

REGULATORY OVERVIEW

Our business in the PRC is subject to oversight and regulation from the PRC Government. This section sets out a summary of the major relevant laws, regulations, rules and policies which may have material impact on our business.

REGULATIONS ON THE STANDARDS FOR OPHTHALMIC HOSPITALS

The Circular of The Ministry of Health On Issuing the Basic Standards for Ophthalmic Hospitals (for Trial Implementation), the Basic Standards for Obstetrics and Gynecology Hospitals (for Trial Implementation) and the Basic Standards for Otolaryngology Hospitals (for Trial Implementation) (《衛生部關於發佈〈眼科醫院基本標準(試行)〉、〈婦產醫院基本標準(試行)〉、〈耳鼻喉醫院基本標準(試行)〉的通知》) promulgated on June 11, 1996 and the Circular of The Ministry of Health on Relevant Provisions on the Administration of Examination and Approval of the Establishment of Specialized Hospitals (《衛生部關於專科醫院設置審批管理有關規定的通知》) promulgated on December 5, 2011 set different standards on the number of registered beds, departments, personnel, buildings, equipment and registered capital for different classes of ophthalmic hospitals, and ophthalmic hospitals must satisfy the standards for Class II or Class III ophthalmic hospitals. In particular, Class III ophthalmic hospitals shall have more than 80 registered beds.

The Circular of the National Health Commission on Issuing the Basic Standards and Administrative Practices for Three Types of Medical Institutions Including Medical Disinfection Supply Centers (for Trial Implementation) (《國家衛生健康委員會關於印發〈醫療消毒供應中心等三類醫療機構基本標準和管理規範(試行)〉的通知》) promulgated on May 17, 2018 provides that ophthalmic hospitals shall comply with the relevant standards on the number of registered beds, department establishment, personnel, premises, equipment and management. In particular, the total number of registered beds shall be no less than 20 (including daytime observation beds).

REGULATIONS ON THE ADMINISTRATION AND CATEGORIZATION OF MEDICAL INSTITUTIONS

Law of the People’s Republic of China on Basic Medical and Health Care and the Promotion of Health

Pursuant to the Law of the People’s Republic of China on Basic Medical and Health Care and the Promotion of Health (《中華人民共和國基本醫療衛生與健康促進法》), which was promulgated by the Standing Committee of the National People’s Congress (the “SCNPC”) on December 28, 2019 and came into effect on June 1, 2020, lawful registration and classified management for NMIs and PMIs shall be implemented. Government-organized medical institution shall not set up non-independent legal person medical institution with other organizations, or cooperate with social capital to establish PMIs. It also provides that the government adopts various measures to encourage and guide non-governmental sectors to establish medical and health institutions pursuant to the law, support and standardize cooperation on various types of medical operations, discipline development, personnel training between medical and health institutions established by non-governmental sectors and government-organized medical and health institutions. The law also stipulates that the government will take measures to encourage and guide social forces to organize medical and health-care institutions, and that such medical and health-care institutions will enjoy the same rights as government-organized medical and health-care institutions in a number of areas, such as the designation of basic medical insurance, scientific research and teaching, access to specific medical technologies, and the title assessment of medical staff, etc.

Regulations on the Administration of Medical Institutions and its Implementation Measures

The Regulations on the Administration of Medical Institutions (《醫療機構管理條例》), which was promulgated on February 26, 1994 by the State Council, came into effect on September 1, 1994 and amended on February 6, 2016 and March 29, 2022, and the Implementation Measures of the Regulations on the Administration of Medical Institutions (《醫療機構管理條例實施細則》), which was promulgated by the MOH on August 29, 1994, came into effect on September 1, 1994 and last amended on February 21, 2017 by NHFPC, stipulate that any entity or individual that intends to establish a medical institution

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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》). The Medical Institution Practicing Licenses shall not be fabricated, altered, sold, transferred or lent. Where a Medical Institution Practicing License is fabricated, altered, sold, transferred or lent in violation of this Law, the health department of the people’s government at or above the county level shall order the violator to take corrective action, confiscate any illegal proceeds, and impose a fine of not less than five nor more than 15 times the illegal proceeds on it; if the amount of illegal proceeds is under RMB10,000, the fine shall be calculated based on illegal proceeds of RMB10,000; and in case of serious violation, such Medical Institution Practicing License shall be revoked. The Measures for the Administration of Self-inspection of Medical Institutions’ Practice by Law (《醫療機構依法執業自查管理辦法》) promulgated by the NHC and the National Administration of Traditional Chinese Medicine on September 8, 2020, comprehensively promote the integrated regulatory system of the medical and health industry, implement the main responsibility of self-management of medical institutions in accordance with laws, standardize the practice behavior of medical institutions, and formulate these measures in accordance with the relevant laws and regulations on health.

Administrative Measures for the Inspection of Medical Institutions (for Trial Implementation)

The Administrative Measures for the Inspection 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 June 15, 2009, stipulates that a medical institution’s Medical Institution Practicing License (《醫療機構執業許可證》) is subject to periodic inspections by the registration authorities. For general hospitals, TCM hospitals, TCM and western medicine integrated hospitals, ethnomedicine hospitals and specialty hospitals, nursing homes, rehabilitation hospitals, maternity and child health care hospitals, emergency centers, clinical testing centers and specialty disease prevention and treatment institutions with more than 100 beds, validation period is three years; for other medical institutions, validation period is one year. If a medical institution fails to apply for inspection as required, still fails to apply for completing the inspection procedures within the prescribed time limit or fails to pass the inspection again, the registration authority shall cancel its Medical Institution Practicing License.

Opinions on Implementing Classification Administration of Urban Medical Institutions

The Opinions on Implementing Classification 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, the National Administration of Traditional Chinese Medicine, the Ministry of Finance (the “**MOF**”) and the State Development Planning Commission on July 18, 2000 and came into effect on September 1, 2000, provides that medical institutions in the PRC are mainly identified as PMIs and NMIs, and NMIs is further divided into public NMIs and private 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 the PMIs. On the other hand, NMIs must comply with the pricing guidance for medical services stipulated by governments from time to time, and the regulations and policies issued by the MOH and the MOF including Hospital Finance System and Hospital Accounting System. PMIs can distribute the profits to their [REDACTED] as economic returns. Based on their 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/profit-making 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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Grading of Medical Institutions

The Basic Standard for Medical Institutions (For Trial Implementation) (《醫療機構基本標準(試行)》), which was promulgated by the MOH on September 2, 1994 and amended on August 2, 2010, March 15, 2011 and December 5, 2011, Interim Measures for the Assessment of Hospitals (《醫院評審暫行辦法》), which was promulgated by the MOH on September 21, 2011, and the Measures for the Assessment of Medical Institutions (《醫療機構評審辦法》), which was promulgated by the MOH on July 21, 1995, stipulate that medical institutions in the PRC are graded into three levels (Class I, II and III) and three sub-levels (A, B, C) based on the assessment of competent authorities. The assessment itself is not a requisite for a healthcare institution to carry out its business. Under the relevant regulations, each hospital will be assessed once every four years. The NHC and its Hospital Assessment Committee are responsible for conducting all hospital assessments in the PRC. Health administrative departments at the provincial level shall set up Hospital Assessment Leading Groups, which are responsible for hospitals assessment at the provincial level.

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 NHC on August 13, 2018 and implemented on November 1, 2018, a negative list management system is established for the clinical application of medical technologies. In particular, those listed on the Negative List for Medical Technologies (《醫療技術負面清單》) are deemed to be prohibited medical technologies and the clinical application of which is prohibited; certain medical technologies that are beyond the Negative List for Medical Technologies 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 was promulgated by the NHFPC on January 24, 2006, came into effect on March 1, 2006 and amended on January 19, 2016, medical institutions engaged in the radiological diagnosis and treatment shall be equipped with the conditions required for conducting radiological diagnosis and treatment, and apply for the Permit for Radiological Diagnosis and Treatment (《放射診療許可證》) issued by the competent health administrative authorities. After obtaining the Permit for Radiological Diagnosis and Treatment, medical institutions shall undertake registration of the relevant diagnosis and treatment subject with health administrative authorities, which issued the Medical Institution Practicing License. The Permit for Radiological Diagnosis and Treatment and the Medical Institution Practicing License shall be verified concurrently and testing reports on the performance of radiological diagnosis and treatment equipment and radiation work venues shall be submitted in applying for verification. A medical institution shall make emergency response plan for preventing and disposing radiation incidents. A medical institution shall investigate and handle the incidents in a timely manner if certain radiation incidents occur. Medical institutions that fail to obtain the Permit for Radiological Diagnosis and Treatment or have not registered under diagnosis and treatment disciplines shall not carry out radiodiagnosis and radiotherapy. During the process of radiotherapy, medical institutions shall take protective measures in accordance with the applicable laws and regulations. Where a medical institution provides any services in relation to radiological diagnosis and treatment without obtaining a Permit for Radiological Diagnosis and Treatment, the health authority at or above the county level shall give it a warning and order it to make corrections within a prescribed time limit, and may impose a fine of less than RMB3,000 on it as the case may be; in case of serious violation, its Medical Institution Practicing License shall be revoked.

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

The Regulations on the Safety and Protection of Radioisotopes and Radiation-emitting Devices (《放射性同位素與射線裝置安全和防護條例》), which was promulgated by the State Council on September 14, 2005 and amended on July 29, 2014 and March 2, 2019, and the 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 was promulgated by the State Environment Protection Administration on January 18, 2006 and amended on December 6, 2008, December 20, 2017, August 22, 2019 and January 4, 2021 by the Ministry of Environmental Protection and Ministry of Ecology and Environment respectively, stipulate that any entity conducts activities of production, sale, and use of radioactive isotopes or radial equipment within the territory of the PRC shall obtain the Radiation Safety License (《輻射安全許可證》).

Regulations on the Control of Narcotic Drugs and Psychotropic Drugs

According to the Regulations on the Control of Narcotic Drugs and Psychotropic Drugs (《麻醉藥品和精神藥品管理條例》), which was promulgated by the State Council on August 3, 2005, amended on December 7, 2013, February 6, 2016 and December 6, 2024 and came into effect on January 20, 2025, any medical institution needs to use narcotic drugs and the psychotropic drugs of category I shall be subject to the approval of the relevant health authority, and obtain the seal card for purchasing narcotic drugs and the psychotropic drugs of category I (《麻醉藥品、第一類精神藥品購用印鑒卡》). For any narcotic drug or psychotropic drug which is needed for clinical use but with no supply in the market, if any medical institution which holds the license of preparations of medical institution and the seal card needs to prepare the preparations, it shall be subject to the approval of the department of drug supervision and administration of the people’s government of the province, autonomous region, and municipality at its locality. The preparations of narcotic drugs and psychotropic drugs prepared by any medical institution may only be used in such medical institution, and shall not be sold to external parties.

Administrative Measures for Food Operation Licensing and Record-filing

According to the Administrative Measures for Food Operation Licensing and Record-filing (《食品經營許可和備案管理辦法》), which was promulgated on June 15, 2023 by the State Administration for Market Regulation (the “SAMR”) and implemented on December 1, 2023, a Food Operation License (《食品經營許可證》) shall be obtained in accordance with the law to engage in food selling and catering services within the PRC.

REGULATIONS ON PREVENTION AND TREATMENT OF INFECTIOUS DISEASES

The Law of the People’s Republic of China on the Prevention and Treatment of Infectious Diseases (《中華人民共和國傳染病防治法》), which was promulgated by the SCNPC on February 21, 1989, came into effect on September 1, 1989 and amended on August 28, 2004, June 29, 2013 and April 30, 2025, provides that the infectious diseases are divided into Classes A, B, C and other types pursuant to the outbreak, prevalence and extent of harm of the infectious diseases. Class A infectious diseases refer to those that pose an especially severe threat to human health and life safety, may cause significant economic losses and social impact, and require particularly strict management to control the spread of outbreaks. Class B infectious diseases refer to those that pose a serious threat to human health and life safety, may cause considerable economic losses and social impact, and require strict management to reduce incidence and mitigate harm. Class C infectious diseases refer to those that are common and frequently occurring, cause harm to human health and life safety, may lead to a certain degree of economic losses and social impact, and require monitoring of epidemic trends to control outbreaks and spread. When the medical institution discovers a Class A infectious disease, it shall immediately take the following measures: (1) For patients with Class A infectious diseases and pathogen carriers, isolation treatment and medical observation shall be implemented; (2) For suspected patients with Class A infectious diseases, separate

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isolation treatment shall be carried out before diagnosis is confirmed; (3) For close contacts of patients, pathogen carriers, or suspected patients with Class A infectious diseases, medical observation shall be implemented, along with other necessary preventive measures.

REGULATIONS ON PHARMACEUTICALS IN MEDICAL INSTITUTIONS AND MEDICAL DEVICES

Drug Administration Law of the People’s Republic of China and its Implementing Regulations and Measures for Supervision and Administration of Drugs of Medical Institutions (For Trial Implementation)

According to the Drug Administration Law of the People’s Republic of China (《中華人民共和國藥品管理法》), which was promulgated by the SCNPC on September 20, 1984, amended on February 28, 2001, December 28, 2013, April 24, 2015 and August 26, 2019 and came into effect on December 1, 2019, the Implementing Regulations of the Drug Administration Law of the People’s Republic of China (《中華人民共和國藥品管理法實施條例》), which was promulgated by State Council on August 4, 2002, amended on February 6, 2016, March 2, 2019, December 6, 2024, January 16, 2026 and came into effect on May 15, 2026, and the Measures for Supervision and Administration of Drugs of Medical Institutions (For Trial Implementation) (《醫療機構藥品監督管理辦法(試行)》), which was promulgated by the State Food and Drug Administration on October 11, 2011 and came into effect on the same day, medical institutions must purchase drugs from enterprises qualified to produce and deal in drugs. Drugs used by medical institutions must be purchased uniformly by designated departments in accordance with the provisions, and other departments and medical staff members of medical institutions are forbidden to purchase drugs on their own. Medicinal products shall be imported at a port allowing the import of medicinal products, and enterprises importing medicinal products shall file with the medicinal product regulatory department of the place where the port is located.

Regulations on Supervision and Administration of Medical Devices

In the PRC, medical devices are classified into three categories according to their risk levels. Class I medical devices refer to the medical devices with low risks, whose safety and effectiveness can be ensured through routine administration. Class II medical devices refer to the medical devices with moderate risks, which shall be strictly controlled and administered to ensure their safety and effectiveness. Class III medical devices refer to the medical devices with relatively high risks, which shall be strictly controlled and administered through special measures to ensure their safety and effectiveness. According to the Regulations on Supervision and Administration of Medical Devices (《醫療器械監督管理條例》) promulgated by the State Council on January 4, 2000, amended on March 7, 2014 and May 4, 2017 and February 9, 2021 and December 6, 2024 and came into effect on January 20, 2025, for Class I medical devices, the record-filing management shall be implemented, while for Class II and Class III medical devices, the registration management shall be implemented. To engage in the operation of Class II medical devices, an operating enterprise shall make a record-filing with the relevant authority. To engage in the operation of Class III medical devices, an operating enterprise shall apply for the Medical Device Operation License (《醫療器械經營許可證》).

REGULATIONS ON THE PRICE OF HEALTHCARE SERVICES AND MEDICINE

Notice of Issues Related to the Implementation of Market Price Adjustment of Healthcare Services Provided by Non-Public Medical Institutions

According to the Notice of Issues Related to the Implementation of Market Price Adjustment of Healthcare Services Provided by Non-Public Medical Institutions (《關於非公立醫療機構醫療服務實行市場調節價有關問題的通知》) promulgated and implemented on March 25, 2014 by NDRC, the NHFPC and the Ministry of Human Resources and Social Security (the “MHRSS”), the price of healthcare services provided by non-public medical institutions to be set with reference to the market level. Non-public medical institutions which are profit-making in nature may set the price list for their healthcare services at their own discretion. Non-public medical institutions which are not-for-profit in nature shall set the

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price list for their healthcare services according to the National Standard Price List of Healthcare Services (全國醫療服務價格項目規範》). For non-public medical institutions qualified to become designated medical institutions covered by medical insurance, they should be included as a designated service covered by social insurance such as basic medical insurance for employees and urban residents, new-type rural cooperative medical insurance, work-related injury insurance and maternity insurance in accordance with relevant procedures and adopt the same payment policy as in public hospitals. To efficiently utilize funds, medical insurance agents should determine specific payment methods and standards with such non-public medical institution by ways of negotiation under the requirements of medical insurance payment system reform.

