the Quality Management for the Clinical Trials of Medical Devices

On March 1, 2016, former SFDA and former National Health and Family Planning Commission jointly promulgated the Norms on the Quality Management for the Clinical Trials of Medical Devices, which became effective on June 1, 2016. The regulation includes full procedures of clinical trial of medical devices, including the protocol design, conduction, monitoring, verification, inspection, and data collection, recording, analysis and conclusion and reporting procedure of a clinical trial. For conducting clinical trials of medical devices, an applicant shall organize to formulate scientific and reasonable clinical trial protocols based on the categories, risks and intended use of the medical devices for the clinical study. The applicant shall be responsible for organizing to develop and revise the researcher's manual, clinical trial protocols, informed consent form, case report form, relevant standard operating procedures and other relevant documents, and shall be responsible for organizing necessary trainings for conducting clinical trials. The applicant shall select the clinical trial institutions and its researchers from the qualified medical device clinical trial institutions according to the characteristics of the medical devices to be used in the clinical study. The applicants are responsible for initiating, applying, organizing, and monitoring clinical trials, and are responsible for the authenticity and reliability of clinical trials. For new products that are not approved for marketing inside and outside the PRC and are not medically proven in safety and performance, a feasibility trial on a small sample size shall be conducted first when designing a clinical trial protocol. Upon preliminary confirmation of its safety, subsequent clinical trials shall be conducted on the statistical sample sizes required.

Medical Devices Operation Permit

Former SFDA amended the Measures for Supervision and Administration of Medical Devices Operation, which became effective on November 17, 2017. According to the Measures for Supervision and Administration of Medical Devices Operation, an enterprise engaging in the operation of medical devices shall have business premises and storage conditions suitable for the operation scale and scope, and shall have a quality control system and a quality control department or personnel suitable for the medical devices it operates. An enterprise engaged in the operation of Class II medical devices shall file with the municipal level food and drug supervision and administration department of the PRC and provide proofing materials for satisfying the relevant conditions of engaging in the operation of medical devices, while an enterprise engaged in the

operation of Class III medical devices shall apply for a business operation license to the municipal level food and drug supervision and administration department of the PRC and provide proofing materials for satisfying the relevant conditions of engaging in the operation of such medical devices.

The food and drug supervision and administration department which approves operation permit application shall grant the business operation license of medical devices if the enterprise meets the prescribed requirements. A business operation license of medical devices is valid for 5 years and may be renewed in accordance with the provisions of relevant laws on administrative licensing. An enterprise engaging in medical devices operation shall not operate or use any medical device that has not been legally registered, without qualification certificate, out-dated, invalid or disqualified.

Two-Invoice System for Medical Devices

According to the Notice on Issuing the Implementation Opinions of the "Two-Invoice System" in Drug Procurement by Public Healthcare Institutions (Trial)* (hereinafter referred to as the "Notice") issued by the former Office of the Leading Group for Deepening the Reform of the Medical and Health Care System of the State Council, former National Health and Family Planning Commission, former SFDA and other authorities on December 26, 2016, the "Two-Invoice System" refers to the system that requires one invoice to be issued from pharmaceutical manufacturers to pharmaceutical distributors and the other invoice to be issued from pharmaceutical distributors to medical institutions. The Notice requires public medical institutions to gradually implement the "Two-Invoice System" for drug procurements and encourages other medical institutions to promote the "Two-Invoice System", thus the "Two-Invoice System" will strive to be promoted nationwide by 2018.

According to the Notice on Consolidating the Achievements of Canceling Price Markups on Drugs and Deepening the Comprehensive Reform of Public Hospitals* issued by the former National Health and Family Planning Commission, Ministry of Finance, NDRC and other authorities on March 5, 2018, a classified and centralized mechanism shall be implemented for the procurement of high-value medical consumables and the "Two-Invoice System" shall be gradually implemented for the procurement and sales of high-value medical consumables.

On July 19, 2019, the General Office of the State Council issued the Notice of Issuing the Reform Plan for the Control of High-value Medical Supplies, which encourages the local authorities to reduce the circulation steps of high-value medical consumables through the "Two-Invoice System" and other ways in light of the actual situation, so as to promote the openness and transparency of purchases and sales. As of now, certain provinces in the PRC (such as Fujian, Shaanxi, Anhui, Guangdong) have issued the relevant regulations on the "Two-Invoice System" for the medical consumables.

Pursuant to the Reply of the National Healthcare Security Administration to Recommendation No. 1209 of the Second Session of the Thirteenth National People's Congress* issued by NHSA on July 23, 2019, "Two-Invoice System" for high-value consumables needs to be further discussed given the huge differences between high-value consumables and pharmaceuticals and the complexity of clinical use and after-sales service.

The Reform Plan of High-Value Medical Consumables

According to the Notice of the Ministry of Health on Further Strengthening the Administration of Centralized Procurement of Medical Appliances issued on June 21, 2007, all non-profit medical institutions under all levels of government, industries and state-owned enterprises from different industries shall participate in the centralized procurement of medical devices.

Pursuant to the Notice of Opinions on Reform of the Pricing Mechanism of Drugs and Medical Services* issued and implemented on November 9, 2009, the management on the pricing of medical devices will be strengthened. For high-value medical devices, especially for implantable and interventional medical devices, reasonable price formation can be guided by measures such as limiting the price difference rate in circulation links and publishing market price information.

