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## REGULATORY OVERVIEW

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### APPLICABLE LAWS AND REGULATIONS TO OUR BUSINESS IN THE PRC

#### Regulations on the Reform of Medical Institutions

##### *Opinions on Deepening the Reform of the Medical and Healthcare System*

The Opinions of the Central Committee of the Communist Party of China and the State Council on Deepening the Reform of the Medical and Healthcare System (中共中央、國務院關於深化醫藥衛生體制改革的意見) promulgated on 17 March 2009 encourage social capital to invest in the medical institutions (including investments by the foreign investors), and promote the development of private medical institutions and the reform of public medical institutions (including those established by state-owned enterprises) through social capital investment.

##### *Notice on Further Encouraging and Guiding the Establishment of Medical Institutions by Social Capital*

The Notice of the General Office of the State Council on Forwarding the Opinions of the National Development and Reform Commission, the Ministry of Health and Other Ministries on Further Encouraging and Guiding the Establishment of Medical Institutions by Social Capital (國務院辦公廳轉發發展改革委衛生部等部門關於進一步鼓勵和引導社會資本舉辦醫療機構意見的通知), which was promulgated by the General Office of the State Council on 26 November 2010, stipulates that the PRC government encourages and supports investments by private investors in medical institutions of various types. Private investors are permitted to apply to establish for-profit or not-for-profit medical institutions. Private healthcare institutions are encouraged to engage or authorize domestic or overseas medical institutions with professional experience to participate in the management of hospitals to improve their efficiencies.

##### *Several Opinions on Promoting the Development of Healthcare Service Industry*

The Several Opinions on Promoting the Development of Healthcare Service Industry (國務院關於促進健康服務業發展的若干意見), which was promulgated by the State Council on 28 September 2013, encourage the private sector to invest in the healthcare service industry by various means including new establishment and participation in restructuring and propose the idea of the relaxation of the requirements for Sino-foreign equity joint or cooperative joint medical institutions and gradually expand eligibility in the pilot program for wholly foreign-invested medical institutions.

##### *Several Opinions on Accelerating the Development of Medical Institutions with Social Capital*

The Several Opinions on Accelerating the Development of Medical Institutions with Social Capital (關於加快發展社會辦醫的若干意見), which was promulgated on 30 December 2013 by the National Health and Family Planning Commission (the “**NHFPC**”) and the State Administration of Traditional Chinese Medicine (the “**SATCM**”), stipulate the policies that support the development of private-invested medical institutions, including but not limited to

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the (i) gradual relaxation of investment in medical institutions by foreign capital; (ii) relaxation of requirements for service sectors, allowing social capital’s investment in the areas which are not explicitly prohibited; and (iii) acceleration of the approval procedures regarding the establishment and operation of private hospitals.

### ***Notice on Printing and Distributing the Outline of the National Medical and Healthcare Service System Plan (2015-2020).***

The Notice on Printing and Distributing the Outline of the National Medical and Healthcare Service System Plan (2015-2020) (關於印發全國醫療衛生服務體系規劃綱要(2015-2020年)的通知), which was promulgated by the General Office of the State Council on 6 March 2015, stipulates that private medical institutions are significant and integral parts of the medical and healthcare service system as well as an effective approach to fulfilling people’s multi-level and diversified medical and healthcare service needs. Private medical institutions may provide high-end services to fulfil extra needs which are beyond basic needs. The pilot scheme of establishment of medical institutions solely invested by qualified overseas capitals shall be expanded step by step. The restrictions on service scope shall also be reduced and the social capitals shall be allowed to invest in areas not explicitly prohibited by the laws and regulations.

### ***Several Policies and Measures Regarding the Promotion of Accelerating the Development of the Medical Institutions Invested by Social Capital***

Several Policies and Measures Regarding the Promotion of Accelerating the Development of the Medical Institutions Invested by Social Capital (關於促進社會辦醫加快發展若干政策措  
施的通知), which was promulgated by the General Office of the State Council on 11 June 2015 and came into effect on the same day, stipulate (i) the elimination and cancellation of unreasonable preceding items for examination and approval and the reduction in the time required for making such examination and approval; (ii) the reasonable control of the number and scale of the public medical institutions and the exploration of the space for development of the medical institutions invested by social capital; and (iii) the support for the listing and financing of such eligible and qualified for-profit medical institutions invested by social capital.

### ***Notice on Printing Guiding Principles for the Allocation Planning of Medical Institutions (2016-2020)***

The Notice on Printing Guiding Principles for the Allocation Planning of Medical Institutions (2016-2020) (國家衛生計生委關於印發醫療機構設置規劃指導原則(2016-2020年)的通知), which was promulgated by the NHFPC on 21 July 2016, encourages the establishment of medical institutions by social capital and stipulates (i) the acceleration of the scale and high-level development of medical institutions with social capital, and the involvement of medical institutions with social capital in relevant planning to reserve space for the allocation of resources such as beds and large medical equipment according to a certain proportion, and (ii) the cancellation of limitations on the amount and location of medical institutions with social capital in accordance with total amount and structure of planning.

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### Regulations on the Administration and Categorization of Medical Institutions

#### *Administrative Measures on Medical Institutions and its Implementation Measures*

The Administrative Measures on Medical Institutions (醫療機構管理條例), which was promulgated on 26 February 1994 by the State Council and came into effect on 1 September 1994 and amended on 6 February 2016, and the Implementation Measures of the Administrative Measures on Medical Institutions (醫療機構管理條例實施細則), promulgated by the Ministry of Health of the PRC (the “MOH”) on 29 August 1994 and came into effect on 1 September 1994 and last amended on 21 February 2017 by NHFPC, stipulate that any entity or individual that intends to establish a medical institution must comply with the relevant application and approval procedures and register with the relevant healthcare administrative authorities to obtain a Medical Institution Practicing License (醫療機構執業許可證).

#### *Administrative Measures for the Examination of Medical Institutions (for Trial Implementation)*

The Administrative Measures for the Examination of Medical Institutions (For Trial Implementation) (醫療機構校驗管理辦法(試行)) (the “**Administrative Measures for Examination**”), which was promulgated by the MOH and came into effect on 15 June 2009, stipulate that a medical institution’s Medical Institution Practicing License (醫療機構執業許可證) is subject to periodic examinations and verifications by the registration authorities, and will be cancelled if such medical institution fails to pass the examination.