REGULATIONS ON MEDICAL INSURANCE AND MEDICAL LIABILITY INSURANCE

According to the Interim Measures for the Administration of Medical Insurance Designated Medical Institutions and the Provision of Basic Medical Insurance for Urban Employees (《城鎮職工基本醫療保險定點醫療機構管理暫行辦法》), which was promulgated by the MOH, the Ministry of Labor and Social Security and the National Administration of Traditional Chinese Medicine on May 11, 1999, the Decision of the State Council on Canceling the First Batch of 62 Items Subject to Administrative Examination and Approval of Local Governments Designated by the Central Government (《國務院關於第一批取消62項中央指定地方實施行政審批事項的決定》), which was promulgated by the State Council on October 11, 2015, and the Guiding Opinions of the Ministry of Human Resources and Social Security on Improving the Management of Designated Medical Institutions and Pharmacies of Basic Medical Insurance through Agreements (《人力資源和社會保障部關於完善基本醫療保險定點醫藥機構協議管理的指導意見》), which was promulgated by the MHRSS on December 2, 2015 and came into effect on the same day, the license for qualifying a medical institution as a designated medical institution to provide medical services to urban employees with basic medical insurance was cancelled. Agencies and the medical institutions should strictly comply with the stipulations in the service agreement and perform the agreement seriously. The defaulting party shall be held liable to the violations of the agreement.

Pursuant to the Notice on Applying for National Pilot Program of Payment by Diagnosis Related Groups (《關於申報按疾病診斷相關分組付費國家試點的通知》) promulgated by the National Healthcare Security Administration (the “NHSA”) on December 10, 2018, the NHSA is researching and formulating Diagnosis Related Groups (DRG) standards suitable for China’s medical services system and medical insurance management capabilities, and has launched a pilot program of paying by DRG in certain cities. The NHSA officially issued the Technical Specification for National Health Insurance DRG Grouping and Payment (《國家醫療保障DRG分組與付費技術規範》) and the National Health Insurance DRG (CHS-DRG) Grouping Scheme (《國家醫療保障DRG (CHS-DRG)分組方案》) on October 16, 2019. The data requirements for DRG grouping, data quality control, standardized upload specifications, grouping strategies and principles, and methods for determining weights and rates are regulated, and the national health insurance disease DRG is clarified as a unified standard for the national health insurance sector to carry out DRG payment work.

Regulation of the Receiving of Medical Treatment Covered by the Basic Medical Insurance Away from Home

According to the Notice on Further Strengthening the Regulation of the Receiving of Medical Treatment Covered by the Basic Medical Insurance Away From Home (《關於進一步加強基本醫療保險異地就醫監管的通知》), which was promulgated by the General Office of the MHRSS on December 19, 2016 and came into effect on the same day, handling agencies in all the regions under the overall planning shall include the receiving of medical treatment away from home into the agreement-based administration of medical institutions, making it an indicator for the assessment of medical institutions, detailing and improving the clauses of the agreements, specifying that the services and management regarding, among others, the selection of medical institutions, the recording of medical information, the monitoring of medical practices and the examination and the auditing of medical expenses which are offered to the persons receiving medical treatment away from home are the same as the one to the local insured, and protect the rights and interests of the persons receiving medical treatment away from home.

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REGULATIONS ON CENTRALIZED PROCUREMENT

According to the Notice on Issuance of the Pilot Plan Regarding the National Organization of Centralized Procurement and Use of Drugs by the General Office of the State Council (《國務院辦公廳關於印發國家組織藥品集中採購和使用試點方案的通知》), which was promulgated by the State Council on January 1, 2019, and the Implementation Opinions on Region Expansion of the Organization of Centralized Procurement and Use of Drugs by the State (《關於國家組織藥品集中採購和使用試點擴大區域範圍的實施意見》), which was promulgated by the NHSA, NHC and other relevant departments on September 25, 2019, the State Council plans to organize centralized procurement and the use of certain types of pilot drugs to lower drug prices, reduce patients’ drug cost burden, and lower the transaction costs of pharmaceutical enterprises. On January 22, 2021, the State Council issued the updated Opinion of the General Office of the State Council on Promoting the Normalization and Institutionalization of Centralized Volume-Based Procurement of Drugs (《國務院辦公廳關於推動藥品集中帶量採購工作常態化制度化開展的意見》), to provide additional details and clarification on the centralized procurement scheme. The scheme includes an initial procurement scope covering drugs listed in the Drug Catalog for Basic Medical Insurance, which exhibited widespread usage and high procurement prices, with the goal of gradually expanding to additional drugs which are deemed to be clinical necessities with widespread demand. In principle, all holders of registration certificates of drugs falling under the scope of the centralized volume-based drug procurement and meet the requirements for the centralized volume-based drug procurement in terms of quality standards, production capacity, and supply stability, may participate in such procurement. In addition, all public medical institutions are required to participate in the centralized volume-based drug procurement.

Opinions on Promoting Drug Pricing Reform

The Opinions on Promoting Drug Pricing Reform (《推進藥品價格改革的意見》), which was promulgated by the NDRC, the NHFPC, the State Food and Drug Administration, the Ministry of Commerce of the PRC (the “MOFCOM”) and other three departments on May 4, 2015, sets forth that from June 1, 2015, except for narcotic drugs and Class I psychotropic drugs, the restrictions on the prices of the drugs that were subject to government pricing will be cancelled. In particular, the prices of narcotic drugs and Class I psychotropic drugs are still subject to maximum factory prices and maximum retail prices set by the NDRC for the time being. The medical insurance regulatory authority shall, along with other competent departments, draw up provisions in relation to the standards, procedures, basis, and methods of the payment of drugs paid by medical insurance funds. Regarding patented drugs and exclusively produced drugs, the prices thereof are set through transparent and public negotiation among multiple parties. The prices for blood products not listed in the Medical Insurance Drugs List, immunity and prevention drugs that are purchased by the PRC government in a centralized manner, and AIDS antiviral drugs and contraceptives provided by the PRC government for free, shall be set through tendering purchase or negotiation. Except as otherwise mentioned above, the prices for other drugs may be determined by the manufacturers and the operators on their own based on production or operation costs and market supply and demand.

REGULATIONS ON MEDICAL PRACTITIONERS OF MEDICAL INSTITUTIONS

Physicians Law of the People’s Republic of China

Pursuant to the Physicians Law of the People’s Republic of China (《中華人民共和國醫師法》) promulgated by the SCNPC on August 20, 2021 and came into effect on March 1, 2022, physicians in the PRC must obtain licenses of medical professional qualifications. Anyone who has been awarded the qualifications as a medical physician may apply to the competent health department under the local people’s government at or above the county level for registration. Physicians may, upon registration, work in medical and health institutions according to the registered place, category and scope of practice to engage in the corresponding medical and health services, while assistant practicing physicians should, under the supervision of practicing physicians, practice according to the registered categories and scope of practice at medical and health institutions. Physicians shall adhere to the principle of using medicine in a safe, effective, economical and reasonable manner, follow the drug clinical application guidelines,

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clinical diagnosis and treatment guide and drug instructions in the use of drugs in an appropriate manner. Under special circumstances such as there is no effective or better treatment, after obtaining a patient’s express informed consent, a physician may give treatment by adopting the drug usage that is not specified in the drug instruction but has evidence-based medical evidence.

Administrative Measures for the Registration of Practicing Physicians

Pursuant to the Administrative Measures for the Registration of Practicing Physicians (《醫師執業註冊管理辦法》) promulgated by the NHFPC on February 28, 2017 and came into effect on April 1, 2017, physicians must register and obtain the Physician Practicing Certificate (《醫師執業證書》) before they commence practice and, those who are not registered or have not obtained the Physician Practicing Certificate are not allowed to engage in medical, preventive and healthcare services. The registration details of practicing physicians include place of practice, category and scope of practice. The place of practice refers to the county and provincial administrative region of the medical, preventive and healthcare institutions where the physician is practicing. For practicing physician who wants to practice in multiple institutions within the same place of practice, he/she shall determine a specific institution as the main practicing institution, and apply for registration with the competent health authority which approved the aforesaid institution’s operation; as to other institutions where the practitioner intends to practice, the practicing physician shall apply the record filing with the administrative health and family planning authority to approve the institutions’ operation and indicate the name of the institutions.

Several Opinions on Accelerating the Development of Establishment Medical Institutions by Social Capital and Notice on Issuance of Several Opinions on Promoting and Standardizing Multi-Institution Practice of Physicians

The Several Opinions on Accelerating the Development of Establishment Medical Institutions by Social Capital (《關於加快發展社會辦醫的若干意見》), promulgated on December 30, 2013 by the NHFPC and the National Administration of Traditional Chinese Medicine, specifically stipulates that multi-institution practices of physicians shall be permitted and relevant authorities should permit the orderly movements of the medical personnel among medical institutions of various sponsorships. The Notice on Issuance of Several Opinions on Promoting and Standardizing Multi-Institution Practice of Physicians (《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 MHRSS, the National Administration of Traditional Chinese Medicine and the China Insurance Regulatory Commission on November 5, 2014, stipulates that the clinical, dental and TCM physicians are allowed to practice in multiple places. According to the Administrative Measures for the Registration of Practicing Physicians, for any other institution in which the physician intends to practice, such physician shall apply the record filing with the administrative health and family planning authority to approve the institutions’ operation and indicate the name of the institutions. Physicians practicing in multiple locations should have intermediate or higher professional and technical qualifications, and should have been engaged in the same specialty for five years. Physicians practicing in medical institutions other than the first place of practice, the category of practice should be the same as the first place of practice, and the scope of practice shall be the same as the second level of diagnosis and treatment subjects of the first place of practice.

Regulations on Nurses

The Regulations on Nurses (《護士條例》), promulgated by the State Council on January 31, 2008 and came into effect on May 12, 2008 and amended on March 27, 2020, provides that a nurse must obtain a Nurse 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. Medical institutions shall be equipped with a sufficient number of nurses as stipulated by the health administrative department of the State Council; otherwise, the health administrative department of the local people’s government at or above the county level shall order rectification within a specified period of time and give a warning. If it fails to do so, it shall reduce the number of diagnostic and therapeutic subjects and the number of nurses legally practicing in the medical institution, or suspend its practice for a period of not less than six months but not more than one year.

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Administrative Measures for the Registration of Practicing Nurses

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

REGULATIONS ON MEDICAL INCIDENTS

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 May 28, 2020 and came into effect on 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 process 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 and other applicable provisions on diagnosis and treatment standardization; (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 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 April 4, 2002 and came into effect on September 1, 2002, and the Regulations on the Prevention and Handling of Medical Disputes (《醫療糾紛預防和處理條例》), which was promulgated on July 31, 2018 and came into effect on October 1, 2018, provide 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 on Handling Medical Malpractice, 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 ONLINE MEDICAL SERVICES

Measures for the Administration of Internet Diagnosis and Treatment (for Trial Implementation)

On July 17, 2018, the NHC and the National Administration of Traditional Chinese Medicine jointly issued the Measures for the Administration of Internet Diagnosis and Treatment (for Trial Implementation) (《互聯網診療管理辦法(試行)》), which was amended on September 28, 2018. Pursuant to the Measures for the Administration of Internet Diagnosis and Treatment (for Trial Implementation), internet diagnosis and treatment activities shall be provided by the medical institutions that have obtained a Medical Institution Practicing License, and such medical institution shall file an application for practicing registration of Internet diagnosis and treatment activities with the authority issuing the Medical Institution Practicing License if it intends to provide Internet diagnosis and treatment activities. Medical institutions providing internet diagnosis and treatment activities shall implement the Information Security Level Protection (Level III). The medical institutions shall strictly adhere to relevant laws and regulations concerning information security and confidentiality of medical data. Patients’ information shall be

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securely maintained and shall not be traded or disclosed illegally by the medical institutions. When patients’ information and medical data are disclosed, a medical institution shall report to the competent health administrative department in a timely manner and immediately take effective response measures.

Measures for the Administration of Internet Hospitals (for Trial Implementation)

On July 17, 2018, the NHC and the National Administration of Traditional Chinese Medicine jointly promulgated the Measures for the Administration of Internet Hospitals (for Trial Implementation) (《互聯網醫院管理辦法(試行)》), which was amended on September 28, 2018. Pursuant to the Measures for the Administration of Internet Hospitals (for Trial Implementation), a physical medical institution that establishes an information platform independently or in cooperation with a third-party institution and utilizes physicians registered with the institution and other medical institutions to provide Internet diagnosis and treatment activities shall apply for using the “Internet Hospital” as the second name of physical medical institutions. The information systems of Internet Hospital shall implement Information Security Level Protection (Level III). The Internet Hospital shall strictly adhere to relevant laws and regulations concerning information security and confidentiality of medical data. Patients’ information shall be securely maintained and shall not be traded or disclosed illegally by the Internet Hospital. When patients’ information and medical data are disclosed, the medical institution shall report to the competent health administrative department in a timely manner and immediately take effective response measures.

REGULATIONS ON FOREIGN INVESTMENT

Investment activities in the PRC by overseas investors are principally governed by the Catalog of Encouraged Industries for Foreign Investment (《鼓勵外商投資產業目錄》) (the “**Encouraged Catalog**”), and the Special Administrative Measures (Negative List) for Foreign Investment Access (《外商投資准入特別管理措施(負面清單)》) (the “**Negative List**”), which are promulgated and amended from time to time by the MOFCOM and the NDRC, and together with the Foreign Investment Law of PRC (《中華人民共和國外商投資法》) (the “**Foreign Investment Law**”) and its respective implementation rules and ancillary regulations.

In March 2019, the Foreign Investment Law was promulgated by National People’s Congress and came into effect on January 1, 2020, which replaced three then existing laws on foreign investments in China, namely, the Sino-Foreign Equity Joint Venture Enterprise Law of PRC (《中華人民共和國中外合資經營企業法》), the Foreign Investment Law, by means of legislation, establishes the basic framework for the access, promotion, protection and administration of foreign investment in view of investment protection and fair competition. According to the Foreign Investment Law, foreign investment shall enjoy pre-entry national treatment, except for those foreign invested entities that operate in industries deemed to be either “restricted” or “prohibited” in the Negative List, and the State Council shall promulgate or approve a list of special administrative measures for access of foreign investments. To ensure the effective implementation of the Foreign investment Law, the Regulations on Implementing the Foreign Investment Law of PRC (《中華人民共和國外商投資法實施條例》) (the “**Implementation Regulations**”) was promulgated by State Council on December 2019 and came into effect on January 1, 2020, which further clarifies that the state encourages and promotes foreign investment, protects the lawful rights and interests of overseas investors, regulates foreign investment administration, continues to optimize foreign investment environment, and advances a higher-level opening.

The NDRC and the MOFCOM jointly revised and issued the Special Administrative Measures (Negative List) for Foreign Investment Access (2024 version) (《外商投資准入特別管理措施(負面清單)(2024年版)》) on September 6, 2024, which came into effect on November 1, 2024, to replace the previous Negative List thereunder (the NDRC and MOFCOM commonly revise the list every one to three years), and the latest update of the Negative List has decreased the total number of foreign investment access-restricted industries from 31 to 29, removing two sectors compared to the previous version. Pursuant to the Foreign Investment Law, the Implementation Regulations and the Negative List, overseas investors shall not make investments in prohibited industries as specified in the Negative List unless

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certain conditions and contexts are met, while foreign investments must satisfy certain conditions stipulated in the Negative List for investment in restricted industries. Industries not listed in the Negative List are generally deemed “permitted” for foreign investments.

According to the Measures for the Security Review of Foreign Investment (《外商投資安全審查辦法》) promulgated by the NDRC and the MOFCOM on December 19, 2020 and became effective on January 18, 2021, any foreign investment that has or possibly has an impact on state security shall be subject to security review in accordance with the provisions hereof. A foreign investor or a party concerned in China shall take the initiative to make a declaration to the working mechanism office prior to making the investment in any important infrastructure, important transportation services and other important fields that concern state security while obtaining the actual control over the enterprises invested in.

The Interim Measures for the Administration of Sino-Foreign Equity and Cooperative Joint Venture Medical Institutions (《中外合資、合作醫療機構管理暫行辦法》) and its Supplementary Provisions, which was jointly promulgated by the MOH and the Ministry of Foreign Trade and Economic Cooperation on May 15, 2000 and came into effect on July 1, 2000, stipulates that foreign investors are permitted to partner with Chinese medical 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 or interest percentage of the Chinese partner in the joint venture or cooperative joint venture medical institutions shall not be less than 30%. Establishment of equity joint venture or cooperative joint venture medical institutions shall be subject to approval by relevant authorities.