According to the Trial Regulations on Centralized Procurement of High-Value Consumable Medical Supplies, which was issued and became effective on December 17, 2012, high-value medical consumables are defined as medical consumables directly used on human, with strict requirement on safety, in great demand clinically, relatively highly-priced, and that can pose heavy burdens on society. The online centralized procurement (the "Centralized Procurement") works of high-value medical consumables will be led by government and conducted by each province (region and municipality). Medical institutions and medical consumables production and operation enterprises shall make procurement through the Centralized Procurement platform established by each province (region and municipality). The administrative authorities in charge of the Centralized Procurement in each province (region and municipality) shall be responsible for formulating and preparing a Centralized Procurement list of high-value medical devices within its administrative region. High-value medical consumables listed on the Centralized Procurement list may be procured by way of public tenders and invitational tenders or by other means stipulated by laws and regulations of the State. After the procurement prices are determined, public medical institutions within relevant regions shall make procurement strictly at bidding prices.

On July 19, 2019, the General Office of the State Council issued the Notice on Promulgation of the Reform Plan for the Control of High-value Medical Consumables (hereinafter referred to as the "Reform Plan"), which became effective on July 19, 2019. According to the Reform Plan, high-value medical consumables are defined as medical consumables directly used on human, with strict requirement on safety, in great demand clinically, relatively highly-priced, and that can pose heavy burdens on patients. The Reform Plan releases related reform initiatives aiming at managing high-value medical consumables, including: (i) the classification and codes of high-value medical consumables in the national medical insurance system will be unified gradually, and rules on unique device identification in full life cycle of the high-value medical consumables, including registration, procurement and usage, will be implemented by NHSA, NMPA and NHC by the end of 2020; (ii) the mechanism for including high-value medical consumables in basic medical insurance shall be built, and a list of high-value medical consumables shall be compiled, to strengthen the dynamic adjustment mechanism. The access regulations shall be promulgated by NHC and the Ministry of Finance by the end of June 2020; (iii) the price markups placed on medical consumables at public medical institutions will be abolished, and all medical consumables, including high-value medical consumables will be sold at the procurement price at all public medical institutions by the end of 2019; and (iv) the medical insurance payment policy shall be formulated and implemented by NHSA, Ministry of Finance and

NHC. Meanwhile, the medical insurance payment standards on high-value medical consumables will be formulated and the dynamic adjustment mechanism will be established. The medical insurance funds and patients will share the cost of high-value medical consumables according to the medical insurance payment standards, and medical institutions shall further reduce procurement prices under the guidance of the Reform Plan.

According to the Guiding Opinions on Establishing Centralized Procurement and Use of High-Value Medical Supplies Organized by the State*jointly issued by NHC, NMPA and other relevant government authorities on April 30, 2021, it focuses on the high-value medical consumables with larger clinical consumption, higher procurement amount, more mature clinical use, more keen market competition and higher similarity level counting into the procurement scope, and determine the shortlist criteria according to market sales, clinical use demand, medical technology progress and other factors. All public medical institutions (including military medical institutions) shall participate in the Centralized Procurement of high-value medical consumables in accordance with the regulations. The designated social medical institutions of medical insurance may voluntarily participate in the Centralized Procurement in accordance with the relevant regulations of its provinces (autonomous regions and municipalities).

Medical Devices Recalls

On January 25, 2017, former SFDA promulgated the Measures for the Administration of Medical Device Recalls, which became effective on May 1, 2017. Pursuant to the Measures for the Administration of Medical Device Recalls, which, medical devices manufacturers are the responsible party for controlling and eliminating product defects and shall take the initiative to recall the defective products. In light of the severity of the harm of the medical devices, medical device recalls are divided into three classes, including (i) Class I recall: where the circumstances leading to the recall may cause or have caused serious health hazards; (ii) Class II recall: where the circumstances leading to the recall may cause or have caused temporary or reversible health hazards; or (iii) Class III recall: where the circumstances leading to the recall are not likely to cause harm but still have to be recalled.

Medical device manufacturers shall determine the recall class based on the specific situation and properly design and implement the recall plan based on the recall class and the sales and use of the medical devices.

Sampling and Collecting Human Genetic Resources Filing

On May 28, 2019, the State Council promulgated the Regulation of the People's Republic of China on the Administration of Human Genetic Resources, which became effective on July 1, 2019. According to the provisions therein, the State shall support the rational utilization of human genetic resources to carry out scientific research, develop the biomedical industry, improve diagnosis and treatment technologies, improve the biosafety guarantee capabilities of the PRC, and improve people's health protection level. Foreign organizations, individuals and the institutions established or actually controlled thereby shall not collect or preserve human genetic resources of the PRC within the PRC, nor shall they provide human genetic resources of the PRC outside the PRC. Furthermore, the collection, preservation, utilization, and external provision of human genetic resources of the PRC shall comply with the ethical principles and be subject to ethical review in accordance with relevant regulations of the State.

The National People's Congress (hereinafter referred to as the "NPC") Standing Committee issued the Biosecurity Law of the People's Republic of China on October 17, 2020, which became effective on April 15, 2021. Biosecurity Law of the People's Republic of China reaffirms that the State enjoys sovereignty over China's human genetic and biological resources and make regulations in accordance with the regulatory requirements set out in the Regulation of the People's Republic of China on the Administration of Human Genetic Resources.

Medical Devices Export Registration

According to Measures for Supervision and Administration of Medical Device Production, a manufacturer of medical devices for exportation purpose shall ensure that the medical devices produced meet the requirements of the importing country (region), and the relevant information of the products shall be submitted to the food and drug supervision and administrative department of the local people's governments at the districted city level for record.

Pursuant to the Regulations on the Administration of Export Sales Certificates of Medical Devices, which was promulgated by Former SFDA on June 1, 2015 and became effective on September 1, 2015, if the registration certificate for medical device products and production permit for medical device products have been obtained in China, or the medical device registration and production filing have been completed, the food and drug supervision and administration department may issue Medical Device Product Export Sales Certificate to the relevant manufacturing enterprises. The validity term of the Medical Device Product Export Sales Certificate shall not exceed the earliest deadline for the various documents submitted by the enterprises in the application materials, and the maximum validity term shall not exceed two years either.