#### *Opinions on Implementing Categorization Administration of Urban Medical Institutions*

The Opinions on Implementing Categorization Administration of Urban Medical Institutions (關於城鎮醫療機構分類管理的實施意見), jointly promulgated by the MOH, SATCM, Ministry of Finance (the “MOF”) and National Development and Reform Commission (the “NDRC”) on 18 July 2000 and came into effect on 1 September 2000, provides that medical institutions in the PRC are mainly identified as for-profit medical institutions (the “PMIs”) and not-for-profit medical institutions (the “NMIs”). NMIs and PMIs shall be classified based on their business objectives, service purposes and implementation of various financial, taxation, pricing and accounting policies. Also, governments shall not operate for-profit medical institutions. On the other hand, NMIs must comply with the pricing guidance for medical service stipulated by governments from time to time, and the rules and policies issued by the National Health Commission of the PRC (the “NHC”) and the MOF including Hospital Finance System (醫院財務制度) and Hospital Accounting System (醫院會計制度). PMIs can distribute the profits to their investors as economic returns. Based on its marketing needs, PMIs have the discretion to set the fees and prices for their medical and healthcare services. In establishing internal control system, PMIs can apply the finance and accounting system and other policies suitable for corporate enterprise. The not-for-profit/for-profit status of a medical institution is decided based on the source of its investment and the nature of its business by the health administration and other relevant government authorities and such status is recorded in the registration files of such medical institution.

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### *Law on the Promotion of Basic Medical Care, Hygiene and Health*

Pursuant to the Law on the Promotion of Basic Medical Care, Hygiene and Health (基本醫療衛生與健康促進法), which was released by the SCNPC on 28 December 2019 and came into effect on 1 June 2020, lawful registration and classified management for not-for-profit and for-profit medical institutions shall be implemented. Government-run medical institution shall not set up non-independent legal person medical institution with other organizations, or cooperate with social capital to establish for-profit medical institutions. It also provides that the government will take measures to encourage and guide social resources to set up medical institution, and such institution will enjoy similar benefits as government-run institution, in certain areas including basic medical insurance coverage, research and teaching, access to specific medical technologies, and title assessment of medical staff, etc.

### *Administrative Measures for the Clinical Application of Medical Technologies*

According to the Administrative Measures for the Clinical Application of Medical Technologies (醫療技術臨床應用管理辦法), which was promulgated by the National Health Commission on 13 August 2018 and took effect on 1 November 2018, a negative management system is established for the clinical application of medical technologies. More specifically, those listed on the negative list to be promulgated are deemed to be prohibited medical technologies and the clinical application of which is prohibited; certain medical technologies that are beyond the negative list but possess certain prescribed characteristics are subject to strict record-filing management by the relevant health administrative department which require self-assessment of the medical technologies in question and submission of certain prescribed materials; and those medical technologies that are not categorized as prohibited or restricted medical technologies may be subject to clinical application by medical institutions according to their own functions, objectives, technical capabilities and so on and be strictly managed by the medical institutions themselves.

### *Provisions on the Administration of Radiological Diagnosis and Treatment*

According to the Provisions on the Administration of Radiological Diagnosis and Treatment (放射診療管理規定), which were promulgated by the NHFPC on 24 January 2006, came into effect on 1 March 2006 and amended on 19 January 2016, medical institutions engaged in the radio diagnosis and radiotherapy shall be equipped with the conditions required for conducting radio diagnosis and radiotherapy, and apply for the Radiation Treatment License (放射診療許可證) issued by the competent health administrative authorities. After obtaining the Radiation Treatment License, medical institution shall undertake registration of the relevant diagnosis and treatment subject with health administrative authorities, which issued the Medical Institution Practicing License. Medical institutions shall not conduct radio diagnosis and radiotherapy if failing in obtaining License for radiotherapy or not registering the diagnosis and treatment subject. During the course of radiotherapy, medical institutions shall take protective measures in accordance with the relevant laws and regulations. where a medical institution provides any services in relation to radiological diagnosis and treatment without obtaining a Radiation Treatment License, the relevant health administrative

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departments at or above the county level may issue a warning to the medical institution in violation and order the medical institution to take corrective measures within a prescribed time limit, and may impose a fine not exceeding RMB3,000 depending on the circumstances. If the violation is serious, the relevant health administrative authorities have the power to revoke the medical institution’s Medical Institution Practicing License.

### ***Regulations on the Safety and Protection of Radioisotopes and Radiation Devices and Measures for Administration of the Safety Licensing of Radioactive Isotopes and Radioactive Equipment***

According to Regulations on the Safety and Protection of Radioisotopes and Radiation Devices (放射性同位素與射線裝置安全和防護條例), which were promulgated by the State Council on 14 September 2005, came into effect on 1 December 2005 and revised on 29 July 2014 and 2 March 2019, respectively, and Measures for Administration of the safety Licensing of Radioactive Isotopes and Radioactive Equipment (放射性同位素與射線裝置安全許可管理辦法), which were promulgated by Ministry of Environmental Protection on 18 January 2006 and revised on 6 December 2008, 20 December 2017 and 22 August 2019 stipulate that any entity engaging in the production, sale or use of radioisotopes or radiation devices of different categories shall obtain a Radiation Safety License (輻射安全許可證). If any entity is engaged in the production, sale or use of radioisotopes or radiation devices without a Radiation Safety License, the relevant department of ecology and environment at or above the county level may order such entity to stop the violation and take corrective measures within a prescribed time limit. If the entity fails to take any corrective actions within the prescribed time limit, the entity may be ordered to suspend production or business operation. Further, if any income had been generated from such violation, such income shall be confiscated, and if such income amounts to RMB100,000 or above, a fine of one to five times of the amount of such income may be imposed; if no such income had been generated or such income is less than RMB100,000, a fine of RMB10,000 to RMB100,000 may be imposed.