REGULATIONS ON INTERNET INFORMATION SECURITY

Cybersecurity Law of the People’s Republic of China

On November 7, 2016, the SCNPC promulgated the Cybersecurity Law of the People’s Republic of China (《中華人民共和國網絡安全法》) (the “**Cybersecurity Law**”), which was implemented on June 1, 2017 and amended on October 28, 2025. The Cybersecurity Law requires network operators to comply with laws and regulations and fulfill their obligations to safeguard security of the network when conducting business and providing services. The Cybersecurity Law further requires network operators to take all necessary measures in accordance with applicable laws, regulations and compulsory national standards to safeguard the safe and stable operation of the networks, respond to cybersecurity incidents effectively, prevent illegal and criminal activities, and maintain the integrity, confidentiality and usability of network data.

Regulations on the Security Protection of Critical Information Infrastructure

Under the Regulations on the Security Protection of Critical Information Infrastructure (《關鍵信息基礎設施安全保護條例》), promulgated by the State Council on July 30, 2021 and effective as of September 1, 2021, “critical information infrastructure” refers to important network facilities and information systems in key industries and fields such as public communications and information services, energy, transportation, water resources, finance, public services, e-government, and defense technology, as well as other systems that, if they are destroyed, malfunction, or suffer data breaches, could seriously endanger national security, the economy, people’s livelihoods, or public interests. The competent authorities and supervisory departments of these industries and fields are responsible for: (i) formulating identification rules for critical information infrastructure based on industry and sector realities and submitting them to the Ministry of Public Security for record-filing; (ii) identifying critical information infrastructure within their respective industries and sectors in accordance with the rules and notifying the operators and the Ministry of Public Security of the results.

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Cybersecurity Review Measures

On December 28, 2021, the Cyberspace Administration of China (the “CAC”) and other related authorities promulgated the Cybersecurity Review Measures (《網絡安全審查辦法》), which was implemented on February 15, 2022. The Cybersecurity Review Measures propose the following key matters: (i) the China Securities Regulatory Commission is included as one of the regulatory authorities for purposes of jointly establishing the state cybersecurity review working mechanism; (ii) the Internet platform operators holding personal information of more than one million individuals and seeking a [REDACTED] in foreign countries shall file for cybersecurity review with the Cybersecurity Review Office; (iii) the purchase of network products and services by critical information infrastructure operator, which affects or may affect national security, shall be subject to cybersecurity review in accordance with the Cybersecurity Review Measures; and (iv) furthermore, where members of the cybersecurity review working mechanism believe that network products and services and data processing activities affect or are likely to affect national security, the Cybersecurity Review Office shall report to the Central Cyberspace Affairs Commission for approval as per procedure, and conduct a review in accordance with the Cybersecurity Review Measures.

Notice on Carrying out the Filing of Mobile Internet Applications

On July 21, 2023, the Ministry of Industry and Information Technology (the “MIIT”) issued the Notice on Carrying out the Filing of Mobile Internet Applications (《關於開展移動互聯網應用程序備案工作的通知》), requiring APP operators engaged in Internet information services within the territory of the People’s Republic of China to complete filing formalities in accordance with the Anti-Telecom and Online Fraud Law of the People’s Republic of China (《中華人民共和國反電信網絡詐騙法》) and the Measures for the Administration of Internet Information Services (《互聯網信息服務管理辦法》). APP operators shall complete filing formalities with the provincial-level communications administration bureau where they are domiciled, and their network access service providers and APP distribution platforms (including the distribution platforms of mini programs, quick applications and others) shall submit such applications online for inspection and review through the National Internet Basic Resources Management System.

Administrative Measures for the Cybersecurity of Medical and Healthcare Institution

On August 8, 2022, the NHC, the National Administration of Traditional Chinese Medicine, and National Disease Control and Prevention Administration jointly promulgated the Administrative Measures for the Cybersecurity of Medical and Healthcare Institution (《醫療衛生機構網絡安全管理辦法》) with immediate effect. The Administrative Measures for the Cybersecurity of Medical and Healthcare Institution require strengthening management of cyber security and data security, including but not limited to strengthening management of system development, implementing daily network maintenance and monitoring, conducting annual self-inspection and rectification, and classifying and grading data assets.

REGULATIONS ON PERSONAL INFORMATION AND DATA PROTECTION

Data Security Law of the People’s Republic of China

The Data Security Law of the People’s Republic of China (《中華人民共和國數據安全法》), which was promulgated by the SCNPC on June 10, 2021 and implemented on September 1, 2021, stipulates that relevant entities carrying out data processing activities should comply with laws and regulations to establish and improve the whole process data security management system, strengthen risk monitoring mechanism, organize data security education and training, and take corresponding technical measures and other necessary measures to ensure data security.

REGULATORY OVERVIEW

Regulations on the Administration of Network Data Security

In accordance with the Regulations on the Administration of Network Data Security (《網絡數據安全管理條例》), promulgated by the State Council on September 24, 2024, and effective as of January 1, 2025, “network data” refers to various types of electronic data processed or generated via networks, and “network data processing activities” include the collection, storage, use, processing, transmission, provision, disclosure, and deletion of network data. As a supporting administrative regulation for the Cybersecurity Law of the People’s Republic of China, the Data Security Law of the People’s Republic of China, and Personal Information Protection Law, the Regulations on the Administration of Network Data Security introduce additional or refined requirements regarding notification rules for personal information processing, provision of personal information to other network data processors, personal information transfers, additional legal obligations for network data handlers processing personal information of more than 10 million individuals, security of important data, cross-border security management of network data.

Circular of the Ministry of Industry and Information Technology on Further Enhancing the Service Capacity of Mobile Internet Applications

On February 6, 2023, the MIIT promulgated the Circular of the Ministry of Industry and Information Technology on Further Enhancing the Service Capacity of Mobile Internet Applications (《工業和信息化部關於進一步提升移動互聯網應用服務能力的通知》), which was implemented on February 6, 2023. The Circular of the Ministry of Industry and Information Technology on Further Enhancing the Service Capacity of Mobile Internet Applications stipulates that users shall be informed of personal information processing rules in a concise, clear and easy-to-understand way, and in case of changes, users shall be informed of the latest development in time. The data processors shall highlight the purpose, method and scope of sensitive personal information processing activities, and establish a list of personal information that has been collected, and shall not induce users to agree to personal information processing rules with default check, small prints or lengthy texts.

Measures for the Security Assessment of Cross-Border Data Transfer

On July 7, 2022, the CAC promulgated the Measures for the Security Assessment of Cross-Border Data Transfer (《數據出境安全評估辦法》), which was implemented on September 1, 2022. According to the Measures for the Security Assessment of Cross-Border Data Transfer, where a data processor transfers data abroad, the data processor shall apply to the CAC for a data cross-border transfer security assessment through the local CAC at the provincial level when: (i) a data processor transfers important data abroad; (ii) a critical information infrastructure operator or a data processor processing the personal information of more than one million individuals transfers personal information abroad; (iii) a data processor has cumulatively transferred abroad the personal information of 100,000 individuals or the sensitive personal information of 10,000 individuals since January 1 of the previous year, and (iv) other circumstances in which the data processor shall apply for a data cross-border transfer security assessment as stipulated by the CAC.

Measures on Standard Contract for Cross-Border Transfer of Personal Information

On February 22, 2023, the Measures on Standard Contract for Cross-Border Transfer of Personal Information (《個人信息出境標準合同辦法》) (the “Measures on Standard Contract”) were promulgated by the CAC, which was implemented on June 1, 2023. The Measures on Standard Contract attach the standard contract for cross-border transfer of personal information that could be used to satisfy one of the conditions for cross-border transfer of personal information under Article 38 of the Personal Information Protection Law.

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Regulations on Promoting and Regulating Cross-border Data Flow

On March 22, 2024, the CAC promulgated the Regulations on Promoting and Regulating Cross-border Data Flow (《促進和規範數據跨境流動規定》) (the “New Data Outbound Regulations”), which further clarified the implementation and connection of the existing data cross-border transfer security assessment, personal information cross-border standard contract and personal information protection certification regarding data cross-border transfer. Conditions for cross-border data flow are appropriately relaxed, and the scope of data cross-border transfer security assessment is appropriately narrowed. Among them, the two types of data cross-border transfer that should be subject to data cross-border transfer security assessment are: (i) the operator of critical information infrastructure provides personal information or important data overseas; and (ii) data processors other than critical information infrastructure operators provide important data overseas, or cumulatively transfer abroad the personal information of more than one million individuals (excluding sensitive personal information) or the sensitive personal information of more than 10,000 individuals since January 1 of the year.

Personal Information Protection Law of the People’s Republic of China

On August 20, 2021, the SCNPC promulgated the Personal Information Protection Law of the People’s Republic of China (《中華人民共和國個人信息保護法》) (the “**Personal Information Protection Law**”), which was implemented on November 1, 2021. The Personal Information Protection Law aims to protect the rights and interests of personal information subjects and regulate the processing activities of personal information. The Personal Information Protection Law stipulates certain important concepts with respect to personal information processing activities: (i) “personal information” refers to all kinds of information related to identified or identifiable natural persons recorded by electronic or other means, excluding the information processed anonymously; (ii) “personal information processing activities” include the collection, storage, use, processing, transmission, provision, disclosure and deletion, etc. of personal information; and (iii) “personal information processor” refers to an organization or individual that independently determines the purpose and methods in the processing of personal information. The Personal Information Protection Law also stipulates rules for processing personal information and sensitive personal information, regulations on cross-border transfers of personal information, the rights of individuals in personal information processing activities, and the obligations of personal information handlers.

Measures to Identify Illegal Collection and Use of Personal Information by Apps

On November 28, 2019, the CAC, MIIT, the Ministry of Public Security and SAMR jointly issued the Measures to Identify Illegal Collection and Use of Personal Information by Apps (《App違法違規收集使用個人信息行為認定方法》), which lists six types of activities as illegal collection and use of personal information, including “not publishing rules on the collection and use of personal information” and “failing to expressly state the purpose, method and scope of collecting and using personal information.”

Notice on the Further Special Rectification of App Infringing upon Users’ Personal Rights and Interests, etc.

The MIIT issued the Notice on the Further Special Rectification of App Infringing upon Users’ Personal Rights and Interests (《關於開展縱深推進App侵害用戶權益專項整治行動的通知》) on July 22, 2020, which requires that certain conducts of App service providers should be rectified, including but not limited to (i) collecting or using personal information without the user’s consent, collecting or using personal information beyond the necessary scope of providing services, and forcing users to receive personalized advertisements; (ii) requesting user’s permission in a compulsory and frequent manner, or excessively request system permission or frequently launching the third-parties Apps; and (iii) deceiving and misleading users into downloading Apps or providing personal information. It also sets forth the rectification period and the MIIT will order the non-compliant entities to complete the rectification within five business days, or otherwise the MIIT will make a public announcement, remove the apps from the App stores or impose other administrative penalties.

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Pursuant to the Regulations on Medical Records Management in Medical Institutions (《醫療機構病歷管理規定》) jointly issued by NHFPC and the National Administration of Traditional Chinese Medicine on November 20, 2013 and took effect on January 1, 2014, the medical institutions and medical practitioners shall strictly protect the privacy information of patients, and any leakage of patients’ medical records for non-medical, non-teaching or non-research purposes is prohibited. The NHFPC issued the Measures for the Administration of Population Health Information (for Trial Implementation) (《人口健康信息管理辦法(試行)》) on May 5, 2014, which defines population health information as the basic population information, medical and health service information and other population health information generated in the process of service provision and administration by medical, health and family planning service agencies at all levels and according to laws, regulations and their job responsibilities, and emphasizes that such information cannot be stored in offshore servers, and the responsible organizations shall not store population health information in hosting servers or renting servers deployed abroad. Pursuant to the Management Measures of Standards, Safety and Service of National Health and Medical Big Data (for Trial Implementation) (《國家健康醫療大數據標準、安全和服務管理辦法(試行)》), promulgated by the NHC on July 12, 2018, the medical institutions should establish relevant safety management systems, operation procedures and technical specifications to safeguard the safety of healthcare big data generated in the process of health management service or prevention and cure service of diseases. It also stipulates that such healthcare big data should be stored in the secure and trusted servers within the territory of the PRC and shall not be provided overseas without safety assessment and review.

On February 12, 2025, the CAC issued the Administrative Measures for Personal Information Protection Compliance Audit (《個人信息保護合規審計管理辦法》), which came into effect on May 1, 2025. According to the Administrative Measures for Personal Information Protection Compliance Audit (the “Personal Information Compliance Audit Measures”), “compliance audit of personal information protection” refers to the supervision activities that review and evaluate whether the personal information processing activities by personal information processors comply with laws and administrative regulations. Personal information processors that process the personal information of more than 10 million individuals shall carry out the compliance audit of personal information protection at least once every two years. Personal information processors, in any of the following circumstances, may be required by national cyberspace administration department and other departments performing personal information protection duties (hereinafter collectively referred to as the “Protection Departments”) to entrust a professional agency to conduct a compliance audit of their personal information processing activities:

- (1) Where significant risks are identified in the personal information processing activities that severely impact individual rights or serious lack of security measures;
- (2) Where the personal information processing activities may infringe upon the rights and interests of a large number of individuals;
- (3) In the event of a personal information security incident resulting in the leakage, tampering, loss, or destruction of personal information of more than one million individuals or sensitive personal information of more than 100,000 individuals.

REGULATIONS ON MEDICAL ADVERTISEMENT

Advertisement Law of the People’s Republic of China

The Advertisement Law of the People’s Republic of China (《中華人民共和國廣告法》) (the “**Advertisement Law**”), which was promulgated by the SCNPC on October 27, 1994, came into effect on February 1, 1995 and amended on April 24, 2015, October 26, 2018 and April 29, 2021, provides that advertisements shall not contain false statements and shall not be deceitful or misleading to consumers. Advertisements legally required to receive censorship, including those that are relating to medical treatment, pharmaceuticals and medical equipment, shall be reviewed by relevant authorities in accordance with applicable rules before being published.

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Measures for the Administration of Internet Advertisement

The Measures for the Administration of Internet Advertisement (《互聯網廣告管理辦法》), which was promulgated by the SAMR on February 25, 2023 and came into effect on May 1, 2023, provides that Internet advertisement shall be identifiable and clearly identified as an “advertisement” so that consumers will identify it 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.

Administrative Measures on Medical Advertisement

The Administrative Measures on Medical Advertisement (《醫療廣告管理辦法》), jointly promulgated by the State Administration for Industry and Commerce and the MOH on September 27, 1993, came into effect on December 1, 1993, amended on November 10, 2006 and came into effect on January 1, 2007, requires that medical advertisements shall be reviewed by relevant health administrative department 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 expiration.

Circular on Further Strengthening the Management of Medical Advertisements

The Circular on Further Strengthening the Management of Medical Advertisements (《關於進一步加強醫療廣告管理的通知》), promulgated by the MOH on July 17, 2008, stipulates that the Medical Advertisement Examination Certificate should be strictly examined, that a monitoring system for medical advertisements should be gradually established and perfected, and that penalties for unlawful medical advertisements should be increased.

LAWS AND REGULATIONS ON ENVIRONMENTAL PROTECTION AND FIRE PREVENTION

Environmental Protection

According to the Environmental Protection Law of the PRC (《中華人民共和國環境保護法》) or the Environmental Protection Law, which was last amended by the SCNPC on April 24, 2014 and came into effect on January 1, 2015, any entity that discharges or will discharge pollutants in the course of operation or other activities must implement effective environmental protection measures to control and properly handle hazardous substances such as waste gas, waste water, waste residues, dust, malodorous gases, radioactive substances, noise, vibration and electromagnetic radiation generated in the course of such activities. The state implements a pollutant discharge permit management system in accordance with the law.

According to the Environmental Impact Assessment Law of the PRC (《中華人民共和國環境影響評價法》), which was last amended by the SCNPC on December 29, 2018 and came into effect on the same day, the Regulation on the Administration of Environmental Protection of Construction Projects (《建設項目環境保護管理條例》), which was amended by the State Council on July 16, 2017 and came into effect on October 1, 2017, and the Interim Measures for Environmental Protection Acceptance Inspection Upon Completion of Construction Projects (《建設項目竣工環境保護驗收暫行辦法》), which was promulgated by the former Ministry of Environmental Protection on November 20, 2017 and came into effect on the same day, the PRC implements a system to assess the environmental impact of construction projects. The construction entity shall submit an environmental impact report or an environmental impact statement for approval prior to the commencement of the construction project, or an environmental impact registration form as required by the environmental protection competent administrative department of the State Council for record. In addition, after the completion of a construction project for which an environmental impact report or an environmental impact statement has been prepared, the construction entity shall, in

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accordance with the standards and procedures prescribed by the competent administrative department of environmental protection under the State Council, conduct acceptance inspection on the supporting environmental protection facilities and prepare an acceptance report. For construction projects that are constructed in phases or put into production or used in phases, the corresponding environmental protection facilities shall be inspected and accepted in phases. The construction projects can only be put into production or use after the completed supporting environmental protection facilities have passed the acceptance inspection. Facilities that have not been carried out or have not passed the acceptance inspection shall not be put into production or use.