Advertisements of Medical Devices

According to the Interim Measures for the Administration of Censorship of Advertisements on Drugs, Medical Devices, Dietary Supplements and Formula Foods for Special Medical Purposes promulgated by the State Administration for Market Regulation on December 24, 2019, which became effective on March 1, 2020, an enterprise qualified for engaging in the production or operation of medical devices shall apply for the publication of any medical device advertisement with the market regulation, drug supervision and administration departments of the local people's governments of the provinces, autonomous regions or municipalities, and obtain an approval of such advertisement of medical devices. The validity term of such advertisement approval shall be consistent with that of the registration certificate or record-filing certificate or the production license of the product, whichever is the shortest. Where no validity term is set forth in the registration certificate, record-filing certificate or the production license of the product, the advertisement approval shall be valid for two years.

The advertisement of a medical device shall be true and lawful, and its content shall not be false, exaggerated or misleading. A publisher of a medical device advertisement shall verify approval documents and their authenticity prior to the publication. If no approval document was obtained or the authenticity of any approval document has not been verified or the content of the advertisement is inconsistent with the approval documents, such medical device advertisement shall not be published.

National Medical Insurance System

The national medical insurance system is established according to the Decision of the State Council on Establishing the Urban Employees' Basic Medical Insurance System promulgated by the State Council on December 14, 1998. Accordingly, all employers are required to enroll their employees for the Urban Employees' Basic Medical Insurance, and the basic insurance premiums shall be contributed jointly by employers and employees. According to the Notice on Opinions on Establishment of the New Rural Cooperative Medical System forwarded by the General Office of the State Council on January 16, 2003, the New Rural Coorperative Medical System was launched in specific regions in China to provide medical insurance for rural residents and has been promoted nationwide since then. On July 10, 2007, the State Council issued the Guiding Opinions of the State Council about the Pilot Urban Resident Basic Medical Insurance, under which urban residents in pilot regions may voluntarily participate in the Urban Resident Basic Medical Insurance . On March 6, 2015, the General Office of the State Council issued the Outline for the Planning of the National Medical and Health Service System (2015-2020), aiming to establish a basic medical and health system covering urban and rural residents by 2020.

On January 3, 2016, the State Council issued the Opinions of the State Council on Integrating the Basic Medical Insurance Systems for Urban and Rural Residents, which aims to integrate the Urban Resident Basic Medical Insurance and the New Rural Cooperative Medical System, and to establish a unified system of basic medical insurance for urban and rural residents (hereinafter referred to as the "Medical Insurance for Urban and Rural Residents"), which covers all non-working urban and rural residents, rural migrant workers and flexible employees for participation in the basic medical insurance for urban employees.

According to the Social Insurance Law of the People's Republic of China, which was amended by the NPC Standing Committee and became effective on December 29, 2018, the medical expenses of insured personnel that should be paid by the basic medical insurance fund shall be settled directly by the social insurance agencies, medical institutions and drug trading units.

The State Medical Security Administration issued the Interim Measures for the Management of Medical Consumables for Basic Medical Insurance (Draft for Comments) in June 2020. The draft suggests that the State Council medical security administrative departments, taking into account the functional role of medical consumables, clinical value, cost level, the ability of the medical insurance fund, etc., use the access method to develop the "basic medical insurance medical consumables catalog", which shall be updated regularly and dynamically adjusted. The medical consumables in the "Basic Medical Insurance Medical Consumables Catalogue" shall be included in the scope of payment of the medical insurance fund according to the regulations. However, as of the last practicable date, the Chinese authorities have not yet issued a national or regional medical insurance reimbursement list for medical devices.

In June 2020, the Office of the National Health Security Administration issued the Medicare Diagnosis-Related Grouping of Diseases (CHS-DRG) Subgroup Program (Version 1.0) to advance the DRG payment national pilot in each pilot city. By initiating the Diagnosis-Related Subgroups mechanism, the NMSA controls the price of medical devices and treatments by dividing patients into different diagnosis-related subgroups and paying medical claims based on payment rates set for each subgroup (rather than actual expenses incurred by the patient).

Product Liability and Protection of Consumers' Rights

According to the Product Quality Law of the People's Republic of China, which was amended by the NPC Standing Committee and became effective on December 29, 2018, producers and sellers shall establish a sound internal product quality management system, and strictly implement post-oriented quality specifications, quality liabilities and corresponding assessment methods. Producers and sellers shall bear product quality responsibilities in accordance with the law.

The market regulatory authorities of the State Council shall be in charge of the supervision for product qualities across the nation. The relevant departments of the State Council shall be responsible for supervision for product quality within their respective scope of duties. The product quality shall pass the inspection and unqualified products shall not be passed as qualified products. Industrial products that may endanger human health, personal and property safety must meet the national and industrial standards for personal and property safety; for those which have no formulated national and industrial standards, the minimum requirements for protecting human health and personal and property safety must be met. It is prohibited to produce and sell industrial products that do not meet the standards and requirements for protecting human health and personal and property safety. Producers and sellers shall be responsible for the compensations arising from their illegal acts. For example, those who produce or sell defective, obsolete or ineffective products, forge the origin of products or misuse quality marks, or pass off imitations as genuine, substandard products as quality ones or non-conforming products as conforming, they may have their illegal proceeds confiscated, their business license revoked and fined; and for serious cases, they may be held liable for criminal responsibilities according to the law. Producers and sellers shall be held liable for compensations for any damage to any person or property of others due to the defects of the products resulting from the default of the producers or sellers.

On May 28, 2020, the NPC issued the Civil Code of the People's Republic of China (hereinafter referred to as the "Civil Code"), which became effective on January 1, 2021. According to the Civil Code, if a patient suffers damage due to a defect of a medical device, the patient may request compensation from the producer or the medical institution. If the patient requests compensation from the medical institution, the medical institution shall have the right to recover compensation from the responsible producer after compensation.