### **Regulations on the Supervision over Pharmaceuticals and Medical Equipment in Healthcare Institutions**

#### ***Measures for the Supervision and Administration of Pharmaceuticals in Medical Institutions (for Trial Implementation)***

The Measures for the Supervision and Administration of Pharmaceuticals in Medical Institutions (for Trial Implementation) (醫療機構藥品監督管理辦法(試行)), promulgated by China Food and Drug Administration (the “CFDA”) and came into effect on 11 October 2011, stipulate that medical institutions must purchase pharmaceuticals from enterprises qualified for the production or distribution of pharmaceuticals and comply with certain standards in respect of the storage, dispensation and use of such pharmaceuticals. Pharmaceutical preparation dispensed by a medical institution must only be used by and for that medical institution. Medical institutions are prohibited from selling prescription pharmaceuticals to the public by such means as post, online transaction and open-shelf selection.

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### *Prescription Management*

According to the Administrative Measures for Prescriptions (處方管理辦法), which was promulgated by the MOH on 14 February 2007 and came into effect on 1 May 2007, a registered medical practitioner is entitled to issue prescriptions at his registered practice location. The Measures for the Classification and Administration of Prescription Pharmaceuticals and Non-prescription Pharmaceuticals (For Trial Implementation) (處方藥與非處方藥分類管理辦法(試行)), which were promulgated by CFDA on 18 June 1999 and came into effect on 1 January 2000, set forth different systems for the control of prescription and non-prescription drugs. Medical institutions can decide or recommend the use of non-prescription pharmaceuticals with regard to medical necessary.

### **Laws and Regulations on Medical Personnel of Medical Institutions**

#### *Law on Medical Practitioners of the PRC*

The Law on Medical Practitioners of the PRC (中華人民共和國執業醫師法), which was promulgated by the Standing Committee of the National People’s Congress (the “SCNPC”) on 26 June 1998 and came into effect on 1 May 1999 and amended on 27 August 2009, provides that physicians in the PRC must obtain qualification licenses for their medical profession. Qualified physicians and qualified assistant physicians must register with the relevant public health administrative authorities at or above the county level. After registration, physicians may work at medical institutions in their registered location in the types of jobs and within the scope of medical treatment, disease-prevention or healthcare business as provided in their registration. On 28 February 2017, the NHFPC promulgated the Administrative Measures for the Registration of Medical Practitioners (醫師執業註冊管理辦法) (the “**Medical Practitioners Registration Measures**”), which became effective on 1 April 2017, further stipulate that medical practitioners shall obtain the Practicing Certificate to practice upon registration and provide in detail the requirements and procedures for the registration and the modifications to be made to such registration upon occurrence of certain prescribed circumstances.

#### *Several Opinions on Accelerating the Development of Medical Institutions with Social Capital and Several Opinions on Promoting and Standardizing Multi-Institution Practice of Medical Practitioners*

Several Opinions on Accelerating the Development of Medical Institutions with Social Capital (關於加快發展社會辦醫的若干意見), promulgated on 30 December 2013 by the NHFPC and the SATCM, specifically stipulate that multi-institution practices of medical practitioners shall be permitted and relevant authorities should permit the orderly movements of the medical personnel among medical institutions of various sponsorships. The Several Opinions on Promoting and Standardizing Multi-Institution Practice of Medical Practitioners (關於印發推進和規範醫師多點執業的若干意見的通知), jointly issued by the NHFPC, the NDRC, the Ministry of Human Resources and Social Security, the SATCM and the China Insurance Regulatory Commission on 5 November 2014, stipulate that the clinical, dental and

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traditional Chinese medicine practitioners are allowed to practice in multiple places. According to the Medical Practitioners Registration Measures, for any other institution in which the medical practitioner intends to practice, such medical practitioner shall apply to the health administrative authority for approval on the practice of such institution for separate registration, in which the name of such institution shall be indicated.

### *Administrative Provisions for Short-term Medical Practice of Doctors in the PRC*

According to the Interim Administrative Measures on Foreign physicians’ Short-term Medical Practice in China (外國醫師來華短期行醫暫行管理辦法), promulgated by the MOH on 7 October, 1992, became effective on 1 January 1993 and amended on 28 November 2003 and revised by the NHFPC on 19 January 2016, foreign doctors practicing medicine in China must be registered and obtain the Temporary License for Foreign Physician to Practice Medicine in PRC (外國醫師短期行醫許可證).

### *Regulations on Nurses*

The Regulations on Nurses (護士條例), promulgated by the State Council on 31 January 2008 and came into effect on 12 May 2008 and amended on 27 March 2020, provide that a nurse must obtain a Nurse’s Practicing Certificate (護士執業證書), which is valid for five years. The number of nurses on duty at a medical institution shall not be less than the standard number as prescribed by the public health administrative authority of the State Council.

### *Administrative Measures for the Registration of Practising Nurses*

Pursuant to the Administrative Measures for the Registration of Practising Nurses (護士執業註冊管理辦法) promulgated by the NHFPC on 6 May 2008 and became effective on May 12, 2008 and amended on January 8, 2021, nurses must register and obtain the Nurse Practicing Certificate (護士執業證書) before they practise nursing at the registered practicing place. Those who are not registered or have not obtained the Nurse Practising Certificate are not allowed to engage in nursing activities regulated by medical treatment standards.

## **Laws and Regulations on Medical Malpractice**

### *Civil Code of the People’s Republic of China*

The Civil Code of the People’s Republic of China (中華人民共和國民法典) promulgated on 5 May 2020 and effective from January 1, 2021, requires tortfeasor to assume the responsibilities of infringement if the civil interests of any people has been infringed. If a medical institution or its medical personnel are at fault for damage inflicted on a patient during the course of diagnosis and treatment, the medical institution will be liable for compensation. A medical institution shall be presumed to be at fault under (i) violating laws, administrative regulations, rules or other relevant provisions on diagnosis and treatment practices, (ii) concealing or refusing to provide medical records relating to the dispute; or (iii) losing, forging, tampering with or illegally destroying medical records. If the medical personnel fail

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to perform diagnosis and treatment obligations corresponding to the prevailing medical standards in diagnosis and treatment activities and cause a patient suffer damage, the medical institution shall bear compensation liability. Medical institutions and their medical personnel should protect the privacy of their patients and will be liable for the damage caused by divulging the patients’ private or medical records without consent.