According to the Law of the PRC on Prevention and Control of Environmental Pollution Caused by Solid Wastes (《中華人民共和國固體廢物污染環境防治法》) (the “Law of Solid Wastes”), which was last amended on April 29, 2020 by the SCNPC and came into effect on September 1, 2020, any entity or individual that generates, collects, stores, transports, utilizes or disposes of solid waste shall take measures to prevent or reduce the pollution of solid waste to the environment, and shall be responsible for the environmental pollution caused in accordance with the law. Where hazardous waste exists in solid waste, it shall be managed in accordance with hazardous waste management.

According to the Law of the PRC on the Prevention and Control of Water Pollution (《中華人民共和國水污染防治法》), which was last amended on June 27, 2017 by the SCNPC and came into effective on January 1, 2018, the enterprises, institutions and other production and operation units directly or indirectly discharging industrial waste water and medical sewage to water bodies, and the enterprises, institutions and other production and operation units required to obtain pollutant discharging permit before discharging waste water and sewage must obtain the pollutant discharging permit. Furthermore, environmental impact assessment must be carried out in accordance with the law for newly-formed projects and reconstruction, or extensions projects that directly or indirectly discharge pollutants to water bodies and other installations on water. Water pollution prevention and control facilities should be designed, constructed and put into use at the same time as the main construction of the projects.

According to the Law of the PRC on the Prevention and Control of Atmospheric Pollution (《中華人民共和國大氣污染防治法》), which was last amended by the SCNPC on October 26, 2018 and took effect on the same day, enterprises, institutions and other production and operation units shall, in accordance with the relevant national regulations and monitoring standards, monitor their emissions of industrial waste gases or toxic and hazardous air pollutants listed in the catalogue published according to Article 78 of the Law of the PRC on the Prevention and Control of Atmospheric Pollution, and keep the original monitoring records. Enterprises and institutions that emit industrial waste gas or toxic and hazardous air pollutants listed in the above-mentioned catalogue, as well as other units that implement administration of pollution discharge permits in accordance with the law, shall obtain a pollutant discharging permit. In addition, enterprises, institutions and other production and operation units constructing projects that have an impact on the atmospheric environment shall carry out environmental impact assessment and make environmental impact assessment documents public in accordance with the law; the units that emit pollutants into the atmosphere must comply with the discharging standard for atmospheric pollutants as well as the requirements on control of the total discharging amount of key atmospheric pollutants.

According to the Regulations on the Administration of Pollution Discharge Permits (《排污許可管理條例》), which was promulgated by the State Council on January 24, 2021 and took effect on March 1, 2021, enterprises, institutions and other production and operation units subject to administration of pollution discharge permits shall discharge pollutants in accordance with the Regulations on the Administration of Pollution Discharge Permits, and shall not discharge pollutants without obtaining a pollutant discharging permit. Environmental protection authorities impose various administrative penalties, such as fines, order to correct, restriction or suspension of production for rectification, and order to cease operation, among others, on individuals or enterprises that violate the Environmental Protection Law.

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Pursuant to the List of Pollutant Discharge Permits for Classified Management of Stationary Pollution Sources (2019 Version) (《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 December 20, 2019 and came into effect 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 National Pollutant Discharge Permit Management Information Platform, and register with its basic information, pollutant discharge route, pollutant discharge standards implemented, pollution prevention and control measures adopted, and other information.

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 October 2, 2013 and came into effect on January 1, 2014, requires that urban entities and individuals shall dispose sewage through urban drainage facilities covering their geographical area in accordance with applicable rules. Companies or other entities engaging in medical activities shall apply for a License for Discharging Sewage into the Drainage Network (《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 applicable rules.

Fire Safety

According to the Fire Protection Law of the PRC (《中華人民共和國消防法》), which was last amended by the SCNPC on April 29, 2021 and took effect on the same day, the emergency management department under the State Council and the emergency management department under the local people's governments at or above the county level shall supervise and manage fire protection work. Fire control design and construction of a construction project must comply with national technical standards for fire protection in construction projects.

According to the Interim Provisions on the Administration of Fire Protection Design Review and Acceptance of Construction Projects (《建設工程消防設計審查驗收管理暫行規定》) which was last amended by the Ministry of Housing and Urban-Rural Development of PRC on August 21, 2023 and officially came into effect on October 30, 2023, fire prevention design review and acceptance should be carried out for special construction projects. With respect to the construction projects other than special construction projects, the fire protection acceptance of construction projects shall be filed with the competent authorities.

Medical Waste

The Regulations on the Management of Medical Waste (《醫療廢物管理條例》), promulgated by the State Council on June 16, 2003 and came into effect on the same day and further amended and came into effect on January 8, 2011, and the 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 October 15, 2003 and came into effect on the same day, stipulate that medical institutions must categorize 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. The sewage generated by medical institutions and the excretion of the infectious patients or suspect infectious patients shall be strictly disinfected pursuant to the provisions of the state; and only after those wastes have met the discharge standards set forth by the state, may they be discharged into the sewage disposal system.

Radioactive Pollution and Radioactive Waste

Pursuant to the Law of the People's Republic of China on Prevention and Control of Radioactive Pollution (《中華人民共和國放射性污染防治法》) promulgated by the SCNPC on June 28, 2003 and came into effect on October 1, 2003, stipulates that, an entity generating radioactive waste liquid must, in accordance with the requirements of the national standards on the prevention and control of radioactive pollution, dispose or store the radioactive waste liquid which shall not be discharged to the environment.

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An entity generating radioactive solid wastes shall, in accordance with the provisions of the competent administrative department of environmental protection under the State Council, deliver the radioactive solid wastes it generates to the entity disposing the radioactive solid wastes for disposition after having them treated, and shall assume the disposition expense.

In accordance with the Regulations on Safety of Radioactive Waste Management (《放射性廢物安全管理條例》) which were promulgated by the State Council on December 20, 2011 and came into effect on March 1, 2012, China adopts the classified management of radioactive waste. According to the characteristics and the potential hazardous exposure of the human health and environment, radioactive wastes are divided into high-level radioactive waste, medium-level radioactive waste and low-level radioactive waste. Entities utilizing nuclear technology shall conduct relevant treatment procedures of the liquid radioactive waste (which is generated but cannot be discharged after purifications), and then transformed to solid radioactive waste. Entities utilizing nuclear technology shall deliver disused radioactive sources and other solid radioactive wastes generated by them to a solid radioactive waste storage entity possessing the applicable licenses for centralized storage, or to a solid radioactive waste disposing entity possessing the applicable licenses for disposal.

REGULATIONS RELATING TO LAND AND CONSTRUCTION PROJECTS

Land Grants

Under the Interim Regulations on Assignment and Transfer of the Rights to the Use of the State-Owned Urban Land of the PRC (《中華人民共和國城鎮國有土地使用權出讓和轉讓暫行條例》) promulgated by the State Council on May 19, 1990, last amended on November 29, 2020, and effective on the same date, China adopts a system of assignment and transfer of the right to use state-owned land. The assignment of land use rights may be carried out by agreement, bidding, or auction. The land user shall pay the premium of the land use right to the state, and the state may assign such right to the user for an agreed term. The land user who has obtained the land use right may, within the term of land use, transfer, lease, or mortgage the land use right or use it for other economic activities.

Planning of a Construction Project

Pursuant to the regulations abovementioned and the PRC Urban Real Estate Administration Law (《中華人民共和國城市房地產管理法》) promulgated by the SCNPC on July 5, 1994, last amended on August 26, 2019, and effective on January 1, 2020, an assignment contract shall be signed between the corresponding land administration authority and land users for the assignment of land use rights. The land user is required to pay the land premium as provided in the assignment contract. After the full payment of the land premium, the land user must register with the land administration authority and obtain a land use rights certificate to acquire the land use rights. The land user shall develop, utilize, and operate the land in accordance with the provisions of the assignment contract and the requirements of urban planning.

Pursuant to the Law on Urban and Rural Planning Law of the PRC (《中華人民共和國城鄉規劃法》) promulgated by the SCNPC on October 28, 2007 and last amended on April 23, 2019 and implemented on the same date, a construction project planning permit must be obtained by a construction unit from the relevant competent urban and rural planning authority for the construction of any building, structure, road, pipeline, or other construction project within the planning zone of a city or town.

Pursuant to the Administrative Measures on Construction Permit of Construction Projects (《建築工程施工許可管理辦法》) promulgated by the Ministry of Construction on October 15, 1999, last amended on March 30, 2021, and effective on the same date, within the territory of China, for the construction, renovation, and decoration of all kinds of buildings and the auxiliary facilities thereof, the installation of supporting lines, pipes and equipment, and the construction of municipal infrastructure projects in cities and towns, the construction unit shall, before starting construction, apply to the housing and urban-rural development administrative department of the people’s government at or above the county level where the

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project is located for a construction permit in accordance with the Administrative Measures on Construction Permit of Construction Projects. For a construction project with an investment amount less than RMB300,000 or with a floor area less than 300 square meters, the construction unit is not required to apply for a construction permit.

According to the Provisions on Inspection and Acceptance upon Completion of Buildings and Municipal Infrastructure (《房屋建築和市政基礎設施工程竣工驗收規定》) promulgated by the Ministry of Housing and Urban-Rural Development on December 2, 2013, and effective on the same date, construction units of all types of buildings and municipal infrastructure projects that are newly built, expanded or rebuilt within the territory of China shall file with the competent construction authority of the local people’s government at or above the county level where the project is located within 15 days from the date when the project is completed and passes the acceptance inspection.

REGULATIONS ON LEASING

According to the PRC Civil Code (《中華人民共和國民法典》), an owner of immovable or movable property is entitled to possession, use, earnings, and disposal of such property in accordance with the law. Subject to the consent of the lessor, the lessee may sublease the leased premises to a third party. Where a lessee subleases the premises, the lease contract between the lessee and the lessor remains valid. The lessor is entitled to terminate the lease if the lessee subleases the premises without the consent of the lessor. In addition, if the ownership of the leased premises changes during the lessee’s possession in accordance with the terms of the lease contract, the validity of the lease contract shall not be affected. Moreover, pursuant to the PRC Civil Code, if the mortgaged property has been leased and transferred for occupation prior to the establishment of the mortgage right, the original tenancy shall not be affected by such mortgage right.

On December 1, 2010, the Ministry of Housing and Urban-Rural Development promulgated the Administrative Measures on Leasing of Commodity Housing (《商品房屋租賃管理辦法》), which became effective on February 1, 2011. According to such measures, the lessor and the lessee are required to complete property leasing registration and filing formalities within 30 days from execution of the property lease contract with the development authorities or real estate authorities of the municipality or county where the leased property is located. If a company fails to do as aforesaid, it may be ordered to rectify within a stipulated period, and if such company fails to rectify, a fine ranging from RMB1,000 to RMB10,000 may be imposed on each lease agreement.

REGULATIONS ON INTELLECTUAL PROPERTY

Trademark

According to the Trademark Law of the PRC (《中華人民共和國商標法》) promulgated by SCNPC on August 23, 1982, most recently amended on April 23, 2019 and effective from November 1, 2019, and the Implementation Regulation of the Trademark Law of the PRC (《中華人民共和國商標法實施條例》) promulgated by the State Council on August 3, 2002, later amended on April 29, 2014 and effective from May 1, 2014, registered trademarks are granted a term of ten years which may be renewed for consecutive ten-year periods upon request by the trademark owner. Trademark license agreements must be filed with the Trademark Office for record, and the Trademark Law of the PRC has adopted a “first apply first register” principle with respect to trademark registration. Conducts that shall constitute an infringement of the exclusive right to use a registered trademark include but not limited to using a trademark that is identical with or similar to a registered trademark on the same or similar goods without the permission of the trademark registrant, and the infringing party will be ordered to stop the infringement act immediately and may be imposed a fine. The infringing party may also be held liable for the right holder’s damages, which will be equal to gains obtained by the infringing party or the losses suffered by the right holder as a result of the infringement. Where it is difficult to determine the losses of the right holder or the gains derived by the infringer, the compensation amount shall be determined reasonably with reference to the multiples of the licensing fee of the said trademark. For malicious infringement of exclusive rights to use

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trademarks, in serious cases, the compensation amount shall be determined in accordance with the aforesaid method based on one to five times of the determined amount. The compensation amount shall include reasonable expenses incurred by the right holder to curb the infringement.

Copyright

According to the Copyright Law of the PRC (《中華人民共和國著作權法》) promulgated by the SCNPC, which was latest amended in November 2020, and its related implementing regulations, Chinese citizens, legal persons, or other organizations shall, whether published or not, own copyright in their works, which include, among others, works of literature, art, natural science, social science, engineering technology and computer software. Copyright owners of protected works enjoy personal rights and property rights with respect to publication, authorship, alteration, integrity, reproduction, distribution, lease, exhibition, performance, projection, broadcasting, dissemination via information network, production, adaptation, translation, compilation, and other rights shall be enjoyed by the copyright owners.

Pursuant to the Regulation on Computers Software Protection (《計算機軟件保護條例》) promulgated by the State Council on June 4, 1991 and latest amended on January 30, 2013, and the Measures for the Registration of Computer Software Copyright (《計算機軟件著作權登記辦法》) promulgated on February 20, 2002 and latest amended on June 18, 2004, the National Copyright Administration (《國家版權局》) is mainly responsible for the registration and management of software copyright in China and recognizes the China Copyright Protection Center (《中國版權保護中心》) as the software registration organization. The China Copyright Protection Center shall grant certificates of registration to computer software copyright applicants in compliance with the regulations.

Patent

In accordance with the Patent Law of the PRC (《中華人民共和國專利法》), promulgated by the SCNPC, which was latest amended in October 2020 and became effective on June 1, 2021, and its Implementation Rule, patent is divided in to 3 categories, i.e., invention patent, design patent and utility model patent. The duration of invention patent right, design patent right and utility model patent right shall be 20 years, 15 years and 10 years, respectively, which all calculated from the date of application. Implementation of a patent without the authorization of the patent holder shall constitute an infringement of patent rights, and shall be held liable for compensation to the patent holder and may be imposed a fine, or even subject to criminal liabilities.

Domain Names

The Measures on Administration of Internet Domain Names (《互聯網域名管理辦法》) was promulgated by the MIIT in 2017, which adopts “first apply first register” rule to allocate domain names to applicants, and provide that the MIIT shall supervise the domain names services nationwide and publicize the PRC domain name system. After completion of the registration procedures, the applicant will become the holder of the relevant domain name.

REGULATIONS ON EMPLOYMENT AND SOCIAL WELFARE

Employment

The major PRC laws and regulations that govern employment relationship are the PRC Labor Law (《中華人民共和國勞動法》), the PRC Labor Contract Law (《中華人民共和國勞動合同法》) (the “**Labor Contract Law**”) and its implementation, which impose stringent requirements on the employers in relation to entering into fixed-term employment contracts, hiring of temporary employees and dismissal of employees.

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The Labor Contract Law, which was promulgated by the SCNPC on June 29, 2007, became effective on January 1, 2008 and was latest amended on December 28, 2012, primarily aims at regulating rights and obligations of employment relationships, including the establishment, performance, and termination of labor contracts. Pursuant to the Labor Contract Law, labor contracts must be executed in writing if labor relationships are to be or have been established between employers and employees. Employers are prohibited from forcing employees to work above certain time limits and employers must pay employees for overtime work in accordance with national regulations. In addition, employee wages must not be lower than local standards on minimum wages and must be paid to employees in a timely manner.

The Labor Contract Law imposes stringent requirements on the use of employees of temp agencies, who are known in China as “dispatched workers.” Dispatched workers are entitled to equal pay with full-time employees for equal work. Employers are only allowed to use dispatched workers for temporary, auxiliary or substitutive positions. According to the Interim Provisions on Labor Dispatch (《勞務派遣暫行規定》) which was promulgated by the Ministry of Human Resources and Social Security on January 24, 2014 and came into effect on March 1, 2014, the number of dispatched workers hired by an employer may not exceed 10% of the total number of its employees. Where rectification is not made within the stipulated period, the employers may be subject to a penalty ranging from RMB5,000 to RMB10,000 per dispatched worker exceeding the 10% threshold.