On October 25, 2013, the NPC Standing Committee amended the Law on the Protection of Consumer Rights and Interests of People's Republic of China (hereinafter referred to as the "Law on the Protection of Consumer Rights and Interests"), which became effective on March 15, 2014. According to the Law on the Protection of Consumer Rights and Interests, Protection of Consumer Rights of the People's Republic of China when consumers purchase or use products or receive services, this Law shall be applied to protect the rights and interests of consumers. Business operators shall abide by this law when providing consumers with goods and/or services they produce and sell.

Regulations on Information Security and Data Privacy

On June 10, 2021, the NPC Standing Committee promulgated the Data Security Law of the People's Republic of China (hereinafter referred to as the "Data Security Law"), which became effective on September 1, 2021. According to the Data Security Law, a data classification protection system shall be established to protect data by classification. Entities engaged in data processing

activities shall, in accordance with the laws and regulations, establish a sound whole-process data security management system, organize data security education and training, and take corresponding technical measures and other necessary measures to ensure data security.

According to the Civil Code, personal information of natural persons is protected by law. Any organization or individual who needs to obtain personal information of others shall obtain legally and ensure the information security, and shall not illegally collect, use, process and transmit personal information of others, and shall not illegally trade, provide or disclose personal information of others. On August 20, 2021, the NPC Standing Committee promulgated the Personal Information Protection Law of the People's Republic of China (effective from November 1, 2021), emphasizing the duties and responsibilities of processing personnel for the protection of personal information and stipulating stricter protection measures for processing sensitive personal information.

On November 7, 2016, the NPC Standing Committee promulgated the Cybersecurity Law of the People's Republic of China (hereinafter referred to as the "Cybersecurity Law"), which became effective on June 1, 2017. According to the Cybersecurity Law, network operators shall abide by "legality, legitimacy and necessity" when collecting and using personal information. When collecting and using personal information, network operators shall disclose the rules of collection and application, specify the purpose, mode and scope of the collection and use of information, and obtain the consent of the person to whom the personal information is collected. Network operators shall not collect personal information irrelevant to the services they provide, nor disclose, tamper with or damage the personal information they collect; shall not provide relevant personal information to others without the prior consent of the person whom the personal information is collected, except for the personal information that cannot be identified and restored after processing.

On July 12, 2018, NHC promulgated the Administrative Measures on National Health and Medical Care Big Data Standards, Security and Services (Trial) (hereinafter referred to as the "Measures on Health and Medical Care Big Data"), which became on the same day. The Measures on Health and Medical Care Big Data stipulates the guidelines and principles of health and medical big data standard management, safety management and service management. According to the Measures on Health and Medical Care Big Data, NHC is responsible for the management of national health and medical big data together with other relevant departments, and all health departments above the county level are responsible for the management of health and medical big data within their administrative regions together with other relevant departments. Medical institutions and relevant enterprises, including those engaged by medical institutions to store or operate health and medical big data, shall take measures, such as data classification, important data backup and encryption, to ensure the safety of health and medical big data, and provide safe information query and replication channels. Based on the Cybersecurity Law of the People's Republic of China, the responsible unit shall strictly control the authorization of users at different levels to access and use data to ensure the use of data within the scope of authorization. Without authorization, no unit or individual shall use or disseminate any health and medical big data or data outside the scope of authorization, nor obtain any data in illegal ways. The responsible unit shall abide by relevant national regulations when disclosing health and medical big data, shall not divulge state secrets, trade secrets or personal privacy, shall not infringe upon the interests of the state or the public, and shall not infringe upon the legitimate rights and interests of citizens, enterprise entities or other organizations.

LAWS AND REGULATIONS ON THE ESTABLISHMENT OF COMPANIES AND FOREIGN INVESTMENT

The establishment, operation and management of Chinese enterprise entities are governed by the Company Law of the People's Republic of China (hereinafter referred to as the "China's Company Law"). The law was promulgated by the NPC Standing Committee on December 29, 1993, and finally revised and became effective on October 26, 2018. Limited liability companies and joint stock limited companies established in China are regulated by the China's Company Law. Unless otherwise stipulated in the Foreign Investment Law, foreign-funded companies are also regulated by the China's Company Law.

NPC approved the Foreign Investment Law of the People's Republic of China (hereinafter referred to as the "Foreign Investment Law") on March 15, 2019, which became effective on January 1, 2020 and replaced the Law of the People's Republic of China on Joint Ventures Using Chinese and Foreign Investment (中華人民共和國中外合資經營企業法), the Law of the People's Republic of China on Chinese-Foreign Contractual Joint Ventures and the Law of the People's Republic of China on Wholly Foreign-Owned Enterprises. It has become the legal basis for foreign investment in China. The State Council promulgated the Regulation for Implementing the Foreign Investment Law of the People's Republic of China on December 26, 2019, which became effective on January 1, 2020 and replaced Regulations for the Implementation of the Law of the People's Republic of China on Joint Ventures Using Chinese and Foreign Investment, Interim Provisions on the Contract Term of Chinese-foreign Equity Joint Ventures, the Rules for the Implementation of the Law of the People's Republic of China on Foreign-capital Enterprises and the Detailed Rules for the Implementation of the Law of People's Republic of China On Sino-Foreign Joint Cooperative Ventures.

