
REGULATORY OVERVIEW

Medical device industry of PRC is subject to a large number of laws and regulations and extensive government supervision. Such laws and regulations encompass the areas including manufacturing, sales and trading of medical devices, labor and intellectual property. Principal regulatory authorities of the industry are National Medical Products Administration (the “NMPA”) and its local regulatory branches. In March 2018, the State Council Institutional Reform Proposal passed by the First Session of the Thirteenth National People’s Congress decided the China Food and Drug Administration (“CFDA”) shall cease to exist, and the NMPA was established to undertake the duties of the former CFDA. The National Development and Reform Commission (the “NDRC”) and National Health Commission (the “NHC”) also issue regulations and implementation rules with respect to the pricing and tender process of medical devices.

LAWS AND REGULATIONS RELATING TO MEDICAL DEVICES

Regulation and Classification of Medical Devices

Pursuant to the Regulations on the Supervision and Administration of Medical Devices (醫療器械監督管理條例) amended by the State Council and coming into effect on May 4, 2017, the Food and Drug Administration of the State Council shall be responsible for the supervision of medical devices of the PRC. All relevant departments of the State Council shall be responsible for the supervision of medical devices within their respective scope of duties. Food and drug supervision and administration departments of the local people’s governments at the county level and above are responsible for the supervision of medical devices within their own administrative jurisdictions. The relevant departments of the local people’s governments at the county level and above are responsible for the supervision of medical devices within their respective scope of duties.

In the PRC, medical devices have been classified into three categories based on the degree of risk. Class I medical devices shall refer to those devices with low risk and whose safety and effectiveness can be ensured through routine administration. Class II medical devices shall refer to those devices with medium risk and whose safety and effectiveness should be strictly controlled. Class III medical devices shall refer to those devices with high risk and whose safety and effectiveness must be strictly controlled with special measures.

Registration and Filings of Medical Device Products

Pursuant to the Regulations on the Supervision and Administration of Medical Devices (醫療器械監督管理條例) and the Administrative Measures for the Registration of Medical Devices (醫療器械註冊管理辦法) amended by the CFDA on July 30, 2014 and coming into effect on October 1, 2014, for the filings of the medical device products of Class I, the parties undergoing the filings of medical devices shall submit the filing materials to the food and drug supervision and administration departments of the local people’s government at the districted city level. In case of any amendment to matters stated in the filings, such amendment shall be filed with the original filing department. The medical devices of Class II and Class III shall be subject to the product registration administration. Medical devices of Class II shall be examined by the food and drug supervision and administration departments of the people’s governments of the provinces, autonomous regions or municipality where such applicants are located. A registration certificate for such medical device shall be issued upon approval. Medical devices of Class III shall be examined by the Food and Drug Administration of the State Council. A registration certificate for such medical device shall be issued upon approval. In case of any substantial change of the designs, raw materials, production technologies, scopes of application and application methods, *etc.*, of the registered medical device products of Class II or Class III, which may affect the safety and effectiveness of such medical devices, the registrants shall apply to the original registration departments for undergoing the formalities for registration modification. In case of any non-substantial change thereof, which do not affect the safety and effectiveness of such medical devices, the information on the change shall be reported to the original registration departments for filings.

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The registration certificate for a medical device is valid for five years and the registrant shall apply to the food and drug supervision and administration departments for renewal six months prior to its expiration date.

Pursuant to the Administrative Measures for the Registration of Medical Devices (醫療器械註冊管理辦法), clinical trials are not necessary for the record-filing of Class I medical devices, but are required for applications for the registration of Class II and Class III medical devices. However, medical devices may be exempt from clinical trials under any of the following circumstances:

- (1) The same categories of the marketed medical devices with clear and definite working mechanisms, finalized designs and mature production technologies have been put into clinical application for years, with no record of severely adverse event and with their general purposes unchanged;
- (2) The safety and effectiveness of such medical devices can be proved through non-clinical evaluation;
- (3) The safety and effectiveness of such medical devices can be proved through the analysis and evaluation of the data obtained from the clinical trials or clinical application of the same categories of medical devices.

The medical device catalog of clinical trial exemption shall be formulated, amended and promulgated by the NMPA. Medical device products that are not included in the catalog shall be analyzed and evaluated through the data obtained from the clinical trials or clinical application of the same categories of medical devices. Where the safety and effectiveness of such medical devices can be proved, registrant may specify in the course of registration application and submit relevant proofing materials.

On March 1, 2016, the CFDA and NHC jointly circulated Good Clinical Practice for Medical Device Trials (醫療器械臨床試驗質量管理規範) to instruct and supervise the overall process of a medical device clinical trial from protocol design, implementation, monitoring, auditing and inspection to data collection, recording, analysis and final reporting.

