Our business operations are subject to extensive supervision and regulation by the PRC government. This section sets out an introduction to a summary of the main laws, rules, regulations and policies to which we are subject, which have a significant impact on the following key aspects of our business:

- those relating to the reform of medical institutions affect our ability to implement our current business strategy to expand our hospital network;

- those relating to the administration and classification of medical institutions, supervision over pharmaceuticals in medical institutions, medical equipment and treatment, medical personnel, environmental protection for medical institutions, distribution of pharmaceuticals and medical devices, and labor protection regulate our day-to-day operations and affect our compliance costs;

- those relating to medical malpractice have an effect on our potential liabilities arising from day-to-day operations;

- those relating to foreign investment in China regulate the ability of our Company, as a foreign company, to conduct business in China; and

- those relating to taxation and foreign exchange matters have an impact on our results of operations and business.

For more details on how these regulations may affect our current and future businesses, see "Industry Overview — Healthcare Reform in China", "Financial Information — Factors Affecting Our Financial Condition and Results of Operations — Healthcare Reform, Price Control and Other Healthcare Policies in China" and "Risk Factors — Risk Factors Related to Our Business and Industry — Changes in China's Regulatory Regime for the Healthcare Service Industry, Particularly Changes in Public Medical Insurance Programs or Healthcare Reform Policies, Could Have a Material Adverse Effect on Our Business".

LEGAL SUPERVISION OVER THE HEALTHCARE SECTOR IN CHINA

Categories of Medical Institutions in China

Medical institutions in China can be divided into three main categories: public not-for-profit medical institutions, private not-for-profit medical institutions and private for-profit medical institutions. These categories have different registered business nature and apply different financial, tax, pricing and accounting standards. Public not-for-profit medical institutions, including those invested in by the government and military, are eligible for financial subsidies from governments, while private not-for-profit and private for-profit medical institutions are not. Both public not-for-profit and private not-for-profit medical institutions are required to charge healthcare service fees within a range stipulated by the relevant governmental price control authorities, to implement financial and accounting systems in accordance with standards promulgated by government authorities and to retain profits for their continued development. For-profit medical institutions are permitted to charge healthcare service fees in accordance with market practice, to implement financial and accounting systems in accordance with market practice for business enterprises and to distribute profits to their shareholders.

Regulations on the Reform of Medical Institutions

Opinions on Promoting Further Reform of the Healthcare System

The Opinions on Promoting Further Reform of the Healthcare System (中共中央國務院關於深化醫藥衛生體制改革的意見) (the "Opinions"), which were promulgated by the State Council on March 17, 2009, advocate a range of measures to reform medical institutions in the PRC and establish a basic healthcare system covering urban and rural residents. Measures aimed at reforming medical institutions include the separation of: (i) government agencies from public medical institutions, (ii) for-profit medical institutions from not-for-profit medical institutions, (iii) sponsorship from operations of public hospitals, and (iv) pharmaceutical dispensing from pharmaceutical prescription. The Opinions include proposals for the establishment and improvement of corporate governance systems of public medical institutions, and checks and balances in decision-making, execution and supervision processes between owners and operators of public medical institutions. The Opinions also encourage private capital to invest in medical institutions (including investments by foreign investors), the development of private medical institutions and the reform of public medical institutions (including those established by state-owned enterprises) through private capital investment.

Notice on the Implementation Measures for the Reform of the Healthcare System (2009 to 2011)

The Notice on the Implementation Measures for the Reform of the Healthcare System (2009 to 2011) (國務院關於印發醫藥衛生體制改革近期重點實施方案(2009-2011年)的通知), which was promulgated by the State Council on March 18, 2009, sets out the following main tasks for the reform of the healthcare system from 2009 to 2011:

- Expansion of medical insurance coverage: the healthcare reform aims to provide universal medical insurance coverage to all urban and rural residents through the Urban Employee Basic Medical Insurance Program, the Urban Resident Basic Medical Insurance Program and the New Rural Cooperative Medical Program. As part of the reform, the PRC government has set higher reimbursement rates to the insured residents.

- Establishment of a national essential pharmaceutical system: under the Essential Drug List ("EDL"), the PRC government will catalog a list of necessary pharmaceuticals to be produced and distributed by the NHFPC. EDL aims to lower the price of these medicines for consumers by streamlining the distribution channel in the medicine supply chain and setting a ceiling price.