Foreign Investment Law contains the basic regulatory framework for foreign investment and implements the management systems of pre-establishment national treatment of the negative list for foreign investment. According to this Law, (i) foreign natural persons, enterprises or other organizations (hereinafter referred to as the "foreign investors") shall not invest in any field forbidden by the negative list for access of foreign investment, (ii) for any field restricted by the negative list, foreign investors shall conform to the investment conditions provided in the negative list , and (iii) fields not included in the negative list shall be managed under the principle that domestic investment and foreign investment shall be treated uniformly. Foreign Investment Law also stipulates the necessary mechanisms for promoting, protecting and managing foreign investment, and stipulates the establishment of a foreign investment information reporting system. Foreign investors or foreign-funded enterprises shall submit investment information to the competent departments for commerce through the enterprise registration system and the enterprise credit information publicity system. The organizational form, organization and activity criteria of foreign-funded enterprises shall conform to various laws, including the China's Company Law and the Partnership Enterprise Law of the People's Republic of China (if applicable).

On December 30, 2019, the Ministry of Commerce and the State Administration for Market Regulation promulgated the Measures for the Reporting of Foreign Investment Information, which became effective on January 1, 2020 and replaced the Interim Measures for the Recordation Administration of the Formation and Modification of Foreign-Funded Enterprises. From January 1,

2020, for investment activities directly or indirectly carried out in China, these Measures stipulate that foreign investors or foreign-funded enterprises must submit investment information to the competent departments for commerce through the enterprise registration system and the national enterprise credit information publicity system.

According to the Special Administrative Measures for the Foreign Investment Access (Negative List) (2020 Edition) and the Catalog of Industries for Encouraging Foreign Investment (2020 Edition) issued by the NDRC and the Ministry of Commerce on December 27, 2020, which became effective on January 27, 2021, foreign-funded projects can be divided into three categories: encouragement, restriction and prohibition. Foreign-funded projects not listed in the negative list are permitted foreign-funded projects. As of now, businesses of companies and their Chinese subsidiaries do not belong to the restricted or prohibited industries listed in the Special Administrative Measures for the Foreign Investment Access (Negative List) (2020 Edition).

The Provisions on M&A of a Domestic Enterprise by Foreign Investors was revised and became effective on June 22, 2009. According to the provisions, mergers and acquisitions of domestic enterprises by foreign investors shall comply with the requirements of Chinese laws, administrative regulations and rules on investor qualifications and policies in respect of industry, land, environmental protection and others. According to the Notice of the General Office of the State Council on the Establishment of the Security Review System for Mergers and Acquisitions of Domestic Enterprises by Foreign Investors promulgated by the General Office of the State Council on February 3, 2011, which became effective on March 4, 2011, the scope of mergers and acquisitions security review includes foreign investors' mergers and acquisitions of domestic military facility enterprises, surrounding enterprises of key and sensitive military facilities, and other units related to national defense security; foreign investors' mergers and acquisitions of domestic enterprises related to national security in terms of important agricultural products, important energy and resources, important infrastructure, important transportation services, key technologies, major equipment manufacturing, etc., of which their actual control rights may be acquired by foreign investors. The merger and acquisition of a domestic enterprise by a foreign investor refers to the following circumstances: (i) acquiring the equity interests of a domestic company to change the establishment of the domestic company into a foreign-funded enterprise; (ii) subscribing for the capital increase of a domestic company to change the establishment of the domestic company into a foreign-funded enterprise; (iii) establishing a foreign-funded enterprise, acquiring the assets of a domestic enterprise through the enterprise and operating the assets; and (iv) purchasing the assets of a domestic enterprise and investing with the assets in the establishment of a foreign-funded enterprise.

LAWS AND REGULATIONS ON INTELLECTUAL PROPERTY

Trademark

The NPC Standing Committee revised the Trademark Law of the People's Republic of China on April 23, 2019, which became effective on November 1, 2019, and revised the Regulation on the Implementation of the Trademark Law of the People's Republic of China on April 29, 2014, which became effective on May 1, 2014. They stipulate the requirements for trademark registrants in terms of the application, review and approval, renewal, change, transfer, use and invalidity, and protects the exclusive right of trademark registrants.

According to the above laws and regulations, the term of validity of a registered trademark is ten years, starting from the date of approval of registration. Upon the expiration of the term of validity of a registered trademark, if it is necessary to continue to use it, the renewal shall be processed as required within 12 months before the expiration. If the process cannot be completed during this period, a grace period of six months may be granted. The term of validity of each renewal registration is ten years, starting from the date after the expiration of the term of validity of the trademark. The trademark registrant may, by signing a trademark licensing contract, license others to use its registered trademark.

Patent

According to the Patent Law of the People's Republic of China, which became effective on June 1, 2021, and the Detailed Rules for Implementation of the Patent Law of the People's Republic of China revised by the State Council on January 9, 2010, which became effective on February 1, 2010, the patent administration department under the State Council shall be responsible for the administration of patent work throughout the country; accepting and reviewing patent applications on a consistent basis, and granting patent rights according to law. The patent administration departments of the people's governments of provinces, autonomous regions and municipalities shall be responsible for the administration of patents within their respective administrative regions. Inventions and utility models granted with patent rights shall be novel, creative and practical. Patent rights shall be granted according to law if the designs do not have existing examples, and no entity or individual has filed an application with the patent administration department under the State Council for the same design before the application date and recorded it in the patent documents published after the application date. The term of the patent right for invention is 20 years, the term of the patent right for utility model is 10 years, and the term of the patent right for design is 15 years, all starting from the date of application. Any entity or individual exploiting another person's patent shall conclude an exploitation license contract with the patentee and pay the patentee a patent royalty. Exploiting the patentee's patent without its permission shall constitute an infringement of its patent right.

Copyright

According to the Copyright Law of the People's Republic of China, which became effective on June 1, 2021, works of Chinese citizens, legal persons or other unincorporated organizations, including intellectual achievements in the fields of literature, art and science that are original and can be expressed in a certain form, whether published or not, shall be entitled to copyrights. Copyright owners are entitled to a variety of rights, including the right of publication, authorship and reproduction.