Production permit of medical devices

Pursuant to the Regulation on the Supervision and Administration of Medical Devices (醫療器械監督管理條例) and the Administrative Measures on the Production of Medical Devices (醫療器械生產監督管理辦法) amended by the CFDA and coming into effect on November 17, 2017, a manufacturer of medical device shall satisfy the following conditions:

- (1) possessing production site, environmental conditions, production equipment and professional technicians that are suitable for such medical device produced;
- (2) possessing organizations or professional examination staff and examination equipment that carry out quality examination for such medical device produced;
- (3) formulating a management system which ensures the quality of such medical device;
- (4) having capability of after-sale services that is suitable for such medical device produced;
- (5) satisfying the requirements of the provisions of product research and production technologies.

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The enterprises engaging in the production of medical devices of Class I shall make filings for such medical devices of Class I with the food and drug supervision and administration departments of the local people's governments at the districted city level and submit proofing materials of qualification to engage in the production of such medical devices. The enterprises engaging in the production of medical devices of Class II and Class III shall apply for production licenses to the food and drug supervision and administration departments of the local people's governments of the provinces, autonomous regions or municipalities, submit proofing materials of qualification to engage in the production of such medical devices and registration certificates for such medical devices produced.

A production permit for a medical device is valid for five years and the registrant shall apply to the original departments that issued such permit for renewal six months prior to its expiration date.

Production and Quality Management of Medical Devices

Pursuant to the Administrative Measures on the Supervision of the Production of Medical Devices (醫療器械生產監督管理辦法) and the Standards on Production and Quality Management of Medical Devices (醫療器械生產質量管理規範) promulgated by the CFDA on December 29, 2014 and coming into effect on March 1, 2015, an enterprise engaging in the production of medical devices shall establish and effectively maintain a quality control system in accordance to the requirements of the Standards on Production and Quality Management of Medical Devices. The enterprise engaging in the production of medical devices shall regularly conduct comprehensive self-inspection on the operation of quality management system in accordance with the requirements of the Standards on Production and Quality Management of Medical Devices and submit a self-inspection report to the food and drug supervision and administration departments of the local people's governments of the provinces, autonomous regions, municipalities or the districted city level before the end of every year. The enterprise shall enhance its procurement management and assess its suppliers by establishing an examination system to ensure the purchased products are in compliance with the statutory requirements. 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 of the related products.

Permit for Medical Device Operation

Pursuant to the Regulations on the Supervision and Administration of Medical Devices, an enterprise engaging in the operation of medical devices shall have business premises and storage facilities suitable for the operation scale and scope, and shall have a quality control organ or personnel suitable for the medical devices it operates. An enterprise engaged in the distribution of Class II medical devices shall keep a record with the municipal level food and drug administration and provide proofing materials for satisfying the relevant conditions of engaging in the operation of medical devices, while an enterprise engaged in the distribution of Class III medical devices shall apply for an operation permit to the municipal level food and drug administration and provide proofing materials for satisfying the relevant conditions of engaging in the operation of medical devices.

The food and drug supervision and administration department which accepts operation permit application shall review and examine (if necessary), and will grant the operation permit if the enterprise meets the prescribed requirements. An operation permit is valid for five years and may be renewed pursuant to the relevant regulations. An enterprise engaging in medical devices operation shall not operate or use any medical device that has not been legally registered, without qualification certificate, outdated, invalid or disqualified.

Medical Device Recalls

Pursuant to the Administrative Measures for Medical Device Recalls (醫療器械召回管理辦法), which was promulgated by the CFDA on January 25, 2017 and came into effect on May 1, 2017, in light of the severity harm, medical device recalls are divided into: (1) class I recall where the circumstances leading to the recall may cause or have caused serious health hazards; (2) class II recall where the circumstances leading to the recall may cause or have caused temporary or reversible health hazards; or (3) class III recall where the circumstances leading to the recall are not likely to cause harm.

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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 sale and use of the medical devices. In terms of class I recall, the recall notice shall be published on the NMPA website and major media. In terms of class II and class III recalls, the recall notice shall be published on the website of the food and drug administrative authority of the provinces, autonomous regions or municipalities.

Advertisements of Medical Devices

The State Administration for Market Regulation (the “SAMR”) promulgated the Interim Administrative Measures for Censorship of Advertisements for Drugs, Medical Devices, Dietary Supplements and Foods for Special Medical Purpose (藥品、醫療器械、保健食品、特殊醫學用途配方食品廣告審查管理暫行辦法) (the “Interim Measures for Advertisements”) on December 24, 2019, which came into effect on March 1, 2020 and replaced the Measures for the Examination of Medical Devices Advertisements (醫療器械廣告審查辦法).

According to the Interim Measures for Advertisements, no advertisement for any drug, medical device, dietary supplement or food for special medical purpose may be published without censorship. The SAMR shall be responsible for organizing and guiding the censorship of advertisements for drugs, medical devices, dietary supplements and foods for special medical purpose. Departments for market regulation and drug administration of provinces, autonomous regions and municipalities directly under the central government shall be responsible for the censorship of advertisements for drugs, medical devices, dietary supplements and foods for special medical purpose and may legally entrust other administrative authorities with specifically carrying out advertisement censorship. Advertisements for drugs, medical devices, dietary supplements and foods for special medical purpose shall be authentic and legal, and shall not contain any false or misleading content.