Social Insurance

The PRC Social Insurance Law (《中華人民共和國社會保險法》) (the “**Social Insurance Law**”) issued by the SCNPC in 2010 and latest amended on December 29, 2018, has established social insurance systems of basic pension insurance, basic medical insurance, work-related injury insurance, unemployment insurance and maternity insurance and has elaborated in detail the legal obligations and liabilities of employers who fail to comply with relevant laws and regulations on social insurance. According to the Social Insurance Law and the Provisional Regulations on Collection and Payment of Social Insurance Premiums (《社會保險費徵繳暫行條例》) promulgated by the State Council on January 22, 1999 and most recently amended on March 24, 2019 and effective from the same date, enterprises shall register social insurance with local social insurance and pay or withhold relevant social insurance for or on behalf of its employees. Any employer that fails to make social insurance contributions may be ordered to rectify the non-compliance, pay the required contributions within a prescribed time limit and be subject to a late payment fee computed from the due date at the rate of 0.05% per day. If the employer still fails to make the relevant contributions within the prescribed time, it may be subject to a fine ranging from one to three times the amount overdue.

Housing Provident Fund

In accordance with the Regulations on the Administration of Housing Provident Funds (《住房公積金管理條例》) promulgated by the State Council on April 3, 1999, and amended on March 24, 2002 and March 24, 2019, enterprises must register with the housing provident fund management centers and open bank accounts for depositing employees’ housing provident funds. Employers are also required to pay and deposit housing provident funds, with an amount no less than 5% of the monthly average salary of the employee in the preceding year in full and on time. In case of overdue payment or underpayment by employers, orders for payment within a specified period will be made by the housing provident fund management center. Where employers fail to make payment within such period, enforcement by the people’s court will be applied.

In case of failure to register and open accounts for depositing employees’ housing provident funds, the housing provident fund management center shall order employers to go through the formalities within a specified period, where employers fail to do such formalities within the prescribed time, a fine of not less than RMB10,000 nor more than RMB50,000 shall be imposed.

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REGULATIONS ON FOREIGN EXCHANGE

Regulations relating to Foreign Currency 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》), most recently amended in August 2008. Under the PRC foreign exchange regulations, payments of current account items, such as profit distributions, interest payments and trade and service-related foreign exchange transactions, can be made in foreign currencies without prior approval from SAFE, by complying with certain procedural requirements. By contrast, approval from or registration with appropriate government authorities is required where Renminbi is to be converted into foreign currency and remitted out of China to pay capital account items, such as direct investments, repayment of foreign currency-denominated loans, repatriation of investments and investments in securities outside of China.

The SAFE issued the Circular on Reforming the Management Method of the Settlement of Foreign Currency 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 “**SAFE Circular 19**”) on March 30, 2015, which became effective on June 1, 2015, was partially repealed on December 30, 2019 and was latest amended on March 23, 2023. The SAFE Circular 19 expands a pilot reform of the administration of the settlement of the foreign exchange capitals of foreign-invested enterprises nationwide. The system of willingness-based foreign exchange settlement is adopted for the foreign exchange capital of foreign-invested enterprises. In June 2016, SAFE further promulgated the Notice of the State Administration of Foreign Exchange on Reforming and Standardizing the Foreign Exchange Settlement Management Policy of Capital Account (《國家外匯管理局關於改革和規範資本項目結匯管理政策的通知》) (the “**SAFE Circular 16**”), which was amended on December 4, 2023, among other things, amends certain provisions of SAFE Circular 19. Pursuant to SAFE Circular 19 and SAFE Circular 16, the flow and use of the Renminbi capital converted from foreign currency denominated registered capital of a foreign-invested company is regulated such that Renminbi capital may not be used for business beyond its business scope or to provide loans to persons other than affiliates unless otherwise permitted under its business scope.

In October 2019, SAFE issued the Circular of Further Facilitating Cross-border Trade and Investment (《國家外匯管理局關於進一步促進跨境貿易投資便利化的通知》), which was amended on December 4, 2023, or SAFE Circular 28. SAFE Circular 28 cancels the restrictions on domestic equity investments by capital fund of non-investment foreign invested enterprises and allows non-investment foreign invested enterprises to use their capital funds to lawfully make equity investments in China, provided that such investments do not violate the Negative List and the target investment projects are genuine and in compliance with laws. According to the Circular on Optimizing Administration of Foreign Exchange to Support the Development of Foreign-related Business (《國家外匯管理局關於優化外匯管理支持涉外業務發展的通知》), or SAFE Circular 8, issued by SAFE in April 2020, under the prerequisite of ensuring true and compliant use of funds and compliance with the prevailing administrative provisions on use of income under the capital account, eligible enterprises are allowed to make domestic payments by using their capital funds, foreign credits and the income under capital accounts of overseas listing, without prior provision of the evidentiary materials concerning authenticity to the bank for each transaction. The handling banks shall conduct spot checks afterwards in accordance with the relevant requirements.

According to the Notice on Matters Concerning the Administration of Funds Raised by Domestic Enterprises from Overseas Listings (《關於境內企業境外上市資金管理有關問題的通知》) promulgated by the PBOC and the SAFE on December 26, 2025, and became effective on April 1, 2026, funds raised by domestic enterprises from overseas listings shall, in principle, be repatriated to the PRC in a timely manner. Where such funds are retained outside the PRC for the purpose of conducting overseas direct investment, overseas securities investment, overseas lending, or other similar business activities, the enterprise shall obtain approval or filing documentation from the competent business authority prior to the completion of the overseas listing issuance or the full exercise of the over-allotment option, and shall comply with the relevant cross-border fund administration regulations.

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REGULATIONS ON TAXATION

Enterprise Income Tax

According to the Enterprise Income Tax Law of the PRC (《中華人民共和國企業所得稅法》), which was promulgated by the SCNPC and was latest amended on December 29, 2018, and the Regulation on the Implementation of 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》), which was promulgated by the State Council and was latest amended in December 2024, collectively referred to as the EIT Law, a uniform 25% enterprise income tax rate is imposed to both foreign invested enterprises and domestic enterprises, except where tax incentives are granted to special industries and projects. The enterprise income tax rate is reduced to 20% for qualifying small low-profit enterprises. The high-tech enterprises that need full support from the PRC’s government will enjoy a reduced tax rate of 15% for Enterprise Income Tax.

Value-added Tax

On 25 December 2024, the SCNPC issued the Value-added Tax Law of the PRC (《中華人民共和國增值稅法》), or the VAT Law, which became effective from 1 January 2026. According to the VAT Law, any entities and individuals (including individual businesses) engaged in the sale of goods, services, intangible assets and immovables and importation of goods within the territory of the PRC are VAT payers and shall pay VAT in accordance with the VAT Law. Except for taxpayers’ export of goods, the sale of services or intangible assets within the scope as prescribed by the State Council by domestic entities and individuals across national borders and other circumstances specified for by the State Council, the rate of VAT for sale of goods, labor services of processing, repair or replacement, or tangible movable property leasing services or import of goods is 13% unless otherwise specified, such as the rate of VAT for sale of agricultural products is 9%, and the rate of VAT for sale of transportation, postal, basic telecommunications, construction, or immovable leasing services, sale of immovables, or transfer of the rights to use land is 9%. In addition to the above circumstances, the rate of VAT for sale of services or intangible assets is 6%.

According to the Notice of the Ministry of Finance and the State Taxation Administration on the Adjusting Value-added Tax Rates (《財政部、稅務總局關於調整增值稅稅率的通知》) effective in May 2018, the value-added tax rates of 17% and 11% on sales, imported goods shall be adjusted to 16% and 10%, respectively.

According to the Announcement of the Ministry of Finance, the State Taxation Administration and the General Administration of Customs on Relevant Policies for Deepening the Value-Added Tax Reform (《財政部、稅務總局、海關總署關於深化增值稅改革有關政策的公告》) promulgated on March 20, 2019 and effective from April 1, 2019, the value-added tax rates of 16% and 10% on sales, imported goods shall be adjusted to 13% and 9%, respectively.

Dividends Distribution

The principal laws, rules and regulations governing dividend distributions by foreign-invested enterprises in the PRC are the Company Law and the Foreign Investment Law and its Implementing Regulations. Under these requirements, foreign-invested enterprises may pay dividends only out of their accumulated profit, if any, as determined in accordance with PRC accounting standards and regulations. A PRC company is required to allocate at least 10% of their respective accumulated after-tax profits each year, if any, to fund certain capital reserve funds until the aggregate amount of these reserve funds have reached 50% of the registered capital of the enterprises. A PRC company is not permitted to distribute any profits until any losses from prior fiscal years have been offset. Profits retained from prior fiscal years may be distributed together with distributable profits from the current fiscal year.

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According to the Civil Code of the PRC (《中華人民共和國民法典》), which was promulgated by the National People’s Congress on May 28, 2020 and became effective on January 1, 2021, the limitation period for an action to recover a debt (including the recovery of declared dividends) is three years. The company must not exercise its powers to forfeit any unclaimed dividend in respect of shares until after the expiry of the applicable limitation period.

Pursuant to the Individual Income Tax Law of the PRC (《中華人民共和國個人所得稅法》), which was most recently amended on August 31, 2018, and the Implementation Provisions of the Individual Income Tax Law of the PRC (《中華人民共和國個人所得稅法實施條例》), which was most recently amended on December 18, 2018, dividends distributed by PRC enterprises are subject to individual income tax levied at a rate of 20%. For a foreign individual who is not a resident of the PRC, the receipt of dividends from an enterprise in the PRC is normally subject to individual income tax of 20% unless specifically exempted by the tax authority of the State Council or reduced by relevant tax treaty.

The EIT Law provides that since January 1, 2008, an enterprise income tax rate of 10% will normally be applicable to dividends declared to non-PRC resident 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 the establishment or place of business, to the extent such dividends are derived from sources within the PRC, unless any such non-PRC resident investors’ jurisdiction of incorporation has a tax treaty with China that provides for a preferential withholding arrangement.

Non-resident investors residing in jurisdictions which have entered into treaties or adjustments for the avoidance of double taxation with the PRC might be entitled to a reduction of the Chinese enterprise income tax imposed on the dividends received from PRC companies. The PRC currently has entered into avoidance of double taxation treaties or arrangements with Hong Kong, Macau, and a number of countries and regions including Australia, Canada, France, Germany, Japan, Malaysia, the Netherlands, Singapore, the United Kingdom and the United States. Non-PRC resident enterprises entitled to preferential tax rates in accordance with the relevant taxation treaties or arrangements are required to apply to the Chinese tax authorities for a refund of the enterprise income tax in excess of the agreed tax rate, and the refund application is subject to approval by the Chinese tax authorities.

REGULATIONS ON SECURITIES AND OVERSEAS LISTINGS

Securities Laws and Regulations

The Securities Law of the PRC (《中華人民共和國證券法》) (the “**Securities Law**”), which was promulgated by the SCNPC on December 29, 1998, and was latest amended on December 28, 2019 and took effect on March 1, 2020, comprehensively regulates activities in the PRC securities market including issuance and trading of securities, takeovers by listed companies, securities exchanges, securities companies and the duties and responsibilities of securities regulatory authorities, among others. The Securities Law further regulates that a domestic enterprise issuing securities overseas directly or indirectly or listing their securities overseas shall comply with the relevant provisions of the State Council and for subscription and trading of shares of domestic companies using foreign currencies, detailed measures shall be stipulated by the State Council separately. China Securities Regulatory Commission (中國證券監督管理委員會) (the “**CSRC**”) is the securities regulatory body set up by the State Council to supervise and administer the securities market according to law, maintain order in the market, and ensure the market operates in a lawful manner. Currently, the issue and trading of H shares are principally governed by the regulations and rules promulgated by the State Council and the CSRC.

Overseas Listings

On February 17, 2023, the CSRC released several regulations regarding the management of filings for overseas offerings and listings by domestic companies, including the Trial Measures for the Administration on Overseas Securities Offering and Listing by Domestic Companies (《境內企業境外發行證券和上市管理試行辦法》) (the “**Overseas Listing Trial Measures**”) together with five supporting

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guidelines (together with the Overseas Listing Trial Measures, collectively referred to as the “Overseas Listing Regulations”). Under the Overseas Listing Regulations, PRC domestic companies that seek to offer and list securities in overseas markets, either in direct or indirect means, are required to file the required documents with the CSRC within three working days after its application for overseas listing is submitted.

The Overseas Listing Regulations provides that no overseas offering and listing shall be made under any of the following circumstances: (1) such securities offering and listing is explicitly prohibited by provisions in laws, administrative regulations and relevant state rules; (2) the intended securities offering and listing may endanger national security as reviewed and determined by competent authorities under the State Council in accordance with law; (3) the domestic company intending to make the securities offering and listing, or its controlling shareholders and the actual controller, have committed crimes such as corruption, bribery, embezzlement, misappropriation of property or undermining the order of the socialist market economy during the latest three years; (4) the domestic company intending to make the securities offering and listing is suspected of committing crimes or major violations of laws and regulations, and is under investigation according to law and no conclusion has yet been made thereof; or (5) there are material ownership disputes over equity held by the domestic company’s controlling shareholder or by other shareholders that are controlled by the controlling shareholder and/or actual controller. Additionally, the Overseas Listing Regulations stipulates that after an issuer has offering and listing securities in an overseas market, the issuer shall submit a report to the CSRC within three working days after the occurrence and public disclosure of (1) a change of control thereof, (2) investigations of or sanctions imposed on the issuer by overseas securities regulators or relevant competent authorities, (3) changes of listing status or transfers of listing segment, and (4) a voluntary or mandatory delisting. Overseas offering and listing by domestic companies shall be made in strict compliance with relevant laws, administrative regulations and rules concerning national security in spheres of foreign investment, cybersecurity and data security, among others, and duly fulfill their obligations to protect national security.

On February 24, 2023, the CSRC and three other relevant government authorities jointly promulgated the Provisions on Strengthening the Confidentiality and Archives Administration Related to the Overseas Securities Offering and Listing by Domestic Enterprises (《關於加強境內企業境外發行證券和上市相關保密和檔案管理工作的規定》), or the Provision on Confidentiality. Pursuant to the Provision on Confidentiality, where a domestic enterprise provides or publicly discloses any document or material that involving state secrets and working secrets of state agencies to the relevant securities companies, securities service institutions, overseas regulatory authorities and other entities and individuals, it shall report to the competent department with the examination and approval authority for approval in accordance with the law, and submit to the secrecy administration department of the same level for filing. The working papers formed within the territory of the PRC by the securities companies and securities service agencies that provide corresponding services for the overseas issuance and listing of domestic enterprises shall be kept within the territory of the PRC, and cross-border transfer shall go through the examination and approval formalities in accordance with the relevant provisions of the state.

OVERVIEW OF LAWS AND REGULATIONS IN SINGAPORE

Personal Data Protection Act 2012 of Singapore (“PDPA”)

The PDPA governs the collection, use and disclosure of the personal data of individuals (being data, whether true or not, about an individual, who can be identified from that data or other accessible information), and is administered and enforced by the regulator, the Personal Data Protection Commission (“PDPC”). The PDPA sets out data protection obligations which all organisations are required to comply with in undertaking activities relating to the collection, use or disclosure of personal data and to provide individuals with the right to access and correct their own personal data.

Organisations have mandatory obligations to assess data breaches they suffer, and to notify the PDPC and where applicable, the relevant individuals where the data breach is (or is likely to be) of a significant scale or resulting in (or is likely to result in) significant harm to individuals. Other obligations include accountability, protection, retention, and requirements around the overseas transfers of personal data.

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Organisations are required to, among other things, (i) obtain consent from individuals and inform them of the applicable purposes before collecting, using or disclosing their personal data; and (ii) put in place reasonable measures to (a) protect the personal data in their possession or control from unauthorised access, loss or damage, and (b) prevent the loss of any storage medium or device on which personal data is stored. In the event of a data breach involving any personal data in an organisation’s possession or control, the PDPA requires the organisation to reasonably and expeditiously assess whether the data breach is notifiable and notify the PDPC and, unless exceptions apply, the affected individuals of the data breach, if the data breach is assessed to be one that (a) is likely to result in significant harm or impact to the individuals to whom the information relates, or (b) is, or is likely to be, of a significant scale.