- Improvement of the primary healthcare service system: the PRC government plans to accelerate the construction and renovation of the primary healthcare infrastructure, especially on hospitals at county levels, rural third grade medicine and health service networks and urban community health service institutions, and transform the operating mechanism and service pattern of such institutions to enhance the quality of primary healthcare services.

- Provision of more equitable access to basic healthcare services: the healthcare reform aims to improve the access and quality of public health services and, starting from 2009, provide equally to urban and rural residents basic public health services such as disease prevention and control, maternity and child care and health education.

- Promotion of the pilot reform of public medical institutions: pilot programs have been launched to reform public medical institutions to improve their services in terms of administration, operation and supervision. The PRC government will continue to (i) explore effective ways to specify the powers and responsibilities of the owners and operators of medical institutions to improve their corporate governance, (ii) establish a new supervisory mechanism to oversee quality control and evaluation systems, and (iii) improve the information disclosure of public medical institutions. The economic compensation mechanism will also be reformed with the promotion of a policy to separate the prescription and dispensation of pharmaceuticals. In addition, provincial healthcare administrative authorities are required to steadily advance the reform of certain public hospitals into private hospitals and promote the establishment of not-for-profit hospitals with private investment. Private hospitals will be treated equally as public hospitals with respect to whether they may be approved as a designated medical institution for public medical insurance purposes, the selection of scientific research projects, the evaluation of professional titles and the access to further education programs.

Notice on Further Encouraging and Guiding Private Capital to Invest in Medical Institutions

The Notice of the State Council on Forwarding the Opinions of the NDRC, the NHFPC and other Departments on Further Encouraging and Guiding Private Capital to Invest in Medical Institutions (關於進一步鼓勵和引導社會資本舉辦醫療機構意見的通知) ("Order No.58"), which was promulgated by the General Office of the State Council on November 26, 2010, stipulates that the PRC government encourages and supports investments by private investors in medical institutions of various types. Private investors are permitted to apply to establish for-profit or not-for-profit medical institutions. Private investors are also encouraged to participate in the reform of existing public hospitals, including those established by state-owned enterprises, by converting them into not-for-public medical institutions in order to systematically reduce the proportion of public hospitals in the system. Private medical institutions with experience in the provision of healthcare services and good reputation shall be selected as participants in the restructuring of public hospitals. The restructuring of public hospitals may be carried out through pilot reform programs in hospitals established by state-owned enterprises. Private medical institutions are encouraged to modernize hospital management, establish standardized corporate governance structures, step up cost control and quality management systems, and employ professional managers to manage the hospital. Private investors are encouraged to set up hospital management companies to provide specialized services. Private medical institutions are encouraged to engage or authorize domestic or overseas medical institutions with professional experience to participate in the management of hospitals to improve their efficiencies. Medical institutions are encouraged to develop into large, sophisticated, technology-intensive medical groups and adopt brand-focused development strategies to build good reputation and image. Private medical institutions are encouraged to improve their clinical research and build their research and development teams.

Guidelines for Pilot Programs for the Reform of Public Hospitals

The Notice on the Guidelines for Pilot Programs for the Reform of Public Hospitals (關於印發公立醫院改革試點指導意見的通知), which was jointly promulgated by the NHFPC, the State Commission Office for Public Sector Reform, the NDRC, the Ministry of Finance of the PRC (中華人民共和國財政部, or the "MOF") and the Ministry of Human Resources and Social Security of the PRC (中華人民共和國人力資源和社會保障部, or the "MOHRSS") on February 21,

2010, stipulates that the PRC government encourages the reform of public hospital management, including through exploring effective methods for (i) the separation of administrative organs from public service institutions and the separation of management from operations, (ii) the clarification of powers and responsibilities of owners and operators of public hospitals, and (iii) the establishment of corporate governance structures in hospitals in order to improve the professionalism and specialization of hospital administration. The PRC government encourages, supports and gives guidance to private investors engaged in the development of healthcare services and the establishment of not-for-profit hospitals.