Pursuant to the Advertising Law of the PRC (中華人民共和國廣告法) issued by the Standing Committee of the National People’s Congress (the “SCNPC”) on October 27, 1994 and last amended on October 26, 2018. Any advertisement for medical treatment, pharmaceuticals or medical devices shall not contain the following items:

- (1) any assertion or guarantee for efficacy and safety;
- (2) any statement on cure rate or effective rate;
- (3) comparison with the efficacy and safety of other pharmaceuticals or medical devices or with other medical institutions;
- (4) use of the advertisement endorsers to make endorsements or testimonials; or
- (5) other items as prohibited by laws and administrative regulations.

Any advertisement for medical devices intended for personal use shall indicate the words “please read the product specifications carefully or purchase and use the product according to the suggestions of medical personnel” conspicuously. If any registered certificate of a medical device product contains any contraindication and precaution, the advertisement for the product shall indicate the words “for the contraindication and precaution, please refer to the specifications” conspicuously. Advertisements for medical treatment, pharmaceuticals, medical devices, agricultural pesticides, veterinary medicines and healthcare food, and other advertisements required to be reviewed by laws and administrative regulations shall be reviewed by the relevant authorities before they are published. No such advertisement shall be published without being reviewed.

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OTHER SIGNIFICANT LAWS AND REGULATIONS OF THE PRC AFFECTING OUR BUSINESS

Foreign Investment

Investment in the PRC conducted by foreign investors and foreign-owned enterprises shall comply with the Special Administrative Measures for Access of Foreign Investment (Negative List) (2020 Edition) (外商投資准入特別管理措施(負面清單)(2020年版)) (the “Catalogue”), which was newly amended and promulgated by the Ministry of Commerce of the People’s Republic of China (“MOFCOM”) and the NDRC on June 23, 2020. The Catalogue, as amended, became effective on July 23, 2020 and contains specific provisions guiding market access of foreign capital, stipulating in detail the areas of entry pertaining to the categories of restricted foreign-invested industries and prohibited foreign-invested industries. Restricted category projects are subject to higher-level government approvals. Furthermore, foreign investors are not allowed to invest in companies in industries in the prohibited category. Any industry not listed in the Catalogue is a permitted industry, and is generally open to foreign investment unless specifically prohibited or restricted by the PRC laws and regulations. The medical device industry in which our PRC subsidiaries are primarily engaged does not fall into the category of restricted or prohibited foreign-invested industries.

The establishment procedures, examination and approval procedures, registered capital requirement, foreign exchange restriction, accounting practices, taxation and labour matters of a wholly foreign-owned enterprise are governed by the Foreign Investment Law of the PRC (中華人民共和國外商投資法), (the “Foreign Investment Law”), which was adopted by the National People’s Congress of the PRC on March 15, 2019 and became effective on January 1, 2020, the Implementing Regulations of the Foreign Investment Law of the (中華人民共和國外商投資法實施條例), which was promulgated on December 26, 2019, and became effective on January 1, 2020, and the PRC Company Law (中華人民共和國公司法) which was amended by the SCNPC and became effective on October 26, 2018.

On December 30, 2019, MOFCOM and the SAMR issued the Measures for the Reporting of Foreign Investment Information (外商投資信息報告辦法), which came into effect on January 1, 2020. Since January 1, 2020, for carrying out investment activities directly or indirectly in China, the foreign investors or foreign-invested enterprises shall submit investment information to the commerce authorities pursuant to these measures.

On August 8, 2006, six PRC regulatory agencies, namely, MOFCOM, the State-owned Assets Supervision and Administration Commission of the PRC, the State Administration of Taxation (the “SAT”), the State Administration for Industry and Commerce, the China Securities Regulatory Commission, and the State Administration of Foreign Exchange (the “SAFE”), jointly adopted the Regulations on Mergers and Acquisitions of Domestic Enterprises by Foreign Investors (關於外國投資者併購境內企業的規定) (the “M&A Rules”), which became effective on September 8, 2006 and were amended by MOFCOM on June 22, 2009. The M&A Rules require, among others, that a foreign investor acquiring the equity interest in a non-foreign invested PRC enterprise or purchasing and operating the asset of such enterprise by establishing a foreign invested enterprise shall comply with relevant foreign investment industry policies and shall be subject to approval by MOFCOM or its local competent authorities.

Product Liability and Protection of Consumers’ Rights

Pursuant to the Product Quality Law of the PRC (中華人民共和國產品質量法) amended by the SCNPC and coming into effect on December 29, 2018, producers and sellers shall have their own proper regulations for the management of product quality, rigorously implementing post-oriented quality regulations, quality liabilities and relevant measures for their assessment. Producers and sellers are responsible for the product quality according to the provisions of the laws.

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The product quality supervision and administration departments of the State Council are responsible for the supervision and administration of the quality of products of the whole country. All relevant departments of the State Council shall be responsible for the supervision of product quality within their own functions and duties.