In addition, the PDPA also established a Do-Not-Call Registry (“**DNC Registry**”) which allows individuals to register their Singapore telephone numbers in any of the three (3) Do-Not-Call Registers (“**DNC Register**”) to opt out of receiving specified messages via voice call, specified text messages and specified fax messages. Under the PDPA, before an organisation sends a specified message to a Singapore telephone number, it must check with the DNC Registry to confirm that the number is not listed on the DNC Register, unless the organisation has obtained clear and unambiguous consent in evidential form from the user or subscriber of the number. Non-compliance with the PDPA may attract financial penalties or even criminal liability. The PDPC has broad powers to give any such directions as it thinks fit to ensure compliance, which include requiring an organisation to pay a financial penalty. In this connection, in the case of contravention of the parts of the PDPA which sets out the obligations of organisations relating to data protection (including the obligation to protect and care for personal data, and to conduct assessments of data breaches), the maximum financial penalty that may be imposed: (a) on an organisation whose annual turnover in Singapore exceeds S\$10 million, is 10% of the organisation’s annual turnover in Singapore, if the contravention occurs on or after 1 October 2022; and (b) in any other case is S\$1 million.

Workplace Safety and Health Act 2006 of Singapore (“WSHA”)

The WSHA is administered by the Ministry of Manpower (“**MOM**”). Under the WSHA, every employer has the duty to take, so far as is reasonably practicable, such measures as are necessary to ensure the safety and health of their employees at work. These measures include providing and maintaining for the employees a work environment which is safe, without risk to health, and adequate as regards facilities and arrangements for their welfare at work, ensuring that adequate safety measures are taken in respect of any machinery, equipment, plant, article or process used by the employees, ensuring that the employees are not exposed to hazards arising out of the arrangement, disposal, manipulation, organisation, processing, storage, transport, working or use of things in their workplace or near their workplace and under the control of the employer, developing and implementing procedures for dealing with emergencies that may arise while those persons are at work and ensuring that the person at work has adequate instruction, information, training and supervision as is necessary for that person to perform his work.

Under the WSHA, inspectors appointed by the Commissioner for Workplace Safety and Health (“**CWSH**”) may, among others, enter, inspect and examine any workplace, to inspect and examine any machinery, equipment, plant, installation or article at any workplace, to make such examination and inquiry as may be necessary to ascertain whether the provisions of the WSHA are complied with, to take samples of any material or substance found in a workplace or being discharged from any workplace for the purpose of analysis or test, to assess the levels of noise, illumination, heat or harmful or hazardous substances in any workplace and the exposure levels of persons at work therein and to take into custody any article in the workplace which is relevant to an investigation or inquiry under the WSHA.

Under the WSHA, the CWSH may issue a stop-work order in respect of a workplace if he is satisfied that:

- (a) the workplace is in such condition, or is so located, or any part of the machinery, equipment, plant or article in the workplace is so used, that any process or work carried on in the workplace cannot be carried on with due regard to the safety, health and welfare of persons at work;
- (b) any person has contravened any duty imposed by the WSHA; or

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- (c) any person has done any act, or has refrained from doing any act which, in the opinion of the CWSH, poses or is likely to pose a risk to the safety, health and welfare of persons at work.

The stop-work order shall, amongst others, direct the person served with the order to immediately cease to carry on any work or process indefinitely or until such measures as are required by the CWSH have been taken, to the satisfaction of the CWSH, to remedy any danger so as to enable the work or process in the workplace to be carried on with due regard to the safety, health and welfare of the persons at work.

Work Injury Compensation Act 2019 of Singapore (“WICA”)

Work injury compensation is governed by the WICA. The WICA applies to employees in respect of injuries suffered by them arising out of and in the course of their employment and sets out, amongst others, the amount of compensation they are entitled to and the methods of calculating such compensation. The WICA provides, subject to certain prescribed exceptions, that if in any employment, personal injury by accident arising out of and in the course of the employment is caused to an employee, his employer shall be liable to pay compensation in accordance with the provisions of the WICA. The amount of compensation shall be computed in accordance with the First Schedule of the WICA, subject to a maximum and minimum limit, taking into account factors such as the severity and permanence of the personal injury suffered.

Further, Section 13 of the WICA provides that where any person (referred to as the principal) in the course of or for the purpose of his trade or business contracts with any other person (referred to as the contractor) for the execution by the contractor of the whole or any part of any work, or for the supply of labour to carry out any work, undertaken by the principal, the Commissioner may direct the principal to fulfil the obligations of the employer under the WICA in relation to any employee of the contractor employed in the execution of the work. Where such a direction has been made, the principal shall be liable to pay to any employee of the contractor employed in the execution of the work any compensation which he would have been liable to pay under the WICA if that employee had been immediately employed by the principal, except that the amount of compensation is to be calculated with reference to the earnings of the employee under the contractor.

Every employer is required to maintain work injury compensation insurance for all employees doing manual work (regardless of salary level) and all employees doing non-manual work, earning a salary of \$2,600 or less a month. Failure to do so is an offence carrying a fine of up to S\$10,000 and/or imprisonment of up to twelve (12) months. Under the Work Injury Compensation (Insurance) Regulations 2020 (“WICIR”), every employer entering into a contract of insurance in accordance with the requirements of WICA shall be issued, by the insurer with whom he contracts, with a certificate of insurance which shall contain certain prescribed particulars. The WICIR further provides that such employer shall display a copy of the certificate of insurance at each place of business at which he employs any employee whose claims may be the subject of indemnity under the policy of insurance to which that certificate relates.

Employment Act 1968 of Singapore (“EA”)

The EA is administered by the MOM and sets out the basic terms and conditions of employment and the rights and responsibilities of employers as well as employees. Section 20 of the EA provides that an employer may fix salary periods in respect of which the salary earned is payable. However, a salary period must not exceed one (1) month, and where the employer does not fix the salary period, the salary period is deemed to be one (1) month. Salary earned by an employee under a contract of service, other than additional payments for overtime work, must be paid before the expiry of the seventh (7th) day after the last day of the salary period in respect of which the salary is payable, whereas additional payments for overtime work must be paid not later than fourteen (14) days after the last day of the salary period during which the overtime work was performed.

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Subject to the provisions of the EA, the total salary and any sum due to an employee who has been dismissed must be paid on the day of dismissal or, if this is not possible, within three (3) days thereafter, not being a rest day or public holiday or other holiday. Further, subject to the provisions of the EA, (a) the total salary due to an employee who terminates his contract of service with his employer under Section 11 of the EA (i.e. termination of the contract of service without notice or, if notice has already been given, without waiting for the expiry of that notice, by paying to the other party a sum equal to the amount of salary at the gross rate of pay which would have accrued to the employee during the period of the notice and in the case of a monthly-rated employee where the period of the notice is less than a month, the amount payable for any one day is the gross rate of pay for one day’s work), or after giving due notice to the employer, must be paid to the employee on the day on which the contract of service is terminated, and (b) the total salary due to an employee who terminates his contract of service without giving prior notice to his employer, or, if notice has already been given under that section, but the employee terminates the contract of service without waiting for the expiry of the notice, must be paid to the employee before the expiry of the seventh (7th) day after the day on which the employee terminates the contract of service.

Part 4 of the EA sets out requirements for rest days, hours of work and other conditions of service for workmen who receive salaries not exceeding S\$4,500 a month and employees (other than workmen or persons employed in managerial or executive positions) who receive salaries not exceeding S\$2,600 a month. Section 38(8) of the EA provides that an employee is not allowed to work for more than twelve (12) hours in any one (1) day except in specified circumstances, including, amongst others, where there is an accident, actual or threatened, where work is essential to the life of the community, where work is essential for defence or security, where urgent work is to be done to machinery or plant, or where an interruption of work which was impossible to foresee. In addition, Section 38(5) of the EA limits the extent of overtime work that an employee can perform to seventy-two (72) hours a month. Employers must seek the prior approval of the Commissioner for exemption if they require an employee or class of employees to work for more than twelve (12) hours a day or more than seventy-two (72) overtime hours a month.

The Commissioner may, after considering the operational needs of the employer and the health and safety of the employee or class of employees, by order in writing, exempt such employees from the overtime limits subject to such conditions as the Commissioner thinks fit. Where such exemptions have been granted, the employer shall display the order or a copy thereof conspicuously in the place where such employees are employed.

Under Section 53 of the EA, an employer who breaches the provisions of Part 4 of the EA shall be guilty of an offence and shall be liable on conviction to a fine not exceeding S\$5,000, and for a second or subsequent offence to a fine not exceeding S\$10,000 and/or to imprisonment for a term not exceeding twelve (12) months.

Employment of Foreign Manpower Act 1990 of Singapore (“EFM Act”)

Section 5(1) of the EFM Act provides that no person shall employ a foreign employee unless he has obtained in respect of the foreign employee a valid work pass from the MOM, which allows the foreign employee to work for him. In relation to the employment of semi-skilled or skilled foreign workers, employers must ensure that such persons holds a valid “Work Permit”.

In relation to the employment of foreign mid-level skilled workers, employers must ensure that such persons apply for an “S Pass”. The S Pass is intended for mid-level skilled foreigners who earn a monthly fixed salary of at least S\$3,300. The S Pass minimum qualifying salary will increase from \$3,300 to \$3,600 for new applications from 1 January 2027.

In relation to the employment of foreign professionals, managers and executives, employers must ensure that such persons apply for an “Employment Pass”. The Employment Pass is intended for professionals who earn a monthly fixed salary of at least S\$5,600. The Employment Pass minimum qualifying salary will increase from \$5,600 to \$6,000 for new applications from 1 January 2027.

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In the employment of foreign workers, employers are restricted by, among other things, the foreign worker quota (which is known as the dependency ratio ceiling), the countries of origin, the age and the qualifications of the foreign employees, which differ from sector to sector. The dependency ratio ceiling limits the number of foreign workers that an employer may employ based on the type of work pass held by the foreign employee, and the number of local employees currently in the employer's employment.

Foreign worker levies are payable when employing foreign workers, with the quantum varying based on several factors, such as the type of business activity, the skill level of the foreign employees and the proportion of the employer's workforce that are made up of foreign employees.

Any person who contravenes Section 5(1) of the EFM Act shall be guilty of an offence and shall:

- (a) be liable on conviction to a fine of at least S\$5,000 and not more than S\$30,000 or to imprisonment for a term not exceeding twelve (12) months or to both; and
- (b) on a second or subsequent conviction:
 - (A) in the case of an individual, be punished with a fine of not less than S\$10,000 and not more than S\$30,000 and with imprisonment for a term of not less than one (1) month and not more than twelve (12) months; or
 - (B) in any other case, be punished with a fine of at least S\$20,000 and not more than S\$60,000.

Central Provident Fund Act 1953 of Singapore ("CPF Act")

The CPF Act governs the contributions made by employers and employees into the CPF. The CPF Act is administered by the CPF Board.

Section 7(1) of the CPF Act provides that subject to certain exemptions and regulations, every employer of an employee shall pay to the CPF monthly in respect of each employee contributions at the appropriate rates set out in the First Schedule of the CPF Act. Pursuant to Section 7(2) of the CPF Act, notwithstanding the provisions of any written law or any contract to the contrary, an employer is entitled to recover from the monthly wages of an employee the amount shown in the First Schedule of the CPF Act as so recoverable from the employee.

Section 9(1) of the CPF Act provides that, in respect of an employer, where the amount of the contributions which an employer or the platform operator (as the case may be) is liable to pay under Section 7 of the CPF Act in respect of any month is not paid within such period as may be prescribed, the employer shall be liable to pay interest on the amount for every day the amount remains unpaid commencing from the first day of the month succeeding the month in respect of which the amount is payable and such interest shall be calculated at the rate of 1.5% per month or the sum of S\$5, whichever is greater.

Section 7(3) of the CPF Act provides that where any employer who has recovered any amount from the monthly wages of an employee in accordance with the CPF Act and fails to pay the contributions to the CPF within such time as may be prescribed, he shall be guilty of an offence and shall be liable on conviction to a fine not exceeding S\$10,000 or to imprisonment for a term not exceeding seven (7) years or to both.

Section 61(1) of the CPF Act provides that except as otherwise provided in Section 61(2) of the CPF Act, any person convicted of an offence under the CPF Act for which no penalty is provided shall be liable on conviction (a) to a fine not exceeding S\$5,000 or to imprisonment for a term not exceeding six (6) months or to both; and (b) if that person is a repeat offender in relation to the same offence, to a fine not exceeding S\$10,000 or to imprisonment for a term not exceeding twelve (12) months or to both.

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Section 61(2) of the CPF Act provides that where any person:

- (a) is guilty of an offence under Section 7(5), 8A(5) or 58(1)(b) of the CPF Act; or
- (b) being a director, manager or secretary or any other officer of a body corporate, is guilty of an offence under Section 60 of the CPF Act by virtue of the fact that an offence under Section 7(3) or (5), 8A(3) or (5) or 58(1)(b) of the CPF Act has been committed by that body corporate and is found to have been committed with the consent or connivance of or to be attributable to any act or default on the part of that person,

that person shall be liable on conviction:

- (a) to a fine of not less than S\$1,000 and not more than S\$5,000 or to imprisonment for a term not exceeding six (6) months or to both; and
- (b) if that person is a repeat offender in relation to the same offence, to a fine of not less than S\$2,000 and not more than S\$10,000 or to imprisonment for a term not exceeding twelve (12) months or to both.

OVERVIEW OF LAWS AND REGULATIONS IN GERMANY

The following is a brief summary of the laws and regulations in Germany that currently materially affect our business. The principal objective of this summary is to provide potential investors with an overview of the key laws and regulations applicable to us. The summary does not purport to be a comprehensive description of all the laws and regulations applicable to our business and operations in Germany which may be important to potential [REDACTED]. [REDACTED] should note that the following summary is based on laws and regulations in force as of the date of this document, which may be subject to change.

Regulations on Qualifications of Shareholders of Private Clinics Under the GewO

The private clinics operated by the Care Vision Germany GmbH are regulated by the German Industrial Code (*Gewerbeordnung* — *GewO*) as they are classified as operating “private clinics” within the meaning of the GewO. Under several German local professional laws, ownership in medical institutions in the form of a legal entity under private law (e.g. in the form of a German limited liability company, GmbH) by third party private investors who are not qualified medical practitioners is not allowed. Being structured as a private clinic holding a Concession, this offers the legal possibility of ownership by third party private investors.

According to the GewO, a Concession is issued for for-profit private clinics which provide (partly) in-patient treatment in which the medical and nursing care provided must be at a sufficient level for the provision of (partly) in-patient treatments in order to ensure the patient’s safety. Such for-profit private clinics are neither included in any public clinic plans or state financing nor in any provision contracts with statutory health insurance.

The Concession, according to section 30 of the GewO, as currently held by our clinics operated by the Care Vision Germany GmbH in Germany can serve as an investment vehicle for private investors in healthcare companies and accordingly, is a means for private investors to participate in healthcare companies such as our Group.

As at the Latest Practicable Date, we have obtained Concessions for eight of our centres in Germany.

Certain other centres operated by the Company in Germany do not require a Concession, as these centres are not operated as private clinics and are not used for the provision of medical treatment. In particular, the activities carried out at such centres are limited to preparatory, supportive or organisational functions and do not involve the operation of medical facilities requiring the infrastructure or organisation characteristic of a private clinic within the meaning of section 30 of the GewO.

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Regulations on Healthcare Providers

As a healthcare service provider in Germany, our clinics are subject to regulations concerning a number of aspects including (i) provisions with respect to adequate medical and nursing care for its customers from a sanitary, hygiene, technical, structural and waste disposal point of view; (ii) the qualification and professional guide on the practitioner performing the medical services on behalf of the service provider; (iii) anti-corruption and anti-bribery issues; (iv) compliance in relation to advertisement and marketing; (v) regulations with respect to patients; and (vi) permits, licenses, authorisations and approvals required for the operation of a healthcare service business. Such regulations include the Infection Protection Act (*Infektionsschutzgesetz*), Medical Devices Act (*Medizinproduktegesetz*), Ordinance on Operating Medical Devices (*Medizinbetriebsverordnung*), Regulation on Hygiene and Infection Prevention in medical institutions (*Verordnung zur Hygiene und Infektionsprävention in medizinischen Einrichtungen*), Pharmaceutical Act (*Arzneimittelgesetz*), the GewO, Ordinance on Hazardous Substances (*Gefahrstoffverordnung*) and local waste disposal provisions with respect to medical waste.

The adherence to such provisions is supervised and enforced by competent authorities such as (i) the Trade Supervisory Board (*Gewerbeaufsichtsamt*) and the local health offices (*Gesundheitsbehörden*), (ii) the medical associations on Federal State level as well as the German Medical Association (*Ärztekammern*) and (iii) the authorities competent for permits required for the provision of the company's business.