According to the Measures for the Registration of Computer Software Copyright promulgated by the National Copyright Administration, which became effective on February 20, 2002 and the Regulation on the Protection of Computer Software, which became effective on March 1, 2013, the National Copyright Administration is mainly responsible for the registration and administration of software copyright in China, and recognizes the Copyright Protection Center of China as the software registration authority. For computer software copyright applicants who comply with the requirements of the Measures for the Registration of Computer Software Copyright and the Regulation on the Protection of Computer Software, they shall be granted a registration certificate by the Copyright Protection Center of China.

Domain Name

According to the Measures for the Administration of Internet Domain Names promulgated by the Ministry of Industry and Information Technology on August 24, 2017, which became effective on November 1, 2017, the establishment of domain name root servers and domain name root server operation organizations, domain name registration administration organizations and domain name registration service organizations within China is subject to the permission of the Ministry of Industry and Information Technology or the communications authorities of provinces, autonomous regions or municipalities. The domain name registration service shall follow the "first to apply, first to be registered" principle. The Notice of the Ministry of Industry and Information Technology on Regulating the Use of Domain Names in Internet Information Services, which became effective on January 1, 2018, stipulates the obligations of anti-terrorism and cybersecurity maintenance for the Internet information service providers and other main bodies.

Business Secrets

According to the Anti-Unfair Competition Law of the People's Republic of China, promulgated by The NPC Standing Committee in September 1993 and amended on April 23, 2019, "Business Secrets" refer to the technical information and operational information that is not available to the public, practical and able to create commercial benefits or profits for its legal owner or holder, and regarded as confidential by its legal owner or holder. According to the Anti-Unfair Competition Law of the People's Republic of China, an enterprise shall not infringe upon the business secrets of others in the following ways: (1) obtain the business secrets of the right owner by theft, bribery, fraud, coercion, electronic intrusion or other means; (2) disclose, use or allow others to use the business secrets of the legal owner (hereinafter referred to as the "obligee") obtained by the means specified in item (1) above; (3) disclose, use or allow others to use the business secrets held by the obligee in violation of the obligation of confidentiality or the relevant requirements of the obligee in relation to keeping the business secrets confidential; (4) abet, induce and aid others to obtain, disclose, use or allow others to use the business secrets of the obligee in violation of the obligation of non-disclosure or the confidentiality requirements of the obligee in regards of business secrets. If a third party, who is aware of or should be aware of the above acts being illegal, but still obtains, uses or discloses the business secrets of others, shall be deemed to have infringed upon the business secrets of others. Where operators and other natural persons, legal persons and entitles without legal personality violate the Anti-Unfair Competition Law of the People's Republic of China and infringe upon business secrets, the supervision and inspection authority shall order to cease the illegal act, confiscate the illegal gains and impose a fine.

According to the provisions of the Criminal Law of the People's Republic of China, which became effective on March 1, 2021, for a person who obtains the obligee's business secrets by theft, bribery, fraud, coercion, electronic intrusion or other improper means; for a person who discloses, uses or allows others to use the business secrets of the obligee obtained by the means mentioned in the preceding item; for a person who discloses, uses or allows others to use the business secrets held by the obligee in violation of the obligation of confidentiality or the relevant requirements of the obligee in relation to keeping the business secrets confidential, if the case is serious, shall be sentenced to imprisonment for a definite period of not more than three years and shall or shall only be fined; if the case is particularly serious, shall be sentenced to imprisonment for a definite period of not less than

three years but not more than ten years and shall be fined. For a person who is aware of the acts set out above, obtains, discloses, uses or allows others to use the business secrets, shall be regarded as an infringement of business secrets.

LAWS AND REGULATIONS RELATED TO FOREIGN EXCHANGE

Overall Management of Foreign Exchange

According to the Regulation of the People's Republic of China on Foreign Exchange Administration promulgated on January 29, 1996 and revised on August 5, 2008, which aims at the strengthening foreign exchange management, promotion of international fiscal balance and promotion of healthy development of national economy, and various regulations promulgated by the State Administration of Foreign Exchange and other relevant Chinese government authorities, Renminbi can be converted into other currencies for current account items, such as trade-related receipts and payments and interest and dividend payments. The conversion of Renminbi of the capital account items (such as direct equity investment, loans and capital repatriation) into other currencies and the remittance of foreign currencies outside China after conversion shall be subject to the prior approval of the State Administration of Foreign Exchange or its local office. Payments of transactions in China shall be made in Renminbi. Unless otherwise approved, Chinese companies may remit offshore foreign currencies payments or retain them in that offshore region. Foreign-owned enterprises may, under the limit determined by the State Administration of Foreign Exchange or its local office, retain foreign exchange under the current account items in the account opened at the designated foreign exchange bank. According to relevant national rules and regulations, the foreign exchange income under the current account may be retained or sold to financial institutions engaged in foreign exchange settlement and sales. The foreign exchange income under the capital account to be retained or sold to financial institutions engaged in foreign exchange settlement or sales is subject to the approval of the State Administration of Foreign Exchange, except where approval is not required under relevant Chinese laws and regulations.

LAWS AND REGULATIONS RELATED TO FOREIGN EXCHANGE REGISTRATION OF OVERSEAS INVESTMENT BY CHINESE RESIDENTS

According to the Notice of the State Administration of Foreign Exchange on Issues concerning Foreign Exchange Administration of the Overseas Investment and Financing and the Round-tripping Investment Made by Domestic Residents through Special-Purpose Companies (hereinafter referred to as "Circular 37"), which became effective on July 4, 2014, Chinese residents or entities shall register under the State Administration of Foreign Exchange or its branches for the establishment or control of offshore entities established for overseas investment or financing purposes. In addition, in case of changes in relevant basic information of overseas special purpose companies (including changes in Chinese citizens or residents, names and operating periods), major matters such as increase or decrease of investment amount, equity interest transfer or replacement, merger or division, relevant Chinese residents or entities shall update their registration with the State Administration of Foreign Exchange in a timely manner.