Quality of products shall pass standard examinations and it is not allowed to pass off sub-standard products as standard ones. Industrial products which may be hazardous to the health of the people and the safety of lives and property shall conform to the State and trade standards for ensuring the health of the people and safety of lives and property. In absence of such State or trade standards, the products shall conform to the minimum requirements for ensuring the health of the people and the safety of lives and property. It shall be prohibited to produce or sell industrial products that do not meet the requirements and demands for physical health and safety of body and property. Producers or sellers shall be responsible for any compensation arising from their unlawful acts such as production or sales of defective, eliminated or ineffective products, faking the place of origin or quality marks, mixing or adulterating products or passing off imitations as genuine, substandard products as quality ones or non-conforming products as conforming. Proceeds from the sales may be confiscated, the business license may be revoked and penalties may be imposed. If the case is serious, criminal responsibilities shall be investigated. Producers or sellers shall be liable for any damage to any person or property due to the defects of products resulting from the default of the producers or sellers.

Pursuant to the General Rules of the Civil Law of the PRC (中華人民共和國民法總則) promulgated by the National People's Congress on March 15, 2017 and General Principles of the Civil Law of the PRC (中華人民共和國民法通則) promulgated by the National People's Congress on April 12, 1986, amended and became effective on August 27, 2009, both manufacturers and sellers shall be held liable where relevant defective products result in damage to property of others or bodily injuries. Pursuant to Civil Code of the PRC (民法典) promulgated by National People's Congress on May 28, 2020 and came into effect on January 1, 2021, both manufacturers and sellers shall be held liable where relevant defective products result in damage to property of others or bodily injuries.

Tort Law

Pursuant to the Civil Code of the PRC, manufacturers shall assume tort liability where the defects in relevant products cause damage to others. Sellers shall assume tort liability where the defects in relevant products causing damage to others are attributable to the sellers. The aggrieved party may claim for compensation from the manufacturer or the seller of the relevant product in which the defects have caused damage.

Labor and Social Warfare

Pursuant to the PRC Labor Law (中華人民共和國勞動法), which was promulgated by the SCNPC on July 5, 1994 and became effective on January 1, 1995 and subsequently amended on August 27, 2009 and December 29, 2018, the PRC Employment Contract Law (中華人民共和國勞動合同法), which was promulgated by the SCNPC on June 29, 2007 and subsequently amended on December 28, 2012 and became effective on July 1, 2013, and the Implementing Regulations of the Employment 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 became effective on September 18, 2008, employment contracts in written form shall be executed to establish labor relationships between employers and employees. Wages cannot be lower than local minimum wage. The employer must establish a system for labor safety and sanitation, strictly abide by State 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 State rules, and carry out regular health examination for employees engaged in work involving occupational hazards.

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Social insurance

As required under the Regulation of Insurance for Labor Injury (工傷保險條例) effective on January 1, 2004 and amended on December 20, 2010, the Provisional Measures for Maternity Insurance of Employees of Corporations (企業職工生育保險試行辦法) effective on January 1, 1995, the Decisions on the Establishment of a Unified Program for Basic Old-Aged Pension Insurance of the State Council (國務院關於建立統一的企業職工基本養老保險制度的決定) issued on July 16, 1997, the Decisions on the Establishment of the Medical Insurance Program for Urban Workers of the State Council (國務院關於建立城鎮職工基本醫療保險制度的決定) promulgated on December 14, 1998, The Unemployment Insurance Measures (失業保險條例) promulgated on January 22, 1999 and the Social Insurance Law of the PRC (中華人民共和國社會保險法) effective on July 1, 2011 and subsequently amended on December 29, 2018, enterprises are obliged to provide their employees in the PRC with welfare schemes covering pension insurance, unemployment insurance, maternity insurance, labor injury insurance and medical insurance. These payments are made to local administrative authorities and any employer that fails to contribute may be fined and ordered to make up within a prescribed time limit.

Housing reserve fund

In accordance with the Regulations on the Management of Housing reserve Funds (住房公積金管理條例) which was promulgated by the State Council in 1999 and last amended on March 24, 2019, enterprises must register at the competent managing center for housing reserve funds and upon the examination by such managing center of housing reserve funds, these enterprises shall complete procedures for opening an account at the relevant bank for the deposit of employees' housing reserve funds. Enterprises are also required to pay and deposit housing reserve funds on behalf of their employees in full and in a timely manner.

Employee stock incentive plan

On February 15, 2012, SAFE promulgated the Notices on Issues Concerning the Foreign Exchange Administration for Domestic Individuals Participating in Stock 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 “Stock Option Rules”), which replaced the Application Procedures of Foreign Exchange Administration for Domestic Individuals Participating in Employee Stock Ownership Plans or Stock Option Plans of Overseas Publicly Listed Companies (境內個人參與境外上市公司員工持股計畫和認股期權計畫等外匯管理操作規程) issued by SAFE on March 28, 2007. In accordance with the Stock Option 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 subsidiary of such overseas listed company, and complete certain procedures. We and our employees who are PRC citizens or who reside in China for a continuous period of not less than one year and who participate in our stock incentive plan will be subject to such regulation. In addition, SAT 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, or the IIT. The PRC subsidiaries of an overseas listed company have obligations to file documents related to employee share options or restricted shares with relevant tax authorities and to withhold IIT of those employees related to their share options or restricted shares. If the employees fail to pay, or the PRC subsidiaries fail to withhold, their IIT according to relevant laws, rules and regulations, the PRC subsidiaries may face sanctions imposed by the tax authorities or other PRC government authorities.