### *Regulations on Handling Medical Malpractice*

The Regulations on Handling Medical Malpractice (醫療事故處理條例), which was promulgated by the State Council on 4 April 2002 and came into effect on 1 September 2002, provides a legal framework and detailed provisions regarding the prevention, technical identification, disposition, supervision, compensation and penalties of medical malpractice. For the purpose of the Regulation, medical malpractice refers to an accident involving personal injury to patients caused by medical institutions or medical personnel due to malpractice as a result of violation of the laws, administrative regulations or departmental rules on medical and health administration, or of standards or procedures of medical treatment.

### **Regulations on Medical Advertising in the PRC**

#### *Advertisement Law of the PRC*

The Advertisement Law of the PRC (中華人民共和國廣告法) (the “**Advertisement Law**”), which was promulgated by the SCNPC on 27 October 1994 and came into effect on 1 February 1995 and last amended on April 29, 2021, provides that advertisements shall not contain false statements and be deceitful or misleading to consumers. Advertisements legally required to receive censorship, including those that are relating to pharmaceuticals and medical devices, shall be reviewed by relevant authorities in accordance with relevant rules before being published.

#### *Interim Measures for the Administration of Internet Advertisement*

The Interim Measures for the Administration of Internet Advertisement (互聯網廣告管理暫行辦法), which was promulgated by the State Administration of Industry and Commerce (the “SAIC”) on 4 July 2016 and came into effect on 1 September 2016, provides that Internet advertisement shall be identifiable and clearly identified as an “advertisement” so that consumers will identify it is as such. Paid search advertisements shall be clearly distinguished from natural search results. It is prohibited to publish advertisements for prescription drugs and tobaccos via the Internet. No advertisement of any medical treatment, medicines, foods for special medical purpose, medical apparatuses, pesticides, veterinary medicines, dietary supplement or other special commodities or services which are subject to review by advertisement examination authorities as stipulated by laws and regulations shall be released unless it has passed such examination.



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### *Administrative Measures on Medical Advertisement*

The Administrative Measures on Medical Advertisement (醫療廣告管理辦法), jointly promulgated by the SAIC and the MOH on 27 September, 1993, took effect on 1 December 1993, amended on 10 November 2006 and came into effect on 1 January 2007, require that medical advertisements shall be reviewed by relevant health authorities and obtain a Medical Advertisement Examination Certificate (醫療廣告審查證明) before they may be released by a medical institution. Medical Advertisement Examination Certificate has an effective term of one year and may be renewed upon application.

### **Regulations on Environmental Protection related to Medical Institutions**

#### *Administrative Measures for Pollutant Discharge Licensing*

Administrative Measures for Pollutant Discharge Licensing(for Trial Implementation) (For Trial Implementation) (排污許可管理辦法(試行)), which was promulgated by the Ministry of Environmental Protection (repealed) on 10 January 2018, and amended on 22 August 2019, stipulate that the enterprises, public institutions and other production operators (hereinafter referred to as the “**pollutant discharge entities**”) included in the catalog of classified management of pollutant discharge licenses for stationary pollution sources shall apply for and obtain a pollutant discharge permit as per the prescribed time limit; and those are not included in the catalog are not required to do so for the time of being.

Pursuant to the Classified Management Catalog of Pollutant Discharge Permits for Stationary Sources of Pollution (2019 Edition) (固定污染源排污許可分類管理名錄 (2019年版)), which was promulgated by the Ministry of Ecology and Environment on 20 December 2019 and became effective on the same day, a pollutant discharge entity subject to registration management is not required to apply for a pollutant discharge permit. It shall fill in the pollutant discharge registration form on the management information platform of state pollutant discharge permits, and register with its basic information, pollutant discharge route, pollutant discharge standards implemented, pollution prevention and control measures adopted, and other information.

#### *Regulations on the Management of Medical Waste and its Implementation Measures*

The Regulations on the Management of Medical Waste (醫療廢物管理條例), promulgated by the State Council on 16 June 2003 and came into effect on the same day and further amended and came into effect on 8 January 2011, and the Implementation Measures for the Management of Medical Waste of Medical and Health Institutions (醫療衛生機構醫療廢物管理辦法), promulgated by the MOH on 15 October 2003 and came into effect on the same day, stipulate that medical institutions must categorise the medical waste in accordance with the Classified Catalogue of Medical Waste (醫療廢物分類目錄) for management purpose and timely deliver medical waste to a medical waste disposal entity approved by the environmental protection administrative department at or above the county level for centralized disposal.

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### *Regulations on Urban Drainage and Sewage Treatment*

The Regulations on Urban Drainage and Sewage Treatment (城鎮排水與污水處理條例), which were promulgated by the State Council on 2 October 2013 and came into effect on 1 January 2014, require that urban entities and individuals shall dispose sewage through urban drainage facilities covering their geographical area in accordance with relevant rules.

Companies or other entities engaging in medical activities shall apply for a Sewage Disposal Drainage License (污水排入排水管網許可證) before disposing sewage into urban drainage facilities. Sewage-disposing entities and individuals shall pay sewage treatment fee in accordance with relevant rules.

### *Law of the People's Republic of China on Prevention and Control of Water Pollution*

Pursuant to the Law of the People's Republic of China on Prevention and Control of Water Pollution (中華人民共和國水污染防治法) promulgated by the Standing Committee of the National People's Congress on 11 May 1984 and became effective on November 1 1984, amended on 15 May 1996 and came into effective on the same day, amended on February 28, 2008 and became effective on 1 June 2008, amended on 27 June 2017 and became effective on 1 January 2018, the production and operation units must discharge water pollutants in accordance with national and local standards. If the amount of discharged water pollutants exceeds the national or local standards, the production and operation units will be imposed a fine equivalent to an amount between RMB100,000 and RMB1,000,000. In addition, the environmental protection authority is empowered to order the relevant production and operation units to restrict their production, or stop production for rectification, and in serious circumstances, the case will be reported to the competent government with approval authority to impose an order to suspend or shut-down its operation.