Notice of the State Administration of Foreign Exchange on Further Simplifying and Improving Policies for the Foreign Exchange Administration of Direct Investment (hereinafter referred to as "Circular 13") was issued by the State Administration of Foreign Exchange on February 13, 2015,

which became effective on June 1, 2015, and amended on December 30, 2019. Circular 13 allows Chinese residents or entities to register with the bank for the establishment or control of offshore entities established for overseas investment or financing purposes. However, the remedial registration application made by Chinese residents, who have previously failed to comply with Circular 37, will continue to be under the jurisdiction of the relevant local branches of the State Administration of Foreign Exchange. If the Chinese shareholders holding interests in the SPV fail to register with State Administration of Foreign Exchange as required, the Chinese subsidiaries of the SPV may be prohibited from distributing profits to the offshore parent company and may not carry out cross-border foreign exchange activities thereafter, and ability of the SPV to inject additional capital into its PRC subsidiaries may be limited. In addition, failure to comply with various above-mentioned registration regulations of State Administration of Foreign Exchange, may result in liability under PRC law for evading foreign exchange supervision.

LAWS AND REGULATIONS RELATED TO EMPLOYMENT AND SOCIAL WELFARE

Labor Law and Labor Contract Law

According to the Labor Law of the People's Republic of China, which became effective on December 29, 2018, the Labor Contract Law of the People's Republic of China, which became effective on July 1, 2013, and the Regulation on the Implementation of the Labor Contract Law of the People's Republic of China, which became effective on September 18, 2008, the employer shall strictly abide by the national standards, provide relevant training for workers, and ensure that workers are entitled to labor rights and perform labor obligations. The employer and workers shall sign a written labor contract, which is divided into fixed-term labor contract, unfixed-term labor contract and labor contract with the term of completing certain assignments. Wages paid to the workers by the employer shall not be lower than the local minimum wage standards.

According to the Labor Contract Law of the People's Republic of China, labor contract employment is the basic form of employment of enterprises in China. Labor dispatch employment is a supplementary form and can only be implemented in temporary, auxiliary or alternative jobs. The dispatched workers are entitled to the right to equal pay for equal work with the workers of the employer. Temporary jobs refer to jobs that last no more than six months; auxiliary jobs refer to non-major business posts that provide services to the major business posts; alternative jobs refer to posts that can be replaced by other workers within a certain period when the workers of the employer are unable to work due to off-duty study, vacation and other reasons. The employer shall strictly control the number of labor dispatch, and shall not exceed a certain proportion of its total employment. The specific proportion is determined by Labor Administration Department of the State Council. The Labor Administration Department shall order the employer to make corrections within a certain limit of time, if it violates the relevant regulations on labor dispatch; failure to make corrections within that limit of time shall result in a fine under the standard of not less than RMB5,000 but not more than RMB10,000 per person.

Social Insurance and Housing Provident Funds

According to the Regulation on Work-Related Injury Insurance, which became effective on January 1, 2011, the Trial Measures for Childbirth Insurance for Enterprise Employees promulgated on December 14, 1994 and implemented on January 1, 1995, the Decision on the Establishment of a

Unified Basic Endowment Insurance System for Employees in Enterprises of the State Council, which became effective on July 16, 1997, the Decision of the State Council on Establishing the Urban Employees' Basic Medical Insurance System, which became effective on December 14, 1998, the Regulations on Unemployment Insurance, which became effective on January 22, 1999 and the Social Insurance Law of the People's Republic of China, which became effective on December 29, 2018, enterprises are obliged to provide Chinese employees with welfare plans covering pension, unemployment insurance, maternity insurance, work injury insurance and medical insurance. If an employer fails to pay social insurance premiums in full and on time, the social insurance premium collection agency shall order that employer to pay or complement within a certain limit of time, and an overdue fine of 0.05% per day from the date of arrears shall be imposed; if the payment is overdue, a fine of more than once but not more than three times the amount of arrears shall be imposed by the relevant administrative authority.

According to the Regulation on the Administration of Housing Provident Funds, which became effective on March 24, 2019, the enterprise must register with the competent provident fund management center and complete the relevant bank account opening procedures for housing provident fund deposits of employees after inspection. The enterprise shall pay the housing provident fund in full and on time. If the unit fails to handle the housing provident fund deposit registration or fails to handle the procedures for the establishment of housing provident fund accounts for its employees, the housing provident fund management center shall order that unit to handle the procedures within a certain limit of time; for failure of handling the procedures within a limit, a fine of more than RMB10,000 but not more than RMB50,000 shall be imposed. In addition, in violation of the relevant provisions of the Regulation on the Administration of Housing Provident Funds, if the payment of the housing provident fund is overdue or underpaid by the unit, the housing provident fund management center shall order that unit to make the payment within a certain limit of time; if the payment remains overdue and unpaid, it may apply to the People's Court for enforcement.