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Production Safety

Pursuant to the Production Safety Law of the People's Republic of China (中華人民共和國安全生產法) amended by the SCNPC on August 31, 2014 and coming into effect on December 1, 2014, an enterprise shall provide production safety conditions as stipulated in this law and other laws, administrative regulations, national and industry standards, establish a comprehensive production safety accountability system and production safety rules and develop production safety standards to ensure production safety. Any entity that fails to provide required production safety conditions is prohibited from engaging in production activities.

The person-in-charge of an enterprise shall be fully responsible for the safety of production of the enterprise. An enterprise having more than 100 employees shall establish a department or engage personnel managing production safety specifically. Personnel who is responsible for managing production safety shall inspect the safety of production regularly based on the characteristics of production of the enterprise and shall deal with any safety issue identified during the inspection in a timely manner. Any unsolved issue shall be reported to the person-in-charge in a timely manner and the person-in-charge shall solve such issue immediately. The inspection and measures taken shall be duly recorded. Enterprises and institutions shall provide their employees with trainings on production safety and shall truthfully inform their employees of any potential risks in relation to the workplace and duties, preventive measures and emergency measures. Labor union shall inspect the production safety in accordance with the laws. The formulation of, and amendments to, production safety rules shall take the opinion of labor union into account. In addition, an enterprise shall provide its employees with protective equipment that meet the national or industry standards and supervise and train them to use such equipment.

Regulations relating to Personal Information Protection

Pursuant to the Civil Code of the PRC, the personal information of a natural person shall be protected by the law. Any organization or individual shall legally obtain such personal information of others when necessary and ensure the safety of such information, and shall not illegally collect, use, process or transmit personal information of others, or illegally purchase or sell, provide or make public personal information of others. Pursuant to the Ninth Amendment to the Criminal Law (刑法修正案(九)) issued by the SCNPC in August 29, 2015, which became effective in November 1, 2015, entity who sells or provides any citizen's personal information in violation of the relevant provisions shall be subject to criminal penalty. In addition, Interpretations of the Supreme People's Court and the Supreme People's Procuratorate on Several Issues Concerning the Application of Law in the Handling of Criminal Cases Involving Infringement of Personal Information (最高人民法院、最高人民檢察院關於辦理侵犯公民個人信息刑事案件適用法律若干問題的解釋), issued on May 8, 2017 and effective as of June 1, 2017, clarified certain standards for the conviction and sentencing of the criminals in relation to personal information infringement.

Taxation

Income Tax

Pursuant to the EIT Law (中華人民共和國企業所得稅法) amended by the SCNPC and coming into effect on December 29, 2018 and the Implementation Rules of the EIT Law (中華人民共和國企業所得稅法實施條例) amended by the State Council and coming into effect on April 23, 2019, a domestic enterprise which is established within the PRC in accordance with the laws or established in accordance with any laws of foreign country (region) but with an actual management entity within the PRC shall be regarded as a resident enterprise. A resident enterprise shall be subject to an EIT of 25% of any income generated within or outside the PRC.

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Enterprises that are recognized as high and new technology enterprises in accordance with the Notice of the Ministry of Science, the Ministry of Finance (the “MOF”) and SAT on Amending and Issuing the Administrative Measures for the Determination of High and New Tech Enterprises (科技部、財政部、國家稅務總局關於修訂印發《高新技術企業認定管理辦法》的通知) issued on January 29, 2016 are entitled to enjoy the preferential enterprise income tax rate of 15%. The validity period of the high and new technology enterprise qualification shall be three years from the date of issuance of the certificate of high and new technology enterprise. The enterprise can re-apply for such recognition as a high and new technology enterprise before or after the previous certificate expires.

The Notice Regarding the Determination of Chinese-Controlled Offshore Incorporated Enterprises as PRC Tax Resident Enterprises on the Basis of De Facto Management Bodies (關於境外注冊中資控股企業依據實際管理機構標準實施居民企業認定有關問題的通知) promulgated by SAT on April 22, 2009 and amended on January 29, 2014 sets out the standards and procedures for determining whether the “de facto management body” of an enterprise registered outside of the PRC and controlled by PRC enterprises or PRC enterprise groups is located within the PRC.

The EIT Law provide that an income tax rate of 10% will normally be applicable to dividends payable to investors that are “non-resident enterprises,” and gains derived by such investors, which (a) do not have an establishment or place of business in the PRC or (b) have an establishment or place of business in the PRC, but the relevant income is not effectively connected with the establishment or place of business to the extent such dividends and gains are derived from sources within the PRC. Such income tax on the dividends may be reduced pursuant to a tax treaty between China and the jurisdictions in which our non-PRC shareholders reside.