Regulations on Qualified Healthcare Services Practitioners

German healthcare services practitioners are subject to several laws which regulate their profession. In order to be permitted to practice as a medical practitioner in Germany each practitioner requires a medical license. Additionally, in order to specialise in a specific medical discipline, a practitioner must complete and pass the particular residency.

The German Criminal Act (*Strafgesetzbuch*) and several industry codes regulate the interactions between the healthcare industry and practitioners, in particular with respect to anti-corruption and anti-bribery to ensure independence of practitioners, particularly where a practitioner is also a shareholder of the healthcare service provider and whose interests may be influenced by the business performance and/or financial results of the healthcare institutions.

Healthcare marketing with respect to medical services (in particular towards potential customers) is subject to regulation under certain laws, in particular the Healthcare Advertisement Act (*Heilmittelwerbegesetz*) and the German Act against Unfair Competition (*Gesetz gegen den unlauteren Wettbewerb*).

Before undergoing medical treatment (e.g. a surgery), a patient has to be informed and has to provide his/her consent to the treatment including, among other things, its scope, impact and risks and prospects by the practitioner in charge, according to section 630e of the German Civil Code and section 8 of the Professional Code of Conduct for Physicians in Germany (*Musterberufsordnung für Ärzte*). The scope and level of accuracy of the information required to be disclosed to patients vary depending on the urgency and the prospects of the treatment in issue. The information must be provided in a comprehensible form, the standard of which is determined on a case-by-case basis. It should be ensured that the patients are able to understand such information in German or receive the relevant information in a language that they comprehend. The information must be provided verbally in a personal interview, whereby the patient must be given the opportunity to ask questions. Documents such as standard forms are permitted under section 126b of the German Civil Code but they do not discharge the healthcare services practitioners' obligation to verbally inform the patients and ensure that the patient is fully informed and has consented to the treatment.

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Regulations on Ophthalmological Healthcare Services

The legal and regulatory framework governing an entity’s operations with respect to the provision of medical services in the ophthalmological sector and the service quality is subject to (i) the qualification of the ophthalmologists, (ii) the condition of the specific quality management system with respect to the business of an ophthalmological clinic, in particular the certification under ISO 9001:2015, as well as the adherence to hygienic standards and (iii) the adherence to regulations with respect to the quality of the medical devices and equipment used to perform ophthalmological services offered by the entity.

(i) *Quality management system*

An ophthalmological service provider’s quality management system is subject to the regulations of quality management standard ISO 9001:2015. This standard provides in details the scope of a management system regarding the entity’s organisation, management, quality management, support infrastructure and its operating systems as well as regular evaluations of the its management system in order to ensure the quality of the services offered. The adherence to ISO 9001:2015 is scrutinised by the respective authority (e.g. a TÜV entity) and certificated in case of compliance for a specific term (e.g. three years). In order for the certification to be renewed, the entity has to be reconsidered by the authorities on a regular basis.

(ii) *Medical devices and equipment*

Medical devices and equipment used to perform medical services offered by the ophthalmologists have to be used and prepared in accordance with respective provisions, including but not limited to the Ordinance on Operating Medical Devices (*Medizinproduktebetreiber — Verordnung*). This is supervised by competent local health offices.

Regulations on Data Protection

Care Vision Germany GmbH is subject to regulation of data protection under the General Data Protection Regulation — GDPR, which is promulgated by the European Union. The GDPR prescribes a risk-based approach to the processing of personal data, meaning that entities will have to establish appropriate risk management practices in order to be able to document and demonstrate compliance, for example, conducting regular and ad-hoc risk assessments in various contexts related to the processing of personal data, or risk mitigation.

In addition to the GDPR, the Federal Data Protection Act (*Bundesdatenschutzgesetz — BDSG*) also applies in Germany. Under the BDSG, companies in Germany have an obligation to formally appoint a data protection officer, which can be an employee or external service provider. The data protection officer is in charge of ensuring and monitoring data protection compliance and reports directly to the management of the entity.

The GDPR and BDSG require entities to process personal data in compliance with a set of general principles that are reflected in specific compliance requirements stipulated by them, for instance:

- Before processing the personal data, an entity must ensure that the processing will comply with the general principles. These general principles are mainly related to principles of fairness, transparency, purpose limitation, security of the personal data and accountability.
- Once the entity has assessed the case, a legal basis for processing the data must be identified. These bases are listed in the GDPR and BDSG.
- The GDPR confers data subjects a number of rights with respect to the entity that is processing their personal data and at the same time imposing corresponding obligations on the entity.
- The GDPR requires an entity to maintain a record of its processing activities under its responsibility.

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- The GDPR also imposes a requirement for companies of which the processing of personal data is outsourced to have written data processing agreements.
- The GDPR imposes rules and requirements for the transfer of personal data to countries outside the European Union.

Non-compliance with the GDPR can result in fines of up to EUR 20 million or 4% of the entity’s total worldwide annual turnover, whichever is higher. Penalties such as imprisonment may also be imposed. Furthermore, an entity may be held liable for the damages suffered by the data subjects as a result of the non-compliant processing of personal data.

Employment Laws

Care Vision Germany GmbH currently has 376 employees (status as of 6 May 2026). German labour and employment relations are regulated by a number of different laws and regulations (for example, Act on Protection against Unfair Dismissal, Act on Working Hours, Federal Vacation Act, Act on Continued Remuneration with regard to sick pay, Minimum Wage Act, Act on Temporary Employment, Works Constitution Act, Act on Collective Bargaining Agreements), case law, collective bargaining agreements, works agreements and individual employment contracts.

In general, in business units with more than 10 employees, the requirements for a valid notice and restrictions on terminations are governed by the Act on Protection Against Unfair Dismissal. The employer must observe certain form requirements for terminations. In particular a termination requires a justification on social grounds and is restricted in case of officially acknowledged handicapped or pregnant employees

Contracts and General Compliance

The German Civil Code (*Bürgerliches Gesetzbuch*) and the German Commercial Code (*Handelsgesetzbuch*) govern any contractual agreements between Care Vision Germany GmbH and its contractual partners which are subject to German law.

German anti-bribery laws are not laid down in one single legislation, but in several laws and regulations. In addition, potentially also foreign legislation might apply to Care Vision Germany GmbH due to the extraterritorial effect of such legislation.

Care Vision Germany GmbH must carry out an energy audit under the regime of the Energy Services Act (*Energiedienstleistungsgesetz — EDL-G*) and the Energy Efficiency Act (*Energieeffizienzgesetz — EnEfG*) regime at least every four years. Failure to comply could result in fines.

OVERVIEW OF LAWS AND REGULATIONS IN SPAIN

This section sets out a summary of material laws and regulations related to our business in Spain.

FDI Regulations

Under Spanish foreign direct investment regulations (namely, Spanish Law 19/2003, of 4 July, on the legal regime regulating the movements of capital and foreign economic transactions with foreign countries, Spanish Royal Decree-Law 34/2020, of 17 November, on urgent measures to support business solvency and the energy sector, and on tax matters and Spanish Royal Decree 571/2023, of 4 July, on foreign investment, and Regulation (EU) 2019/452 of the European Parliament and of the Council of 19 March 2019 establishing a framework for the screening of foreign direct investments into the Union, all of them as amended, developed or supplemented from time to time, together, the “**Spanish FDI Regulations**”), the direct or indirect acquisition of at least 10% of the share capital of a Spanish company, or the acquisition of control over it (control being understood as the ability to exercise decisive influence over the target, for instance via veto rights over strategic decisions), by a foreign investor, requires prior

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authorization from the Spanish Council of Ministers when: (i) the Spanish target operates in a sector considered sensitive under Spanish FDI Regulations (including, among others, healthcare and critical technologies); and/or (ii) the investor is deemed “FDI-sensitive”, i.e. subject to mandatory screening regardless of the target’s sector. Spanish FDI Regulations provide several definitions and thresholds for “foreign investors”, each with different treatment. Non-EU/EFTA investors, as well as EU/EFTA-resident entities in which a non-EU/EFTA resident ultimately owns or controls more than 25% of the share capital or voting rights, or otherwise controls it, are subject to FDI screening when investing in sensitive sectors. The authorization process ordinarily takes up to three months, although the actual timeline may vary depending on the information requested by the competent authorities.

Obtaining FDI authorization in Spain is an obligation of the investor — the party responsible for submitting the filing is the foreign investor, who is also the only party subject to fines (of up to the transaction value of the relevant Spanish company) in the event of a breach of the Spanish FDI Regulations. If a transaction is completed without the required prior FDI authorization, the Spanish FDI authorities may impose fines on the unauthorized foreign investor, and the transaction shall be ineffective in Spain (with all shareholder rights — both economic and political — of the unauthorized foreign investor being suspended) unless and until the FDI authorization is subsequently obtained.

Under the Spanish FDI Regulations, cross-border investments are also subject to mandatory declaration obligations to the Spanish Foreign Investment Registry, in certain cases, for statistical and administrative control purposes. These obligations apply to both foreign investments in Spain and Spanish investments abroad and require the submission of standardized forms to the competent authority within specific deadlines. The regime is declarative in nature, so non-compliance does not affect the validity of the transaction itself but may result in an administrative breach and subsequent fines.

Competition Regulations

Spanish companies are subject to, on the one hand, EU antitrust and merger control legislation, i.e. articles 101 and following of the Treaty on the Functioning of the EU and the Council Regulation (EC) No 139/2004 of 20 January 2004 on the control of concentrations between undertakings (together, the “**EU Competition Regulation**”) and, on the other hand, Spanish antitrust and merger control legislation, i.e. the Spanish Law 15/2007, of 3 July, on the Defense of Competition together with its implementing regulation Royal Decree 261/2008 of 22 February, approving the Competition Regulation (the “**Spanish Competition Law**”). The EU Regulation applies to restrictive practices, which may affect trade between Member States, and it is mainly enforced by the European Commission, whereas the Spanish Competition Law applies to restrictive practices with effects in Spain or in more geographically-limited markets within Spain, and it is enforced by the Spanish national competition authority (the Spanish National Markets and Competition Commission) and regional competition authorities, where they exist and have such powers.

Competition regulations aim at protecting and fostering free, undistorted and effective competition in all sectors of the economy, which is considered a general interest. The main fields of regulation are the following:

- The prohibition of any agreements or concerted practices that have as their object or effect the prevention, restriction or distortion of competition. These practices include, *inter alia*, price fixing; limiting or controlling production, distribution, technical development or investment; or sharing or allocating markets. Except for those cases where conduct can benefit from an exemption if certain conditions are met, prohibited agreements and practices are null and void and may lead to fines of up to 10% of the total worldwide turnover of the infringing company in the preceding business year.
- The prohibition of abusive conducts if a company holds a dominant position in each market. Abuse of dominance is also subject to fines of up to 10% of the total worldwide turnover of the infringing company in the preceding business year.

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- Control of concentration between companies. In case a company enters certain corporate transactions, such as mergers, acquisitions or the incorporation of full-function joint ventures, they may require prior notification and authorization by competition authorities. Failure to comply with the obligation to notify or implementation of the transaction prior to obtaining clearance may result in the imposition of fines and the request to file the notification. This may, in turn, lead the competent authority to impose conditions in its clearance decision or, where the transaction is ultimately found to be prohibited, to order the unwinding of the concentration.
- Control of State aid measures, i.e., any economic advantage — in any form whatsoever — conferred from State resources to companies on a selective basis and resulting in a distortion of competition. EU Competition Regulation establishes a general prohibition of State aid, but such aid can be considered admissible or justified under certain conditions. State aid measures require in some cases prior authorization from the European Commission before they are granted. In case of breach of applicable EU State aid law, it may be required to pay back such aid with interests.

Takeover Offer Regulations

Takeover offers in Spain are governed by articles 108 et seq. of Spanish Law 6/2023, of 17 March, on securities markets and investment services and Spanish Royal Decree 1066/2007, on the rules governing tender offers for securities, which implements Directive 2004/25/EC of the European Parliament and of the Council of 21 April 2004 (all, the “**Spanish Takeover Regulations**”). The Spanish Takeover Regulations apply to any natural or legal person launching a tender offer for all issued shares of a Spanish listed company, such as CB.

Takeover offers may be either mandatory or voluntary. A mandatory takeover offer must be launched, whenever a person or entity acquires control of a Spanish listed company, for all its shares and relevant securities at an equitable price, without conditions. Control is deemed to exist when a person acquires, directly or indirectly, 30% or more of the voting rights, or acquires less than 30% but appoints more than half of the board within 24 months of that acquisition. Control may be obtained through share acquisitions, shareholder agreements, or certain indirect means such as mergers, share capital decreases or changes in the target’s treasury stock. In calculating voting rights, the Spanish Takeover Regulations attributes to the bidder rights held by its group companies, directors, persons acting in concert with it, and nominees, among others.

The price of a mandatory takeover offer is considered equitable when it is at least equal to the highest price paid by the bidder (or persons acting in concert) for the same securities in the 12 months preceding the takeover bid announcement, or where no prior acquisitions have been made, other rules used to calculate the equitable price are set forth in the Spanish Takeover Regulations, though the Spanish National Securities Markets Commission (“**CNMV**”) may adjust the equitable price in exceptional circumstances. Mandatory takeover offers must be launched as soon as possible and in any event within one month of obtaining control. In case of control through indirect means, the obligation to launch a tender offer does not apply if, within three months from the date such control was obtained, such holder disposes of a number of shares necessary to reduce the voting rights in excess of 30% and in the meantime does not exercise its voting rights exceeding such percentage, or obtains a waiver from the CNMV.

Voluntary tender offers may be launched in those cases in which a mandatory offer is not legally required. Voluntary offers may be launched at any price and may be subject to conditions (such as amendments to the articles of association or adoption of certain resolutions by the general shareholders’ meeting of the target company, acceptance of the offer by a minimum number of shares of the target company, approval of the offer by the general shareholders’ meeting of the bidder and any other condition deemed by the CNMV to be in accordance with law).

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The Spanish Takeover Regulations also address a range of shareholder rights and structural protections. The board of the target company is subject to passivity rules restricting it from taking frustrating or defensive actions against the takeover offer, though reciprocity exceptions apply in cross-border situations. Defensive measures in the target company’s bylaws and shareholder agreements generally remain in force during a takeover offer unless shareholders decide otherwise, with compensation available to adversely affected shareholders. Finally, squeeze-out and sell-out rights apply where, following a takeover offer, the bidder holds at least 90% of the target’s voting capital and the offer has been accepted by holders of at least 90% of the voting rights over which it was launched.

Significant Shareholdings Regulations

Under Spanish Royal Decree 1362/2007, of 19 October, with respect to transparency requirements regarding information on issuers whose securities are admitted to trading on an official secondary market or on another regulated market within the European Union (“**Royal Decree 1362/2007**”), any individual or legal entity that purchases or transfers shares carrying voting rights in a Spanish listed company, such as CB, must notify both the company and the CNMV whenever, as a result of such transaction, their proportion of voting rights reaches, exceeds or falls below any of the following thresholds: 3%, 5%, 10%, 15%, 20%, 25%, 30%, 35%, 40%, 45%, 50%, 60%, 70%, 75%, 80% and 90% of total voting rights. The notification must be made using the CNMV’s standard form within four trading days from the date on which the obligation arose, with the obliged party deemed to have become aware of the triggering event within two trading days of the relevant transaction.

The reporting obligation also applies where the relevant thresholds are crossed because of a change in the company’s total number of voting rights, without any actual purchase or transfer taking place. Furthermore, the obligation extends to holdings of financial instruments that, on maturity, grant the holder an unconditional or discretionary right to acquire voting shares already issued, or that are otherwise referenced to such shares and carry a similar economic effect, whether physically or cash settled. Regardless of the actual ownership of the shares, any individual or legal entity with a right to acquire, transfer or exercise voting rights granted by the shares, and any individual or legal entity which acquires, transfers or holds, whether directly or indirectly, other securities or financial instruments which grant a right to acquire shares with voting rights, will also have an obligation to notify of the holding of a significant stake. In certain circumstances, the notification requirements also apply to any person or legal entity that, directly or indirectly, and independently of the ownership of the shares or financial instruments, may acquire, transfer or exercise the voting rights granted by those shares or financial instruments, provided that the aggregated proportion of voting rights reaches, increases above or decreases below the percentages set forth above.

For persons or groups resident in non-cooperative jurisdictions (as defined in Spanish Order HFP/115/2023) or in countries with no effective tax information exchange with Spain, the triggering threshold is reduced to 1% and each successive multiple thereof. Additionally, in the context of a takeover offer, any acquisition reaching or exceeding 1% of the company’s voting rights, and any increase or decrease in the percentage held by shareholders already holding 3% or more, must be notified to the CNMV, which is then required to make such information immediately public.