### **Laws and Regulations Related to Intellectual Property Rights**

#### *Trademark*

Pursuant to the Trademark Law of the PRC (中華人民共和國商標法) which became effective on 1 March 1983, and was amended on 30 August 2013 and 23 April 2019 and took effect on 1 November 2019, and the Regulation for the Implementation of Trademark Law of the PRC (中華人民共和國商標法實施條例) which became effective on 15 September 2002 and was amended on 29 April 2014 and took effect on 1 May 2014, the Trademark Office of the administrative department for industry and commerce under the State Council is responsible for the registration and administration of trademarks in the PRC. A trademark registrant enjoys an exclusive right to the trademark. A trademark registrant may, by entering into a trademark licensing contract, license another party to use its registered trademark. Where another party is licensed to use a registered trademark, the licensor shall report the license to the Trademark Office for recordation, and the Trademark Office shall publish the same. An unrecorded license may not be used as a defence against a third party in good faith.

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### *Domain Names*

On 28 May 2012, the China Internet Network Information Centre (the “CNNIC”) issued the Implementing Rules for Domain Name Registration (中國互聯網絡信息中心域名註冊實施細則) which took effect on 29 May 2012 setting forth the detailed rules for registration of domain names. Pursuant to the Measures for the Administration of Internet Domain Names (互聯網域名管理辦法) promulgated on 24 August 2017 and became effective on 1 November 2017, registration of domain name shall follow the principle of “first apply, first register.” The Measures of the China Internet Network Information Centre on Domain Name Dispute Resolution (2014 Revision) (中國互聯網絡信息中心域名爭議解決辦法(2014年修訂)), implemented by the CNNIC on 1 September 2014, require domain name disputes to be submitted to institutions authorized by the CNNIC for resolution.

### **Laws and Regulations Related to Data Security and Data Privacy**

#### *Data Security*

On June 10, 2021, the SCNPC promulgated the Data Security Law of the PRC (中華人民共和國數據安全法), which took effect in September 2021. The Data Security Law introduces a data classification and hierarchical protection system based on the materiality of data in economic and social development, as well as the degree of harm it will cause to national security, public interests, or legitimate rights and interests of persons or entities when such data is tampered with, destroyed, divulged, or illegally acquired or used. It also provides for a security review procedure for the data activities which may affect national security. Violation of Data Security Law may subject the relevant entities or individuals to warnings, fines, suspension of operations, revocation of permits or business licenses, or even criminal liabilities.

#### *Data Privacy*

On August 20, 2021, the SCNPC promulgated the Personal Information Protection Law of the PRC (中華人民共和國個人信息保護法), which became effective on November 1, 2021. The Personal Information Protection Law stipulates certain important concepts with respect to personal information processing: (a) “personal information” refers to all kinds of information relating to identified or identifiable natural persons recorded by electronic or other channel and methods, excluding the information processed anonymously; (b) “processing of personal information” includes the collection, storage, use, processing, transmission, provision, disclosure and deletion, etc. of personal information; and (c) “personal information processor” refers to an organization or individual that independently determines the purpose and method of the processing in the processing of personal information.

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Except as otherwise provided in the Personal Information Protection Law, a personal information processor may only process personal information under the circumstances where the relevant individuals’ consents have been obtained or where certain contractual arrangements, employment relationships, public emergencies, performance of statutory duties or obligations or publishing of press release for public interests require so.

### **Laws and Regulations Related to Foreign Investment in the PRC**

#### ***Company Law of the PRC***

The Company Law of the PRC (中華人民共和國公司法) (the “**Company Law**”), which was promulgated by the SCNPC on 29 December 1993 and came into effect on 1 July 1994, last amended on 26 October 2018, provides that companies established in the PRC may take form of company of limited liability or company limited by shares. Each company has the status of a legal person and owns its assets itself. Assets of a company may be used in full for the company’s liability. The Company Law applies to foreign-invested companies unless relevant laws provide otherwise.

#### ***Laws and Regulations in Relation to Sino-Foreign Joint Ventures***

The Law on Sino-Foreign Equity Joint Ventures (中華人民共和國中外合資經營企業法) (the “**EJV Law**”) was promulgated and implemented on 8 July 1979. It was subsequently amended on 4 April 1990, 15 March 2001 and 3 September 2016. The Implementation Rules for the Law on Sino-Foreign Equity Joint Ventures of the PRC (中華人民共和國中外合資經營企業法實施條例) (the “**EJV Rules**”) were promulgated by the State Council on 20 September 1983, and last amended on 2 March 2019. The EJV Law and its implementation rules state the establishment and approval procedures, requirements on registered capital, restrictions on foreign exchange, accounting practices, taxation, labour requirements and other issues applicable to Sino-foreign equity joint ventures. On 1 January 2020, the EJV Law was terminated and replaced by the Foreign Investment Law of the PRC (中華人民共和國外商投資法).

#### ***The Provisional Measures for the Filing Administration of Establishment and Changes of Foreign-Invested Enterprises***

The Provisional Measures for the Filing Administration of Establishment and Changes of Foreign-Invested Enterprises (2018 Revision) (外商投資企業設立及變更備案管理暫行辦法(2018年修正)), which was promulgated by the MOFCOM on 29 June 2018 and implemented on 30 June 2018, set out the prescribed procedures for the establishment and modifications of foreign-invested enterprises which are not subject to the special management measures on admission as stipulated by the PRC to be filed for records with the delegated commerce authorities and specify the procedures and requirements for such filing in detail. Foreign-invested enterprises and their investors shall provide information for filing and completing the declaration form for filing application truthfully, accurately and completely according to such provisional measures without any false records, misleading statements or material omission.

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On 1 January 2020, the Provisional Measures for the Filing Administration of Establishment and Changes of Foreign-Invested Enterprises (2018 Revision) was terminated and replaced by the Measures on Reporting of Foreign Investment Information (外商投資信息報告辦法).

### *The Measures for the Reporting of Foreign Investment Information*

The Measures for the Reporting of Foreign Investment Information (外商投資信息報告辦法), which was promulgated by the MOFCOM and the State Administration for Market Regulation (the “SAMR”) on December 30 2019 and came into effect on January 1, 2020, stipulates that a foreign investor who establishes a foreign-invested enterprise within China shall submit an initial report through the enterprise registration system when undergoing formation registration of the foreign-funded enterprise, a foreign investor that acquires a domestic non-foreign-invested enterprise by equity merger shall submit an initial report through the enterprise registration system when undergoing modification registration of the acquired enterprise.