Value-added Tax

Pursuant to the Provisional Regulations of the PRC on Value-Added Tax (中華人民共和國增值稅暫行條例), which was promulgated by the State Council on December 13, 1993 and amended on November 10, 2008, February 6, 2016 and November 19, 2017, and the Implementation Rules for the Implementation of the Provisional Regulations of the PRC on Value-Added Tax (中華人民共和國增值稅暫行條例實施細則), which was promulgated by the MOF and SAT on December 18, 2008 and became effective on January 1, 2009 and as amended on October 28, 2011, entities or individuals engaging in sale of goods, provision of processing services, repairs and replacement services or importation of goods within the territory of the PRC shall pay value-added tax (“VAT”).

Since January 1, 2012, the MOF and SAT have implemented the Pilot Plan for Imposition of Value-Added Tax to Replace Business Tax (營業稅改徵增值稅試點方案) (the “VAT Pilot Plan”), which imposes VAT in lieu of business tax for certain “modern service industries” in certain regions and eventually expanded to nation-wide application in 2013. According to the implementation circulars released by the MOF and SAT on the VAT Pilot Program, the “modern service industries” include research, development and technology services, information technology services, cultural innovation services, logistics support, lease of corporeal properties, attestation and consulting services. Following the implementation of the VAT Pilot Plan, most of our PRC subsidiaries and affiliates have been subject to VAT, at a rate of 6% or 17%, instead of business tax. Pursuant to the Notice on Adjusting Value-added Tax Rates (關於調整增值稅稅率的通知), which was jointly promulgated by the MOF and SAT on April 4, 2018 and came into effect on May 1, 2018, where a taxpayer engages in a taxable sales activity for the VAT purpose or imports goods, the previous applicable 17% tax rates are adjusted to be 16%. On March 20, 2019, the MOF, SAT and General Administration of Customs jointly promulgated the Announcement on Policies for Deeping the VAT Reform (關於深化增值稅改革有關政策的公告) (the “Notice 39”), which came into effect on April 1, 2019. Notice 39 further changes the VAT tax rates of 16% to 13%.

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Intellectual Property

Patents

Pursuant to the Patent Law of the PRC (中華人民共和國專利法) (the “Patent Law”) promulgated by the SCNPC on March 12, 1984, last amended on October 17, 2020 and being effective from June 1, 2021 and the Implementation Rules of the Patent Law of the PRC (中華人民共和國專利法實施細則), promulgated by the State Council on June 15, 2001 and latest amended on January 9, 2010, there are three types of patent in the PRC: invention patent, utility model patent and design patent. The protection period is 20 years for invention patent and 10 years for utility model patent and design patent, commencing from their respective application dates. Any individual or entity that utilizes a patent or conducts any other activity in infringement of a patent without prior authorization of the patentee shall pay compensation to the patentee and is subject to a fine imposed by relevant administrative authorities and, if constituting a crime, shall be held criminally liable in accordance with the law.

Existing patents can become narrowed, invalid or unenforceable due to a variety of grounds, including lack of novelty, creativity, and deficiencies in patent application. In China, a patent must have novelty, creativity and practical applicability. Under the Patent Law, novelty means that before a patent application is filed, no identical invention or utility model has been publicly disclosed in any publication in China or overseas or has been publicly used or made known to the public by any other means, whether in or outside of China, nor has any other person filed with the patent authority an application that describes an identical invention or utility model and is recorded in patent application documents or patent documents published after the filing date. Creativity means that, compared with existing technology, an invention has prominent substantial features and represents notable progress, and a utility model has substantial features and represents any progress. Practical applicability means an invention or utility model can be manufactured or used and may produce positive results. Patents in China are filed with the State Intellectual Property Office (the “SIPO”). Normally, the SIPO publishes an application for an invention patent within 18 months after the filing date, which may be shortened at the request of applicant. The applicant must apply to the SIPO for a substantive examination within three years from the date of application.

Trademarks

The Trademark Law of the PRC (中華人民共和國商標法) amended by the SCNPC on April 23, 2019 and coming into effect on November 1, 2019 and the Implementation Rules of the Trademark Law of the PRC (中華人民共和國商標法實施條例) amended by the State Council on April 29, 2014 and coming into effect on May 1, 2014, stipulate the application, examination and approval, renewal, alternation, transfer, use and invalidation of trademark registration, and protect the trademark rights entitled to trademark registrants. According to the aforesaid laws and regulations, the registration of a trademark shall be valid for 10 years from the date of approval. Upon the expiry of the trademark registration, a renewal shall be made in accordance with requirements within 12 months if necessary. If the renewal is not made within the stipulated period, the valid period may be extended for a further period of six months. Each renewal of registration of trademark shall be valid for 10 years from the date of the expiry of the previous trademark registration. A trademark registrant may license others the right to use his/her trademark by entering into a trademark license agreement.