LAWS AND REGULATIONS ON ENVIRONMENTAL PROTECTION

According to the Environmental Protection Law of the People's Republic of China, which became effective on January 1, 2015, the Law of the People's Republic of China on Environmental Impact Assessment, which became effective on December 29, 2018, the Regulations on the Administration of Construction Project Environmental Protection, which became effective on October 1, 2017, the Interim Measures for the Inspection and Acceptance of Environmental Protection upon Completion of Construction Projects, which became effective on November 20, 2017, for construction projects that are required to prepare an environmental impact report and an environmental impact statement, the construction unit shall submit the environmental impact report and the environmental impact statement to the competent administrative authority of environmental protection with the power of examination and approval for examination and approval before the commencement of construction; for construction projects that should fill in the environmental impact registration form in accordance with the law, the construction unit shall submit the environmental impact registration form to the competent administrative authority of environmental protection for the record; for construction projects that are required to prepare environmental impact report and environmental impact statement, the construction unit shall conduct acceptance inspection before operation, and only after passing the acceptance inspection, can they be put into production or use. After the environmental impact assessment documents of the construction project are approved, and in

case of significant changes regarding the nature, scale, location, production technology adopted, or measures to prevent pollution and ecological damage of the construction project, the construction unit shall re-submit the environmental impact assessment documents of the construction project for approval.

LAWS AND REGULATIONS RELATED TO TAXATION

Corporate Income Tax

According to the Enterprise Income Tax Law of the People's Republic of China, which became effective on December 29, 2018 and the Regulation on the Implementation of the Enterprise Income Tax Law of the People's Republic of China, which became effective on April 23, 2019, taxpayers include resident enterprises and non-resident enterprises. Resident enterprises refer to enterprises established in China according to law, or enterprises established in accordance with foreign (regional) laws, but the actual management authority is within China. Non-resident enterprises refer to enterprises established in accordance with foreign (regional) laws in which the actual management authority is not within China, but there are institutions or sites that are established within China, or there are no institutions or sites that are established within China, but the source of income is within China. According to the Enterprise Income Tax Law and the relevant implementing regulations, the unified enterprise income tax rate is 25%. However, if a non-resident enterprise has no institutions or sites that are established within China, or although an institution or site is established, its income has no actual connection with its established institution or site, enterprise income tax at the rate of 10% shall be paid in relation to its income from China.

Value-Added Tax and Business Tax

Notice on Implementing the Pilot Program of Replacing Business Tax with Value-Added Tax in an All-round Manner became effective on May 1, 2016. The pilot plan of replacing business tax with value-added tax has fully launched nationwide on May 1, 2016.

The Interim Regulation of the People's Republic of China on Value-Added Tax (hereinafter referred to as "Value-Added Tax Regulation") was promulgated by the State Council on December 13, 1993, and revised on November 10, 2008, February 6, 2016, and November 19, 2017. The Detailed Rules for the Implementation of the Interim Regulation of the People's Republic of China on Value-Added Taxes (hereinafter referred to as "Value-Added Tax Implementation Detailed Rules") was promulgated by the Ministry of Finance on December 25, 1993, first revised on December 15, 2008, then revised on October 28, 2011, and became effective on November 1, 2011. According to the Value-Added Tax Regulation and Value-Added Tax Implementation Detailed Rules, units and individuals selling goods or providing processing, repairing and replacement services, sales services, intangible assets, real estate and imported goods within China are taxpayers of value-added tax and must pay value-added tax. Unless otherwise specified, the tax rate for taxpayers selling or importing goods and providing processing, repairing and replacement services within China is 17% and 11% under certain specific circumstances.

According to the Notice of the Ministry of Finance and the State Administration of Taxation on Adjusting Value-Added Tax Rates, which became effective on May 1, 2018, the taxpayers with regard to the occurrence of value-added tax taxable sales or imported goods, that were originally applied to

the tax rates of 17% and 11%, the tax rates were adjusted to 16% and 10% respectively. According to the Announcement on Relevant Policies for Deepening the Value-Added Tax Reform, which became effective on April 1, 2019, the ordinary value-added tax taxpayers with regard to the occurrence of value-added tax taxable sales or imported goods that were originally applied to the tax rate of 16%, the tax rate were adjusted to 13%; if they were originally applied to the tax rate of 10%, the tax rate were adjusted to 9%.

Dividend Withholding Tax

According to the Arrangement between the Mainland of China and the Hong Kong Special Administrative Region for the Avoidance of Double Taxation and the Prevention of Fiscal Evasion with respect to Taxes on Income signed on August 21, 2006, the withholding tax rate on dividends paid by Chinese companies to Hong Kong residents shall not exceed 5%, provided that the recipient is a company directly holding at least 25% of the capital of Chinese companies. The withholding tax rate of 10% applies to dividends paid by Chinese companies to Hong Kong residents when the recipient is a company directly holding less than 25% of the capital of Chinese companies.

In addition, according to the Notice of the State Administration of Taxation on the Issues concerning the Application of the Dividend Clauses of Tax Agreements, which became effective on February 20, 2009, for a tax resident of the other party to the tax agreement directly owns a certain proportion or more of the capitals (generally 25% or 10%) of a Chinese resident company which pays the dividends, the dividends obtained by the tax resident of the other party may be entitled to the tax rate prescribed in the tax agreement where all of the following requirements are satisfied simultaneously: (i) the tax resident of the other party who obtains dividends should be limited to a company according to the tax agreement; (ii) the proportion of the equity interests and the proportion of the voting shares of the Chinese resident company directly owned by the tax resident of the other party satisfy the relevant provision; and (iii) the capital ratio of the Chinese resident company directly owned by the tax resident of the other party reaches the percentage specified in the tax agreement at any time within 12 months prior to acquiring the dividends.

In addition, according to the Announcement of the State Taxation Administration on Issuing the Measures for Non-resident Taxpayers' Enjoyment of Treaty Benefits, which became effective on January 1, 2020, tax treatment of non-resident taxpayers under relevant treaties shall adopt the approach of "self-judgment, declaration for enjoyment and retention of relevant data for examination." If non-resident taxpayers consider that they are eligible for treatments under the tax treaties through self-assessment, they may, at the time of filing tax returns or making withholding tax filings through withholding agents, enjoy the treatments under the tax treaties, and shall concurrently collect and retain the relevant documents for inspection according to the regulations of "the Measures", and accept tax authorities' post-filing administration.