### *Interim Provisions on Investment Made by Foreign-Invested Enterprises in China*

The Interim Provisions on Investment Made by Foreign-Invested Enterprises in China (關於外商投資企業境內投資的暫行規定), jointly promulgated by the Ministry of Foreign Trade and Economic Cooperation of the PRC and the SAIC on 25 July 2000 and amended on 28 October 2015, stipulates that a foreign-invested enterprise (the “FIE”) are not permitted to invest in any sector prohibited to foreign investment. Where the FIE makes investment in a restricted sector, the FIE must file an application with the provincial commercial department of the place where the investee company is located. The relevant company registration authority will, in accordance with the relevant provisions of the Company Law and the Regulations on the Administration of Company Registration of the PRC (中華人民共和國公司登記管理條例), decide whether or not to approve the registration. If the registration is approved, a Business License of an Enterprise Legal Person will be issued with the designation “Invested by a Foreign-Invested Enterprise.” The FIE is required to report the establishment of the investee company within 30 days of the date of its establishment to the original examination and approval authority for record-filing.

### **Domestic Regulations on Establishment of Foreign Invested Medical Institutions**

#### *The Catalogue for the Guidance of Foreign Investment Industries and The Special Administrative Measures (Negative List) for the Access of Foreign Investment*

Investment in the PRC conducted by foreign investors and foreign-owned enterprises shall comply with the Catalogue for the Guidance of Foreign Investment Industries (外商投資產業指導目錄) (the “Catalogue”), which was first issued in 1995 and amended from time to time. The Catalogue promulgated by the MOFCOM and the NDRC on 28 June 2017 and became effective on 28 July 2017 (the “2017 Catalogue”), contains specific provisions guiding market access of foreign capital and stipulates in detail the areas of entry pertaining to the categories of encouraged foreign investment industries, restricted foreign investment industries

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and prohibited foreign investment industries. The latter two categories are included in the negative list, which was first introduced into the 2017 Catalogue, and listed, in a unified manner, the restrictive measures for the entry of foreign investment.

The Special Administrative Measures (Negative List) for the Access of Foreign Investment (2021) (外商投資准入特別管理措施(負面清單) (2021年版)) (the “2021 Negative List”), was issued on December 27, 2021 and came into effect on January 1, 2022. According to the 2021 Negative List, medical institutions are limited to the form of joint ventures.

### *Interim Administrative Measures on Sino-Foreign Equity Medical Institutions and Sino-Foreign Cooperative Medical Institutions*

The Interim Administrative Measures on Sino-Foreign Equity Medical Institutions and Sino-Foreign Cooperative Medical Institutions (中外合資、合作醫療機構管理暫行辦法), which was promulgated by MOH (repealed) and the Ministry of Commerce on 15 May 2000 and came into effect on 1 July 2000, allow foreign investors to partner with Chinese entities to establish a medical institution in China by means of equity joint venture or cooperative joint venture. Establishment of equity joint venture or cooperative joint venture shall meet certain requirements, including the total investment sum shall not be less than RMB20 million and the equity percentage of the Chinese partner in the joint venture shall not be less than 30%. Establishment of equity joint venture or cooperative medical institutions shall be subject to approval by relevant authorities.

### *Administrative Measures on Sino-Foreign Equity and Cooperative Medical Institutions in the Sichuan Province*

The Administrative Measures on Sino-Foreign Equity and Cooperative Medical Institutions in the Sichuan Province (《四川省中外合資、合作醫療機構管理辦法》), which was promulgated by the Sichuan Ministry of Health and Sichuan Ministry of Commerce on March 15, 2012, became effective on April 15, 2012 and amended on January 16, 2015, stipulates that equity ratio or interests attributable to the joint venture and Chinese party of Sino-Foreign joint ventures and cooperative medical institutions shall not be less than 10%.

### *Regulations on Mergers and Acquisitions of Domestic Companies by Foreign Investors*

The Regulations on Mergers and Acquisitions of Domestic Companies by Foreign Investors (關於外國投資者併購境內企業的規定), jointly promulgated by the MOFCOM, State-owned Asset Supervision and Administration Commission of the State Council, SAT, SAIC, China Securities Regulatory Commission and the SAFE on 8 August 2006, came into effect on 8 September 2006 and subsequently amended by the MOFCOM on 22 June 2009, require the domestic companies, enterprises or natural persons, when merging or acquiring domestic companies associated with them in the name of the companies in foreign countries legally established or controlled by them, shall report to the Ministry of Commerce for approval.

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### Regulations on the Management of Lease Housing

#### *Administrative Measures on Leasing of Commodity Housing*

Pursuant to (i) the Law on Administration of Urban Real Estate of the PRC (中華人民共和國城市房地產管理法), promulgated by the SCNPC on 5 July 1994 and was amended on 27 August 2009 and 26 August 2019 and took effect on January 1, 2020, and (ii) the Administrative Measures on Leasing of Commodity Housing (商品房屋租賃管理辦法), promulgated by the Ministry of Housing and Urban-Rural Development on 1 December 2010 and came into effect on 1 February 2011, when leasing premises, the lessor and lessee are required to enter into a written lease contract, containing such provisions as the leasing term, use of the premises, rental and repair liabilities, and other rights and obligations of both parties. Both lessor and the lessee shall complete property leasing registration and filing formalities within 30 days from the execution of the property lease contract with the real estate administration department where the leased property is located. If the lessor and lessee fail to go through the registration and filing procedures, both lessor and lessee may be subject to fines.

### Laws and Regulations Related to Labour Protection

According to the (i) Labour Law of the PRC (中華人民共和國勞動法) effected on 1 January 1995 and amended on 29 December 2018, (ii) the Labour Contract Law (中華人民共和國勞動合同法) effected on 1 January 2008 and amended on 28 December 2012 and took effect on 1 July 2013, and (iii) the Regulations on the Implementation of the Labour Contract Law of the PRC (中華人民共和國勞動合同法實施條例) issued and became effective on 18 September 2008, an employer must enter into a written labour contract with any employees and the wage or salary must not be lower than the local minimum wage or salary. In addition, an employer must establish a system related to occupation health and safety, provide job training for employees to avoid occupational hazards and protect the rights of employees. When an employer recruits any employees, such employer must inform the employees of the work content, work conditions, work place, occupational hazards, safety conditions and labour compensations.