Domain Names

Pursuant to the Administrative Measures for Internet Domain Names (互聯網域名管理辦法) promulgated by the Ministry of Industry and Information Technology on August 24, 2017 and effective from November 1, 2017, “domain name” shall refer to the character mark of hierarchical structure, which identifies and locates a computer on the internet and corresponds to the Internet protocol (IP) address of

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such computer. The principle of "first come, first served" applies to domain name registration service. After completing the domain name registration, the applicant will become the holder of the registered domain name. Furthermore, the holder shall pay operation fees for registered domain names on schedule. If the domain name holder fails to pay corresponding fees as required, the original domain name registry shall deregister the relevant domain name and notify the holder of deregistration in written forms.

Environmental Protection

Construction Project Environment Protection

The main PRC environmental protection laws and regulations applicable to us include 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 and whose amendments were made on April 24, 2014 and became effective as from January 1, 2015, the Appraising of Environmental Impacts Law of the PRC (中華人民共和國環境影響評價法) (the "Appraising of Environmental Impacts Law") promulgated by the SCNPC on October 28, 2002 and last amended on December 29, 2018 and, the Regulations on Administration of Construction Project Environmental Protection (建設項目環境保護管理條例) promulgated by the State Council and effective as from November 29, 1998, amended on July 16, 2017 and effective as from October 1, 2017, the Rules on the Administration of Filing of Environmental Impact Registration Form of the Construction Project (建設項目環境影響登記表備案管理辦法) promulgated by the Ministry of Environmental Protection on November 16, 2016 and effective as from January 1, 2017 and other relevant laws and regulations.

In accordance with the Appraising of Environmental Impacts Law and the Regulations on Administration of Construction Project Environmental Protection, the development of each construction project is subject to the environmental impact assessment which assesses the pollution the construction project is likely to produce and its impact on the environment and stipulates the preventive and curative measures. The environmental impact report and environmental impact statement of a construction project shall be submitted to the relevant environmental protection authorities for examination and approval and the State implements the record-filing administration over the environmental impact registration forms. In accordance with the Rules on Acceptance Inspection, after completion of the project, the construction entity shall also apply to the relevant environmental protection authorities for checks and acceptance of the corresponding environmental protection facilities. The said construction project may be put into operation or use only after the completion of the said checks and acceptance procedures.

Pollutant Discharge

The Environmental Protection Law stipulates that the government shall implement the pollutant emission license administration system. Pollutant discharge by enterprises, public institutions and other producers and business operators is subject to relevant pollutant emission license. The Environmental Protection Law requires any entity operating a facility that produces pollutants or other hazardous materials to adopt environmental protection measures in its operations, and to establish an environmental protection responsibility management system. Effective measures to control and properly dispose of waste gas, waste water, waste residue, dust or other waste materials shall be adopted. Any entity operating a facility that discharges pollutants shall report to and register with the competent authority pursuant to applicable regulations. According to the Environmental Protection Law, in the event that an entity discharges pollutants in violation of the pollutant discharge standards or volume control requirement, the entity would be subject to administrative penalties, including order to suspend business for rectification, and even order to terminate or close down business under severe circumstances.

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Overseas Investment

Pursuant to the Administrative Measures for the Outbound Investment of Enterprises (企業境外投資管理辦法), which was promulgated by the NDRC on December 26, 2017 and became effective on March 1, 2018, the State adopts approval administration and filing administration for overseas investment projects respectively according to different circumstances. An overseas investment project that involves any sensitive country or region or any sensitive industry is to be approved by the NDRC. Under the circumstances, with regard to an overseas investment project that has the Chinese party’s investment amount of not less than US\$300 million, the NDRC is in charge of the record-filing.

Pursuant to the Measures on the Administration of Overseas Investment (境外投資管理辦法), promulgated by MOFCOM on September 6, 2014 and became effective on October 6, 2014, overseas investments refer to possessing of non-financial enterprises abroad or acquisition of the ownership of, control over, business management right of, or other rights and interests of existing overseas non-financial enterprises by enterprises established in the PRC through newly establishment or mergers and acquisitions or other methods. Other than the overseas investments involving sensitive countries, regions or sensitive industries which are subject to approval, all other overseas investments are subject to filing administration.

Foreign Exchange

The principal regulations governing foreign currency exchange in China are the Foreign Exchange Administration Regulations of the PRC (中華人民共和國外匯管理條例) which was promulgated by the State Council on January 29, 1996, became effective on April 1, 1996 and was subsequently amended on January 14, 1997 and August 5, 2008 and the Regulations on the Administration of Foreign Exchange Settlement, Sale and Payment (結匯、售匯及付匯管理規定) which was promulgated by the People’s Bank of China on June 20, 1996 and became effective on July 1, 1996. Pursuant to these regulations and other PRC rules and regulations on currency conversion, Renminbi is freely convertible for payments of current account items, such as trade and service-related foreign exchange transactions and dividend payments, but not freely convertible for capital account items, such as direct investment, loan or investment in securities outside China unless prior approval of SAFE or its local counterpart is obtained.