Exchange Control Regulations

Pursuant to Spanish Royal Decree 1816/1991, of 20 December, relating to economic transactions with non-residents, as amended by Spanish Royal Decree 1360/2011, of 7 October, and Council Directive, of 24 June 1988, for the implementation of Article 67 of the Treaty, charges, payments or transfers between non-residents and residents of Spain must be effected through an official payment services supplier registered with the Bank of Spain and/or the CNMV, through bank accounts opened abroad with a foreign bank or a foreign branch of a registered entity, in cash or by check payable to bearer. All charges, payments or transfers which exceed EUR 6,010.12 (or its equivalent in another currency), if made in cash or by check payable to bearer, must be notified to the Spanish exchange control authorities.

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Corporate Restrictions on Dividend Distributions

Under the Spanish Companies Law, enacted by Spanish Royal Legislative Decree 1/2010, dated July 2, the general shareholders meeting of a Spanish company resolves on the application of the financial year's result in accordance with the approved balance sheet, and dividends may only be distributed out of the profit for the year or freely distributable reserves, provided that the value of the company's net equity is not, and would not as a result of the distribution become, less than the share capital. If prior-year losses have reduced the company's net equity below the share capital figure, profits must first be applied to offset those losses. In addition, no profit distribution is permitted unless the amount of distributable reserves is at least equal to the amount of research and development expenses recorded as an asset on the statement of financial position. In all cases, an amount equal to at least 10% of the profit for the year must be allocated to a legal reserve until that reserve reaches at least 20% of the share capital. Such legal reserve cannot be distributed to shareholders except upon liquidation.

The general shareholders' meeting determines the timing and form of payment; in the absence of any such determination, the dividend is payable at the registered office from the day following the resolution, and the maximum period for full payment is twelve months from the date of the general shareholders' meeting's distribution resolution. Interim dividend payments are also permitted, but subject to certain conditions: the distribution of amounts on account of dividends may only be agreed by the general shareholders' meeting or the directors where the directors prepare an accounting statement showing sufficient liquidity, and the amount distributed may not exceed the results obtained since the end of the last financial year, after deducting prior-year losses, mandatory reserve allocations and the estimated tax on those results. Any dividend distribution that contravenes these rules must be repaid by the shareholders who received it, together with the applicable legal interest, where the company proves the recipients knew or could not have been unaware of the irregularity.

Healthcare Activity Regulations

Healthcare clinics and facilities

In Spain, the operation of healthcare clinics, such as CB's clinics, is subject to healthcare operating authorization to be granted by the relevant regional authorities on a case-by-case basis. Obtaining this authorization would require (i) complying with minimum material requirements (e.g. space, facilities, resources, policies and procedures, personnel) and (ii) submitting detailed documentation to the health authorities, who would also carry out an inspection visit to verify the accuracy of the information prior to granting the authorization. The authorization must specifically mention each type of healthcare service that the relevant entity is authorized to perform (e.g. surgery, anesthesia, etc.). In some regions, some specific activities are subject to a different regime and require specific ad hoc authorization additional to the general healthcare authorization (e.g. to maintain a medicines deposit, etc.).

The healthcare operating authorization will be registered with the General Register of Healthcare Centers, Services and Establishments (both regional and national). In most regions, the healthcare operating authorization is granted for a limited period, ranging, generally, from three to five years, and the holder must apply for the renewal of the authorization.

In addition, more generally, in Spain, all business activities (such as running a healthcare clinic) are controlled by the public authorities as regards the impact of the business activity on the surroundings and the environment. Depending on the type of activity, the level of control may be stringent and may vary from mere prior communication to the city council to environmental authorization from the regional or national authorities. In the case of healthcare facilities city councils usually control the business activity through an administrative procedure that requires obtaining two consecutive licenses: (i) the activity license, which authorizes the implementation of the project, and (ii) the opening license, which authorizes the starting up of the activity. In certain regions or municipalities, these licenses have been replaced by

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prior communications with the city council (i.e. once the preliminary communication is made, the business activity can start). Where construction works are carried out, (i) a works license and, where applicable, (ii) a first occupation license may also be required (or the corresponding prior communications to the city council).

If the business activity is carried out without the necessary municipal licenses (or prior communications), the operator may be deemed to have incurred an administrative breach that could be sanctioned with economic penalties, temporary professional disqualification, or the total or partial closure of the business activity (permanent or temporary). The exact amount of the sanction depends on the region.

Waste

In relation to waste, it should be noted that ophthalmological facilities presumably produce “healthcare hazardous waste”. In Spain, producers of hazardous waste currently must (i) submit a prior notice to the regional authority and (ii) be registered with the Spanish Registry of Hazardous Waste Producers. Registration is automatic upon filing the prior notice. Other documentary obligations (such as keeping a chronological record of the waste generated) also apply. Hazardous waste must be managed by an authorized waste manager. The producer of hazardous waste is legally obliged to hand over the waste to such a manager (unless it holds the necessary authorization to process them itself). Therefore, a contract between the producer and the manager must be executed.

Legionella

In Spain, certain equipment may be subject to legislation on legionella prevention, mainly Spanish Royal Decree 487/2022, of 21 June, on the prevention and control of legionella (“**RD 487/2022**”). Under this framework, all operators of such equipment are required to implement a Legionella Prevention and Control Plan or a Health Plan against Legionella, and to maintain comprehensive records of all maintenance activities carried out. In addition, operators of cooling towers and evaporative condensers are subject to a specific obligation to submit a notification to the competent regional health authority regarding their operations. The regional authorities may further extend this notification requirement to other types of equipment beyond those expressly listed in RD 487/2022. If these obligations are not complied with, the operator may be committing an administrative infringement sanctioned with economic fines and, in addition, the competent authorities may order the temporary or permanent closure of the facilities.

Employment Regulations

The employment relationships of Spanish companies are primarily governed by the Spanish Workers’ Statute, enacted by Royal Legislative Decree 2/2015, of 23 October (the “**WS**”), which constitutes the principal statutory framework regulating the rights and obligations of employers and employees in Spain. Senior management personnel are subject to the special regime established by Spanish Royal Decree 1382/1985, of 1 August, regulating the special employment relationship of senior executives, which affords greater contractual autonomy to the parties in the regulation of their professional relationship.

Employment conditions in Spain are also ruled by applicable sectorial collective bargaining agreements (“**CBAs**”) that supplement and improve upon the minimum standards established by the WS. CBAs in Spain may be negotiated at national, sectoral, provincial or company level and, once registered, are binding on all employers and employees within their scope of application.

Regarding formal obligations, employers must register their employees within the Spanish Social Security system and must make mandatory employer and employee Social Security contributions each month in accordance with the applicable rates established under the Spanish General Social Security Law, enacted by Spanish Royal Legislative Decree 8/2015, of 30 October. They are also subject to Spanish Law 31/1995, of 8 November, on the prevention of occupational risks, which imposes an obligation to ensure the health and safety of employees in all work-related aspects.

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Finally, and since CB frequently engages self-employed professionals (e.g. doctors, surgeons, anaesthesiologists, etc.), it is relevant to note the provision of services by freelancers is regulated under Spanish Law 20/2007, of 11 July, on the statute of self-employed workers, together with the applicable Social Security regulations.

Legal Compliance Regulations

Criminal compliance system

Spain does not impose a general legal obligation on companies to have crime prevention measures in place, and the absence of a compliance program does not automatically trigger sanctions. Nevertheless, Spanish companies can be held criminally liable where criminal offences are committed on their behalf and for their direct or indirect benefit by their legal representatives, directors, managers or employees. The range of penalties available is broad, spanning from fines to dissolution of the company or, for those engaged in public procurement, debarment from entering into public contracts. Beyond criminal liability, companies may also face civil liability as secondary civil defendants for damages arising from criminal acts committed by their representatives or employees in the course of their duties, even where the company itself is not criminally convicted.

Spanish companies may, however, be exempt from criminal liability or have such liability mitigated if, at the time the offence was committed, they had an effective criminal compliance program in place satisfying the requirements of the Spanish Criminal Code, enacted by Spanish Organic Law 10/1995, of 23 November. To qualify, such a program must include: (i) a designated compliance body with decision-making authority to supervise and monitor the crime prevention model; (ii) identification of the activities in connection with which criminal offences may be committed; (iii) internal protocols and procedures governing how decisions are approved and executed; (iv) adequate financial resource management controls; (v) a whistleblowing channel enabling reporting of infringements to the compliance officer or supervisory body; (vi) a disciplinary system that adequately sanctions non-compliance; and (vii) regular analysis and updating of the program by the relevant supervisory body.

Internal whistleblowing system

Spanish Law 2/2023, of 20 February, on the protection of persons who report violations of the law and the fight against corruption (“**Law 2/2023**”) seeks to strengthen compliance culture across public and private entities by protecting whistleblowers who, in a professional context, report breaches of certain EU laws, administrative infringements and criminal offences. Law 2/2023 imposes obligations on legal entities with 50 or more employees, entities operating within the scope of EU law on financial services, money laundering prevention, transport safety or environmental protection, and political parties, trade unions, business organizations and publicly funded foundations. In practice, Law 2/2023 requires the implementation of an internal whistleblowing system comprising: (i) an internal reporting channel permitting anonymous communications in writing, verbally, or both; (ii) a policy or strategy setting out the general principles of the system; (iii) a communications-management procedure complying with the mandatory content prescribed; and (iv) the appointment of a responsible officer or internal body to supervise, monitor and manage the system.

Non-compliance or improper implementation of the whistleblowing system may expose companies to significant sanctions. Where an infringement is classified as “very serious”, penalties may include: (a) a fine of up to EUR 1,000,000; (b) a public reprimand; (c) a ban on obtaining subsidies and tax benefits for up to four years; or (d) a ban on contracting with the public sector for up to three years. Furthermore, sanctions for very serious infringements of at least EUR 600,001 imposed on legal persons may be published in the Spanish Official State Gazette once the relevant administrative decision becomes final.

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Data Protection and Cybersecurity Regulations

CB, as part of its day-to-day business, processes “personal data” (i.e., data regarding identifiable persons such as employees, clients or providers) and, therefore, is obliged to comply with the Regulation (EU) 2016/679, of 27 April, on the protection of natural persons with regard to the processing of personal data and on the free movement of such data (“**GDPR**”) and Spanish Law 3/2018, of 5 December, on personal data protection and digital rights guarantee (“**Spanish Data Protection Law**”), as well as guidelines, decisions, recommendations and other binding and non-binding instruments that the data protection supervisory authorities issue from time to time (together, the “**Spanish Data Protection Regulations**”). The Spanish Data Protection Authority (“**Spanish DPA**”) is the supervisory authority in Spain as regards compliance with the Spanish Data Protection Regulations.

Spanish Data Protection Regulations impose certain obligations to companies that process personal data. Some of these obligations are internal obligations (e.g., to draft an internal record of processing activities or to implement accountability measures), and some of them must be complied with vis-à-vis the data subjects (i.e., the data holders, such as employees or contact persons) (e.g., to provide them with certain data protection information or to process the personal data according to certain principles such as transparency or lawfulness). In particular, personal data related to health information is a special category of personal data, with specific requirements.

In general terms, failure to comply with Spanish Data Protection Regulations may entail fines of up to EUR 20,000,000 or, in the case of an undertaking, an amount equal to 4% of its total worldwide annual turnover in the preceding financial year, whichever is higher. When deciding on the amount, the data protection supervisory authorities or law enforcement authorities, respectively, consider several elements, such as the company’s size, the categories of personal data affected by the infringement, the actions taken to mitigate the damage or the number of individuals affected.

Under the GDPR, in the event of a security breach affecting personal data, the affected company must notify the competent supervisory authority. Additionally, if the breach is likely to result in a high risk to the affected individuals, it must also be communicated to them. In this regard companies are required to implement appropriate measures to manage cybersecurity risks, including identification, assessment, and mitigation of potential threats as well as the appointment of a cybersecurity correspondent and providing continuous training to staff on this matter.

In addition, CB operates its websites. Under the Spanish Law 34/2002, of 11 July, on information society services and e-commerce (“**LSSI**”), companies operating websites in Spain must include on the relevant websites a legal notice containing mandatory information to identify the operator of the website. Furthermore, using cookies requires providing certain mandatory information and obtaining the user’s informed consent. In addition, where personal data is processed through the website, Spanish Data Protection Regulations must also be complied with. Failure to comply with the LSSI obligations could result in the imposition of fines of up to EUR 150,000 or up to EUR 1,000,000 or 8 times the benefit obtained if there are consumer protection infringements, in addition to any potential sanctions for data protection matters.

Publicity Regulations

With regard to publicity, CB’s activities in this area are generally subject to the Spanish General Advertising Law, enacted by Spanish Law 34/1988, of 11 November, and, specifically in the healthcare sector, to Spanish Royal Decree 1907/1996, of 2 August, on the advertising and commercial promotion of products, activities, or services with purported health purposes, as well as to other applicable regulations in the areas of health, consumer protection, and unfair competition. The regulation of health-related advertising constitutes a shared competence, with the Spanish Autonomous Communities being responsible for inspection and oversight within the scope of their health-related powers, without prejudice to basic state regulations.

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Tax Regulations

Corporate income tax (“CIT”)

Under Spanish Law 27/2014, of 27 November, on corporate income tax (the “**CIT Law**”), public and private limited companies, investment funds, venture capital funds and pension funds (among others) that are tax resident in Spain — by virtue of having been incorporated under Spanish law, having their registered office in Spanish territory, or having their place of effective management in Spain — are subject to CIT at a general rate of 25% on their worldwide income. CIT is calculated based on accounting results, subject to specific adjustments provided for by the CIT Law.

Value added tax (“VAT”)

Under Spanish Law 37/1992, of 28 December, on value added tax (the “**VAT Law**”), the supply of goods, the provision of services, intra-EU acquisitions and imports located in Spanish VAT territory are subject to VAT. The general VAT rate is 21%; however, reduced VAT rates of 10% and 4% may apply. Certain transactions may also be VAT-exempt (e.g., some medical or healthcare services). VAT taxpayers are entitled to deduct input VAT incurred in connection with their taxable activities. However, the specific percentage of VAT input that may be recovered will ultimately depend on the proportion of the VAT taxpayer’s activities that give rise to a right of deduction (i.e., in general, activities which are subject to, and not exempt from, VAT). Where net input VAT exceeds output VAT, taxpayers may request a refund of the excess amount.

Other taxes and obligations

Other taxes may become payable by Spanish tax resident companies:

- Withholding obligations on account of CIT, Personal Income Tax or Non-residents Income Tax may apply upon specific payments (e.g., dividend distributions, interest payments or service fees paid to non-residents).
- Transfer Tax and Stamp Duty upon the execution of specific transactions, such as the acquisition of real estate assets or the formalization of mortgages or guarantees.
- Real Estate Tax upon holding certain rights (such as ownership) over real estate assets.
- Tax on the Increase of Value of Urban Land upon the disposal of specific rights over urban plots, which taxes the increase in value of such urban land accrued during the taxpayer’s ownership period.
- Business Activities Tax, payable upon carrying out economic activities in Spanish territory. This tax is independent of CIT and is computed as a lump sum for the mere exercise of such economic activity (irrespective of the income obtained, although exemptions apply for income below EUR 1M).
- Tax on Constructions, Installations and Works, which becomes payable upon obtaining a municipal license to carry out such constructions, installations and works.
- Pillar II as regulated by Spanish Law 7/2024, of 20 December, which applies to multinational groups with consolidated revenue above EUR 750 million and which purpose is that the group pays a minimum effective tax rate of 15% in every jurisdiction in which it operates.
- Spanish companies must value transactions with related parties at arm’s length for tax purposes. Pursuant to article 18 of the CIT Law, related parties include (among others) a company and its shareholders, entities within the same group, or entities in which the same

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shareholders hold at least 25% of their share capital or voting rights. Transactions with related parties should be documented in both local files and master files (and country by country report where applicable) (provided that the thresholds set out in the applicable legislation are exceeded).

- Spanish companies must comply with the invoicing obligations set out in Spanish Royal Decree 1619/2012, of 30 November, approving the regulations governing invoicing obligations. Among others, VAT taxpayers must issue invoices upon carrying out supplies of goods and provisions of services — even if exempt, with the exceptions provided by such regulations, and such invoices must comply with the formal requirements established therein.
- Spanish companies must prepare and retain all invoices, accounting and tax books and other tax documentation and reporting obligations (e.g., transfer pricing supporting documentation, VAT books or the Immediate Supply of Information system) and make them available to the Spanish tax authorities upon request or where legally required.