Implementation Measures for the Promotion of the Healthcare System in Beijing from 2010 to 2011

The Implementation Measures for the Promotion of the Healthcare System in Beijing from 2010 to 2011 (北京市2010-2011年深化醫藥衛生體制改革實施方案), which were promulgated by the Beijing government in June 2010, indicate that the Beijing government encourages public hospital reform, the establishment of corporate governance for hospitals, the clarification of ownership and management rights of public hospitals and, especially in light of the establishment and restructuring of medical institutions by private funds, private capital investment in the development of the healthcare sector.

Regulations on the Administration and Classification of Medical Institutions

Administrative Measures on Medical Institutions and the Medical Institution Practicing License

The Administrative Measures on Medical Institutions (醫療機構管理條例), which were promulgated on February 26, 1994 by the State Council and came into effect on September 1, 1994, and the Implementation Measures of the Administrative Measures on Medical Institutions (醫療機構管理條例實施細則), which were promulgated by the NHFPC on August 29, 1994 and came into effect on September 1, 1994, stipulate that the establishment of medical institutions shall comply with the relevant regional planning requirements as well as the basic standards of medical institutions. Any entity or individual that intends to establish a medical institution must follow the application approval procedures and register with the relevant healthcare administrative authorities to obtain a Medical Institution Practicing License (醫療機構執業許可證).

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

The Administrative Measures for the Examination of Medical Institutions (For Trial Implementation) (醫療機構校驗管理辦法(試行)) (the "Administrative Measures for Examination"), which were promulgated by the NHFPC and came into effect on June 15, 2009, stipulate a medical institution's Medical Institution Practicing License is subject to periodic examinations and verifications by registration authorities, and will be cancelled if such medical institution fails to pass the examination.

The Classification of Medical Institutions

The Interim Measures for the Assessment of Hospitals (醫院評審暫行辦法), the Measures for the Assessment of Medical Institutions (醫療機構評審辦法) and the Basic Standards for Medical Institutions (醫療機櫃基本標準(試行)), which were promulgated by the NHFPC on

September 21, 2011, July 21, 1995 and September 2, 1994, respectively, stipulate that medical institutions in China are graded into three levels (Grade I, II and III) and three sub-levels (A, B, C) based on the assessment of competent authorities. The highest standard is Grade IIIA (三級甲等). Under the relevant regulations, each hospital will be assessed once every four years. The NHFPC and its Hospital Assessment Committee are responsible for conducting all hospital assessments in China.

Interim Measures for the Administration of Medical Insurance Designated Medical Institutions and the Provision of Basic Medical Insurance for Urban Employees

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 were jointly promulgated by MOHRSS, the NHFPC and the State Administration of Traditional Chinese Medicine (國家中藥管理局) on May 11, 1999, require medical institutions that provide healthcare services to employees in urban areas under public medical insurance policies to obtain a Qualifying Certificate as a Medical Insurance Designated Medical Institution (定點醫療機構資格證書) from the labor and social security regulatory authorities upon examination and approval of such authorities.

Regulations on the Supervision over Pharmaceuticals in Medical Institutions

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

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

Administrative Measures for the Control of Radioactive Pharmaceuticals

The Administrative Measures for the Control of Radioactive Pharmaceuticals (放射性藥品管理辦法), which were promulgated by the State Council and came into effect on January 13, 1989 and revised on January 8, 2011, require medical institutions to comply with relevant national regulations and rules concerning radioisotope health protection when using radioactive pharmaceuticals. Any medical institution that wants to use radioactive pharmaceuticals must obtain a License for the Use of Radioactive Pharmaceuticals from the public security departments, the environmental protection departments and the public health departments at provincial, regional or municipal levels, as applicable. The License for the Use of Radioactive Pharmaceuticals is valid for five years and is of varying grades based on the technical skill and professional level of the radiological personnel and the equipment of the medical institution. In addition, before a medical institution holding a License for the Use of Radioactive Pharmaceuticals commences the preparation of radioactive materials for clinical use, it must submit an application to the health administration department at the provincial, regional or municipal level for approval and complete filing procedures with the NHFPC.