Foreign invested enterprises are permitted to convert their after tax dividends into foreign exchange and to remit such foreign exchange out of their foreign exchange bank accounts in the PRC. However, foreign exchange transactions involving overseas direct investment or investment and exchange in securities, derivative products abroad are subject to registration with SAFE and approval from or filing with the relevant PRC government authorities (if necessary).

SAFE promulgated the Notice on Reforming the Administration of Foreign Exchange Settlement of Capital of Foreign Invested 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 “Circular 19”) on March 30, 2015, further expanding the extent of convertibility under direct investment. The Circular 19 stipulates that the use of capital funds and exchange settlement funds by foreign-invested enterprises shall be subject to foreign exchange management regulations, and implement negative list management.

On June 9, 2016, SAFE promulgated the Circular on Reforming and Regulating Policies on the Management of the Settlement of Foreign Exchange of Capital Accounts (國家外匯管理局關於改革和規範資本項目結匯管理政策的通知) (the “SAFE Circular 16”). The SAFE Circular 16 unifies the Discretionary Foreign Exchange Settlement for all the domestic institutions. The Discretionary Foreign Exchange Settlement refers to the foreign exchange capital in the capital account which has been confirmed by the relevant policies subject to the Discretionary Foreign Exchange Settlement (including foreign exchange capital, foreign loans and funds remitted from the proceeds from the overseas listing) can be settled at the banks based on the actual operational needs of the domestic institutions. The

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proportion of Discretionary Foreign Exchange Settlement of the foreign exchange capital is temporarily determined as 100%. Violations of the Circular 19 or the SAFE Circular 16 could result in administrative penalties in accordance with the Regulations of the People's Republic of China on Foreign Exchange Control and relevant provisions.

Furthermore, SAFE Circular 16 stipulates that the use of foreign exchange incomes of capital accounts by foreign-invested enterprises shall follow the principles of authenticity and self-use within the business scope of enterprises. The foreign exchange incomes of capital accounts and capital in Renminbi obtained by the foreign invested enterprises from foreign exchange settlement shall not be used for the following purposes: (1) directly or indirectly used for the payment beyond the business scope of the enterprises or the payment prohibited by relevant laws and regulations; (2) directly or indirectly used for investment in securities or financial schemes other than bank guaranteed products unless otherwise provided by relevant laws and regulations; (3) used for granting loans to non-connected enterprises, unless otherwise permitted by its business scope; and (4) used for the construction or purchase of real estate that is not for self-use (except for the real estate enterprises).

SAFE Circular 37

On October 21, 2005, SAFE promulgated the Circular Concerning Relevant Issues on the Foreign Exchange Administration of Raising Funds through Overseas Special Purpose Vehicle and Investing Back in China by Domestic Residents (關於境內居民通過境外特殊目的公司融資及返程投資外匯管理有關問題的通知), which became effective on November 1, 2005 (the "Circular 75"). The notice requires PRC domestic resident natural persons to register or file with the local SAFE branch in the following circumstances: (1) before establishing or controlling any company outside the PRC for the purpose of capital financing, (2) after contributing their assets or shares of a domestic enterprise into overseas special purpose vehicles, or raising funds overseas after such contributions, and (3) after any major change in the share capital of the special purpose vehicle without any round-trip investment being made. On July 4, 2014, SAFE promulgated the Circular Concerning Relevant Issues on the Foreign Exchange Administration of Overseas Investment, Financing and Round-trip Investments by Domestic Residents through Special Purpose Vehicles (關於境內居民通過特殊目的公司境外投融資及返程投資外匯管理有關問題的通知) (the "Circular 37") for the purpose of simplifying the approval process and for the promotion of the cross-border investment. The Circular 37 supersedes the Circular 75 and revises and regulates the relevant matters involving foreign exchange registration for round-trip investment. Under the Circular 37, in the event the change of basic information of the registered offshore special purpose vehicle such as the individual shareholder, name, operation term, etc., or if there is a capital increase, decrease, equity transfer or swap, merge, spin-off or other amendment of the material items, the domestic resident shall complete the change of foreign exchange registration formality for offshore investment. In addition, according the procedural guideline as attached to the Circular 37, the principle of review has been changed to "the domestic individual resident only registered the SPV directly established or controlled (first level)." At the same time, SAFE has issued the Operation Guidance for the Issues Concerning Foreign Exchange Administration over Round-trip Investment (返程投資外匯管理所涉業務操作指引) with respect to the procedures for SAFE registration under the Circular 37, which became effective on July 4, 2014 as an attachment to Circular 37.

Under the relevant rules, failure to comply with the registration procedures set forth in the Circular 37 may result in restrictions being imposed on the foreign exchange activities of the relevant onshore company, including the payment of dividends and other distributions to its offshore parent or affiliate, and may also subject relevant PRC residents to penalties under PRC foreign exchange administration regulations. PRC residents who hold any shares in the company from time to time are required to register with SAFE in connection with their investments in the company.