According to (i) the Social Insurance Law of the PRC (中華人民共和國社會保險法), which was implemented on 1 July 2011 and amended on 29 December 2018, (ii) the Provisional Regulations on Collection and Payment of Social Insurance Premiums (社會保險費徵繳暫行條例), issued and effected on 22 January 1999 and revised on 24 March 2019, (iii) the Provisional Measures on Maternity Insurance of Enterprise Employees (企業職工生育保險試行辦法), issued on 14 December 1994 and effected 1 January 1995, (iv) the Regulations on Unemployment Insurance (失業保險條例), issued and effective on 22 January 1999, and (v) the Regulations on Work Related Injuries (工傷保險條例), effected on 1 January 2004 and

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amended on 20 December 2010 and took effect on 1 January 2011, an employer must make contributions to a number of social security funds for its employees, including the basic pension insurance, basic medical insurance, maternity insurance, unemployment insurance and work-related injury insurance. According to the Regulations on Management of Housing Provident Fund (住房公積金管理條例), effected on 3 April 1999 and last amended on 24 March 2019, an employer must open a housing fund account with the department responsible for the management of housing fund for its employees and make contributions to such housing fund.

### Laws and Regulations Related to Taxation

#### *Enterprise Income Tax*

According to (i) the PRC EIT Law, which was promulgated by the National People’s Congress on 16 March 2007 and came into effect on 1 January 2008, and further amended on 24 February 2017 and 29 December 2018, and (ii) the Implementation Regulations on the Enterprise Income Tax Law of the PRC (中華人民共和國企業所得稅法實施條例) (the “**EIT Rules**”), which was promulgated by the State Council on 6 December 2007 and came into effect on 1 January 2008 and revised on 23 April 2019, the tax rate for both domestic-funded enterprises and foreign-invested enterprises is 25%. Under the PRC EIT Law and PRC EIT Rules, enterprises are classified as either “resident enterprises” or “non-resident enterprises.” Enterprises established outside the PRC whose “de facto management bodies” are located in the PRC are considered “resident enterprises” and subject to the uniform 25% PRC EIT rate for their global income. According to the PRC EIT Rules, a “de facto management body” refers to a managing body that exercises, in substance, overall management and control over the manufacture and business, personnel, accounting and assets of an enterprise. Dividends, bonuses and other equity investment proceeds distributed between qualified resident enterprises shall be tax-free income.

The PRC EIT Law provides that a non-resident enterprise refers to an entity established under foreign law whose “de facto management bodies” are not within the PRC but which have an establishment or place of business in the PRC, or which do not have an establishment or place of business in the PRC but have income sourced within the PRC. PRC EIT Rules provide that after 1 January 2008, an income tax rate of 10% will normally be applicable to dividends declared to non-resident enterprise investors which do not have an establishment or place of business in the PRC, or which have such establishment or place of business but the relevant income is not effectively connected with such establishment or place of business, to the extent such dividends are derived from source within the PRC. The income tax on the dividends may be reduced pursuant to a tax treaty between the PRC and the jurisdiction in which the non-resident enterprise investors is located if the non-resident enterprise investor is determined by the competent PRC tax authority to have satisfied relevant conditions and requirements.



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The Announcement on Several Issues Concerning the Enterprise Income Tax on Indirect Transfer of Assets by Non-Resident Enterprises (關於非居民企業間接轉讓財產企業所得稅若干問題的公告) (the “**SAT Circular 7**”) was issued by the SAT on 3 February 2015 and last amended on 29 December 2017, provides comprehensive guidelines heightening the PRC tax authorities’ scrutiny on, indirect transfers by a non-resident enterprise of assets, including assets of organizations and premises in PRC, immovable property in the PRC, equity investments in PRC resident enterprises. On 17 October 2017, the SAT issued the Announcement on Issues Relating to Withholding at Source of Income Tax of Non-resident Enterprises (關於非居民企業所得稅源泉扣繳有關問題的公告), which took effect on 1 December 2017 and amended on 15 June 2018, the balance after deducting the equity net value from the equity transfer income shall be the taxable income amount for equity transfer income.

Under the SAT Circular 7 and the Law of the People’s Republic of China on the Administration of Tax Collection (中華人民共和國稅收徵收管理法), which was promulgated by the SCNPC on 4 September 1992 and amended on 24 April 2015, in the case of an indirect transfer, entities or individuals obligated to pay the transfer price to the transferor shall act as withholding agents. If they fail to make withholding or withhold the full amount of tax payable, the transferor of equity shall declare and pay tax to the relevant tax authorities within seven days from the occurrence of tax payment obligation.

### *Tax Treaties*

According to the Treaty on the Avoidance of Double Taxation and Tax Evasion between Mainland and Hong Kong (內地和香港特別行政區關於對所得避免雙重徵稅和防止偷漏稅的安排) (the “**Tax Treaty**”) entered into between Mainland China and HKSAR on 21 August 2006, if the non-PRC parent company of a PRC enterprise is a Hong Kong resident which beneficially owns 25% or more interest in the PRC enterprise, the 10% withholding tax rate applicable under the EIT Law may be lowered to 5% for dividends and 7% for interest payments once approvals have been obtained from the relevant tax authorities.

Pursuant to the Notice on the Several Issues of the Implementation of Tax Treaty (國家稅務總局關於執行稅收協定股息條款有關問題的通知), which was promulgated by the SAT and came into effect on 20 February 2009, the non-resident taxpayer or the withholding agent is required to obtain and keep sufficient documentary evidence proving that the recipient of the dividends meets the relevant requirements for enjoying a lower withholding tax rate under a tax treaty. Pursuant to the Administrative Measures for Tax Treaty Treatment for Non-resident Taxpayers (非居民納稅人享受稅收協定待遇管理辦法), which was promulgated by the SAT on 27 August 2015 and amended on 15 June 2018, and further replaced by the Administrative Measures on Non-resident Taxpayers Enjoying Treaty Benefits (國家稅務總局關於發佈《非居民納稅人享受協定待遇管理辦法》的公告), which took effect on 1 January 2020, any non-resident taxpayer satisfying the conditions for enjoying the tax treaty treatment may be entitled to the tax treaty treatment on its own when filing a tax return or making a withholding declaration through a withholding agent, subject to the subsequent administration by the tax authorities.