Regulations on the Administration of Narcotic Pharmaceuticals and Psychotropic Substances

The Regulations on the Administration of Narcotic Pharmaceuticals and Psychotropic Substances (麻醉藥品和精神藥品管理條例), which were promulgated by the State Council on August 3, 2005 and came into effect on November 1, 2005, provide that, where a medical institution needs to use any narcotic pharmaceutical or Class I psychotropic substance, it shall, upon approval by the competent public health department, obtain the Seal Card for the Purchase and Use of Narcotic Pharmaceuticals and Class I Psychotropic Substances (the "Seal Card"). If a medical institution with a Pharmaceutical Preparation Certificate for Medical Institutions (醫療機構制劑許可證) and a Seal Card needs to dispense for clinical use any narcotic pharmaceutical or psychotropic substance which is not available on the market, the preparation shall be subject to approval by the competent provincial, regional or municipal pharmaceutical regulatory department where the medical institution is located. The pharmaceutical preparations of a narcotic pharmaceutical or psychotropic substance dispensed by the medical institution may only be used in the institution itself and may not be marketed.

Laws and Regulations on Medical Equipment and Treatment by Medical Institutions

Administrative Measures on the Deployment and Use of Large Medical Equipment

The Administrative Measures on the Deployment and Use of Large Medical Equipment (大型醫用設備配置與使用管理辦法), which were jointly promulgated by the NHFPC, the NDRC and the MOF on December 31, 2004 and came into effect on March 1, 2005, provide that medical institutions that wish to purchase large medical equipment (referring to those medical equipment listed in the catalog issued by the public health administrative authorities of the State Council or those medical equipment deployed for the first time within the provincial regions with a unit price above RMB5 million) must apply to the competent public health administrative authorities and purchase the approved large medical equipment upon receipt of a License for the Deployment of Large Medical Equipment.

Administrative Measures on the Radiotherapy

The Administrative Measures on the Radiotherapy (放射診療管理規定), which were promulgated by the NHFPC on January 24, 2006 and came into effect on March 1 2006, set out the basic statutory framework for medical institutions engaged in the clinical diagnosis and treatment using radioisotopes and radiation-emitting devices. Depending on the specific radiotherapy treatment, medical institutions shall apply for and obtain the License for radiotherapy issued by the competent public health administrative authorities. During the course of radiotherapy, medical institutions shall take protective measures in accordance with the relevant laws and regulations.

Regulations on the Safety and Protection of Radioisotopes and Radiation-emitting Devices

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 were promulgated by the State Council on September 14, 2005 and came into effect on December 1, 2005, stipulate that any entity engaging in the production, sale or use of radioisotopes or radiation-emitting devices of different categories shall obtain a corresponding license. In addition, medical institutions using radioisotopes or radiation-emitting devices for diagnosis and treatment shall obtain a license for diagnostic and therapeutic technique with radioactive sources and medical radiation.

Regulations on the Safety Management of Oxygen Chambers for Medical Usage

The Regulations on the Safety Management of Oxygen Tanks for Medical Usage (醫用氧艙安全管理規定), which were jointly promulgated by the State Bureau of Quality and Technical Supervision (which was subsequently reorganized into the General Administration of Quality Supervision, Inspection and Quarantine (中華人民共和國國家質量監督檢驗檢疫總局, or the "AQSIQ") and the NHFPC on September 18, 1999 and came into effect on January 1, 2000, stipulate that medical institutions with a Medical Institutions Practicing License are permitted to use oxygen tanks for medical purposes, such as air compression chambers, oxygen tanks and the multi-functional loading pressure cabins for hyperbaric oxygenation. Before the purchase of an oxygen chamber, medical institutions must apply to the competent public health administrative authority where the medical institution is located and obtain an Approval for the Installation of Oxygen Chamber for Medical Usage from the provincial public health administrative. Before the oxygen chamber is brought into operation, the medical institution should register with the local AQSIQ branch where the medical institution is located and obtain a License for the Use of an Oxygen Chamber for Medical Usage. Medical institutions are also required to arrange annual and triennial examinations in accordance with the relevant regulations and rules.

Law on Maternal and Infant Healthcare and Its Implementation Measures

The Law of the People's Republic of China on Maternal and Infant Healthcare (中華人民共和國母嬰保健法), which was promulgated by the Standing Committee of the NPC on October 27, 1994 and came into effect on June 1, 1995, and the Implementation Measures of the Law of the People's Republic of China on Maternal and Infant Health Care, which were promulgated by the State Council on June 20, 2001 and came into effect on the same day, stipulate that medical institutions engaged in (i) genetic disease diagnosis and prenatal diagnosis, (ii) pre-marital medical examinations, or (iii) midwifery services, ligature operations or operations for termination of gestation, shall be licensed by the public health administrative authority of different level as stipulated to obtain the corresponding qualification certificates.

Laws and Regulations on Medical Personnel of Medical Institutions

Law on Medical Practitioners of the People's Republic of China

The Law on Medical Practitioners of the People's Republic of China (中華人民共和國執業醫師法), which was promulgated by the Standing Committee of the NPC on June 26, 1998 and came into effect on May 1, 1999, provides that doctors in China must obtain qualification licenses for their medical profession. Qualified doctors and qualified assistant doctors must register with the relevant public health administrative authorities at or above the county level. After registration, doctors may work at medical institutions in their registered location in the types of jobs and within the scope of medical treatment, disease-prevention or healthcare business as provided in their registration.

Regulations on Nurses

The Regulations on Nurses (護士條例), which were promulgated by the State Council on January 31, 2008 and came into effect on May 12, 2008, provide that a nurse must obtain a nurse's Practicing Certificate, which is valid for five years. The number of nurses on staff at a medical institution shall not be less than the standard number as prescribed by the competent public health administrative authorities.

Laws and Regulations on Medical Malpractice

Tort Liability Law of the People's Republic of China

The Tort Liability Law of the People's Republic of China (中華人民共和國侵權責任法), which was promulgated by the Standing Committee of the NPC on December 26, 2009 and came into effect on July 1, 2010, provides that, if a medical institution or its medical personnel are at fault for damage inflicted on a patient during the course of diagnosis and treatment, the medical institution will be liable for compensation. The damage caused to the patient by the failure of the medical personnel to fulfill their statutory obligations in the course of diagnosis and treatment will be paid by the medical institution. Medical institutions and their medical personnel will protect the privacy of their patients and will be liable for 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 were promulgated by the State Council on April 4, 2002 and came into effect on September 1, 2002, provide a legal framework and detailed provisions regarding the prevention, identification, disposition, compensation and penalties of or relating to cases involving personal injury to patients caused by medical institutions or medical personnel due to malpractice.

Regulations on Environmental Protection related to Medical Institutions

Administrative Measures on Urban Drainage License

The Administrative Measures on Licensing of Urban Drainage (城市排水許可管理辦法), which were promulgated by the Ministry of Construction (which was subsequently reorganized to the Ministry of Housing and Urban-rural Development) on December 25, 2006 and came into effect on March 1, 2007, provide that enterprises discharging sewage into the urban drainage network and its ancillary facilities must apply for and obtain a License for Urban Drainage.

Regulations on the Management of Medical Waste and its implementation measures

The Regulations on the Management of Medical Waste (醫療廢物管理條例), which were promulgated by the State Council on June 16, 2003 and came into effect on the same day, and the Implementation Measures of the Management of Medical Waste (醫療衛生機構醫療廢物管理辦法), which were promulgated by the NHFPC on October 15, 2003 and came into effect on the same day, stipulate that medical institutions must timely deliver medical waste to a specially designated location for centralized disposal of medical waste and categorize the medical waste in accordance with the Classified Catalog of Medical Waste. High-risk waste such as the culture medium or specimens of pathogens and the preserving liquid of bacteria strains or virus strains must be sterilized on the spot before disposal. Sewage generated by any medical institution and excretion of its patients or patients suspected of infectious diseases must be sterilized in accordance with the relevant laws, rules and regulations, and must not be discharged into sewage until the relevant standards are met.

Laws and Regulations on Pharmaceutical Distribution

Pharmaceutical Administration Law of the People's Republic of China and its Implementation Regulations

The Pharmaceutical Administration Law of the People's Republic of China (中華人民共和國藥品管理法) (the "Pharmaceutical Administration Law"), which was promulgated by the Standing Committee of the NPC on September 20, 1984, revised on February 28, 2001 and came into effect on December 1, 2001, sets forth the regulatory framework governing pharmaceutical manufacturers, pharmaceutical distributors, pharmacies in medical institutions, and the packaging, pricing advertising and the inspection of pharmaceuticals. The Pharmaceutical Administration Law also provides specific regulations on the relevant licenses and approvals required for pharmaceutical manufacturing and related operating activities.

The Regulations for the Implementation of the Pharmaceutical 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) (the "Regulations for the Implementation of the Pharmaceutical Administration Law"), which were promulgated by the State Council on August 4, 2002 and came into effect on September 15, 2002, provide detailed implementing measures of the Pharmaceutical Administration Law.