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The Announcement of the State Administration of Taxation on Issues Relating to “Beneficial Owner” in Tax Treaties (國家稅務總局關於稅收協定中“受益所有人”有關問題的公告) issued by the SAT on 3 February 2018 and came into effect on 1 April 2018, provides that the “beneficial owner” shall mean a person who has the ownership and control over the income and the rights and property from which the income is derived. When an individual who is a resident of the treaty counterparty derive dividend income from the PRC, the individual may be determined as a “beneficial owner.”

### ***Value-Added Tax***

The Interim Provisions on Value-added Tax of the PRC (中華人民共和國增值稅暫行條例), which was promulgated by the State Council on 13 December 1993, came into effect on 1 January 1994, and last amended on 19 November 2017, and the Implementing Rules of the Interim Provisions on Value-added Tax of the PRC (中華人民共和國增值稅暫行條例實施細則), promulgated by the MOF and became effective on 25 December 1993, and last amended on 28 October 2011, set out that all taxpayers selling goods or providing processing, repairing or replacement services and importing goods in the PRC shall pay a value-added tax. The tax rate for taxpayers engaging in the sales of goods, labour services, tangible movables lease services or the importation of goods shall be 17% unless otherwise stipulated.

According to the Trial Scheme for the Conversion of Business Tax to Value-added Tax (營業稅改徵增值稅試點方案), which was promulgated by the MOF and the SAT, the government launched gradual taxation reforms starting from 1 January 2012, whereby it collected value-added tax in lieu of business tax on a trial basis in regions and industries showing strong economic performance, such as transportation and certain modern service industries.

Furthermore, according to the Notice of the Ministry of Finance and the State Administration of Taxation on Overall Implementation of the Pilot Program of Replacing Business Tax with Value-added Tax (財政部、國家稅務總局關於全面推開營業稅改徵增值稅試點的通知), all business tax payers in consumer service industry shall pay value-added tax in lieu of business tax from 1 May 2016 and the medical service provided by the medical institution could be the exempted from value-added tax.

### **Laws and Regulations over Foreign Exchange**

The Regulations on the Control of Foreign Exchange of the PRC (中華人民共和國外匯管理條例), which was promulgated by the State Council on 29 January 1996, became effective on 1 April 1996 and was last amended on 5 August 2008, set out that foreign exchange receipts of domestic institutions or individuals may be remitted back to the PRC or deposited abroad and that SAFE shall specify the conditions relating to the requirements, time periods and other aspects of such remittance and deposits in accordance with the international receipts, payments status and requirements of foreign exchange administration. Domestic institutions or individuals that make direct investments abroad or are engaged in the distribution or sale of valuable securities or derivative products overseas shall register according to SAFE regulations. Such institutions or individuals subject to prior approval or record-filing with

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other competent authority shall complete the required approval or record-filing prior to foreign exchange registration. The exchange rate for RMB follows a managed floating exchange rate system based on market demand and supply.

The Regulations on the Administration of the Settlement, Sale and Payment of Foreign Exchange (結匯、售匯及付匯管理規定), which was promulgated by the People’s Bank of China on 20 June 1996 and came into effect on 1 July 1996, provide that foreign exchange earnings under the current account of FIEs may be retained to the fullest extent specified by the relevant foreign exchange bureau. Any portion in excess of such amount shall be sold to a designated foreign exchange bank or through a foreign exchange swap centre.

On 30 March 2015, the SAFE promulgated Notice on Reforming the Mode of Management of Settlement of Foreign Exchange Capital of Foreign-Funded Enterprises (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”, which came into effect on 1 June 2015. According to Circular 19, the foreign exchange capital of FIEs shall be subject to the discretionary foreign exchange settlement (the “**Discretionary Foreign Exchange Settlement**”) and its proportion is temporarily determined as 100%. Furthermore, Circular 19 stipulates that the use of capital by FIEs shall follow the principles of authenticity and self-use within the business scope of enterprises. The capital of an FIE and capital in RMB obtained by the FIE from foreign exchange settlement shall not be used for certain purposes as prescribed in the Circular 19. On 9 June 2016, the SAFE promulgated the Circular on Reforming and Regulating Policies on the Management of the Settlement of Foreign Exchange of Capital Accounts (關於改革和規範資本項目結匯管理政策的通知) (the “**SAFE Circular 16**”) SAFE Circular 16 unifies policies on discretionary settlement of foreign exchange receipts under capital accounts of domestic institutions.

Circular of the State Administration of Foreign Exchange on Issues concerning Foreign Exchange Administration over the Overseas Investment and Financing and Round-trip Investment by Domestic Residents via Special Purpose Vehicles (國家外匯管理局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), which was issued and effected on 4 July 2014, provides that PRC residents shall register with the SAFE and its local branches in connection with their direct establishment or indirect control of an offshore entity, for the purpose of overseas investment and financing, with assets or equity interests of onshore companies or offshore assets or interests held by the PRC residents. Following the initial registration, any change of basic information such as individual shareholder, name and term of operation or upon capital increase or deduction, share transfer or swap, merger or division and other significant change, shall report to the SAFE for foreign exchange alteration of the registration formality for offshore investment in time.

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The Notice on Further Simplifying and Improving Foreign Exchange Administration Policies in Respect of Direct Investment (關於進一步簡化和改進直接投資外匯管理政策的通知), which was issued on 13 February 2015 and effected on 1 June 2015, provides that PRC residents may register with qualified banks instead of SAFE in connection with their establishment or control of an offshore entity established for the purpose of overseas investment or financing. The SAFE and its branches shall implement indirect supervision over foreign exchange registration of direct investment via the banks.

### **Laws and Regulations Related to Dividend Distribution**

The principal laws and regulations governing distribution of dividends of FIEs include the Company Law, the EJV Law, and the EJV Rules. FIEs in the PRC may pay dividends only out of their accumulated profits, if any, determined in accordance with PRC accounting standards and regulations. In addition, FIEs are required to draw certain proportion of their respective accumulated profits after tax each year, if any, to fund certain reserve funds.