Pursuant to the Pharmaceutical Administration Law and the Regulations for the Implementation of the Pharmaceutical Administration Law, the establishment of enterprises engaged in the pharmaceutical wholesale or retail business requires the approval of the relevant pharmaceutical regulatory departments, and such enterprises are required to obtain a Pharmaceutical Distribution Certificate (藥品經營許可證). The term of validity of a Pharmaceutical Distribution Certificate is five years. Pharmaceutical distributors must keep authentic and complete records of the procurement and sales of pharmaceuticals. Medical institutions are subject to the examination and permission of the competent public health authorities in the dispensing of pharmaceutical preparations and must obtain the Pharmaceutical Preparation Certificate for Medical Institutions (醫療機構制劑許可證) issued by the relevant pharmaceutical regulatory authorities. The term of validity of the Pharmaceutical Preparation Certificate for Medical Institutions is five years. The pharmaceutical preparations shall not be marketed in any form, and the advertisement of such pharmaceutical preparations shall not be released.

Administrative Measures on Pharmaceutical Distribution Certificates

The Administrative Measures on Pharmaceutical Distribution Certificates (藥品經營許可證管理辦法), which were promulgated on February 4, 2004 and came into effect on April 1, 2004 by the CFDA, set out the application requirements and procedures, the changes and renewal of and the supervision and inspection over Pharmaceutical Distribution Certificates. The CFDA and its local branches are responsible for the approval and issuance of the Pharmaceutical Distribution Certificates and the supervision over both Pharmaceutical Distribution Certificates and pharmaceutical distribution enterprises.

Guidelines on Good Supply Practices for Pharmaceutical Products and the Administrative Measures for Certification thereof

The Guidelines on Good Supply Practices for Pharmaceutical Products (藥品經營質量管理規範), which were promulgated by the NHFPC on January 22, 2013 and came into effect on June 1, 2013, and the Administrative Measures for the Certification of the Good Supply Practice for Pharmaceutical Products (藥品經營質量管理規範認證管理辦法), which were promulgated by the CFDA on April 24, 2003, provide that each retail or wholesale operator of pharmaceutical products must conduct business in accordance with the Good Supply Practices for Pharmaceutical Products, which comprise a set of quality guidelines for operations related to pharmaceutical products, and obtain the Good Supply Practices for Pharmaceutical Products Certificate (the "GSP Certificate") which is valid for five years and may be extended three months prior to its expiration upon a re-examination by the relevant authority.

Administrative Measures on the Supervision of the Distribution of Pharmaceutical Products

The Administrative Measures on the Supervision of the Distribution of Pharmaceutical Products (藥品流通監督管理辦法), which were promulgated by the CFDA on January 31, 2007 and came into effect on May 1, 2007, govern the procurement and sales of pharmaceutical products by pharmaceutical manufacturers and distribution enterprises as well as the procurement and storage of pharmaceutical products by medical institutions.

Regulations on Prescription Pharmaceuticals and Non-prescription Pharmaceuticals

The Measures for the Classification and Administration of Prescription Pharmaceuticals and Non-prescription Pharmaceuticals (For Trial Implementation) (處方藥與非處方藥分類管理辦法(試行)), which were promulgated by the CFDA on June 18, 1999 and came into effect on January 1, 2000, set forth the basic system for the classification and administration of prescription pharmaceuticals and non-prescription pharmaceuticals. Enterprises engaging in the wholesale distribution of prescription and non-prescription pharmaceuticals should obtain a Pharmaceutical Distribution Certificate.

The Interim Measures on the Distribution of Prescription Pharmaceuticals and Non-prescription Pharmaceuticals (處方藥與非處方藥流通管理暫行規定), which were promulgated by the CFDA on December 28, 1999 and came into effect on January 1, 2000, set forth further rules for the administration of the distribution of prescription and non-prescription pharmaceuticals.

Regulations on Centralized Pharmaceutical Procurement by Medical Institutions

The Opinions on Further Regulating Centralized Pharmaceutical Procurement by Medical Institutions (進一步規範醫療機構藥品集中採購工作的意見) and the Interpretations of Issues Related to the Opinions on Further Regulating Centralized Pharmaceutical Procurement by Medical Institutions (關於進一步規範醫療機構藥品集中採購工作的意見有關問題的說明), which were jointly promulgated by the NHFPC and other six departments on January 17, 2009 and June 19, 2009, respectively, as well as the Standards of Centralized Pharmaceutical Procurement Work for Medical Institutions (醫療機構藥品集中採購工作規範) jointly promulgated by the NHFPC and other six departments on July 7, 2010, stipulate that the general framework and detailed operational procedures with respect to the centralized

pharmaceutical procurement mechanism under which not-for-profit medical institutions established by governments or state-owned enterprises are required to procure pharmaceuticals through the not-for-profit centralized pharmaceutical procurement platform organized by the competent governmental authorities. Medical institutions of other forms, such as for-profit medical institutions, are also encouraged to participate in the centralized pharmaceutical procurement system. All pharmaceuticals used by medical institutions are required to be listed in the catalog of centralized pharmaceutical procurement with the exception of (i) narcotic pharmaceuticals and Class I psychotropic pharmaceuticals, (ii) certain pharmaceuticals under the state's special control such as Class II psychotropic pharmaceuticals, toxic pharmaceuticals for medical uses and radioactive pharmaceuticals, and (iii) Chinese herbs and ready-for-use Chinese herbs. The price generated by the centralized procurement activities of provinces, autonomous regions and municipalities directly under the central government shall be the supply price for pharmaceutical products supplied by pharmaceutical enterprises to all the medical institutions under the centralized pharmaceutical procurement mechanism and medical institutions shall apply the retail price of the pharmaceuticals as determined by the competent pricing control authority. Pharmaceutical manufacturers shall directly participate in the bidding activities during centralized pharmaceutical procurement. Delivery expenses for the bid-winning pharmaceuticals must also be included in the bid price. Bid-winning manufacturers are responsible for product delivery. They may choose to deliver the products either by themselves or through other qualified medical enterprises. If the commissioned enterprise fails to fulfill the delivery task and another medical enterprise needs to be commissioned, the bid-winning manufacturer shall lodge an application for review and approval by the competent provincial department of the medical procurement leading group, but the procurement prices of the bid-winning pharmaceuticals may not be increased under such circumstances.

Pursuant to the Opinions on Further Regulating the Price of Pharmaceuticals and Healthcare Services (關於進一步整頓藥品和醫療服務市場價格秩序的意見), which were jointly promulgated by the NDRC and other departments on May 19, 2006, the profit margin of the pharmaceuticals subject to government pricing sold by medical institutions shall not exceed 15% of the actual procurement cost of such pharmaceuticals, and the profit margin of ready-for-use Chinese herbs shall not exceed 25%.

Regulations on Medical Devices

Regulations on the Supervision and Administration of Medical Devices

The Regulations on the Supervision and Administration of Medical Devices (醫療器械監督管理條例) (the "Regulations on Medical Devices"), which were promulgated by the State Council on January 4, 2000 and came into effect on April 1, 2000, regulate the management of medical device manufactures and the supervision, distribution and use of medical devices as well as relevant legal obligations. Pursuant to the Regulations on Medical Devices, the government shall implement a product registration system for medical devices production. Enterprises to be established for marketing Class I medical devices shall file a record with the competent pharmaceutical regulatory department. Enterprises to be established for marketing Class II and/or Class III medical devices shall be examined and approved by the competent pharmaceutical regulatory department and obtain a Medical Device Marketing Enterprise License. The term of validity of a Medical Device Marketing Enterprise License is five years.

Measures on the Administration of the Medical Device Marketing Enterprise License

The Measures on the Administration of the Medical Device Marketing Enterprise License (醫療器械經營企業許可證管理辦法), which was promulgated by the CFDA on August 9, 2004 and came into effect on the same day, stipulate the specific regulations over the application requirements and procedures, change and renewal of the Medical Device Marketing Enterprise License and relevant supervision, examination and legal responsibilities. The CFAD and its local branches is responsible for the approval and issuance of the Medical Device Marketing Enterprise License and the supervision over these license holders.

Regulations on the Supervision Over the Procurement of Medical Consumables

Rules on Collective Procurement of High Value Medical Consumables

The Standardized Rules on the Collective Procurement of High Value Medical Consumables (For Trial Implementation) (高值醫用耗材集中採購工作規範(試行)), which were jointly promulgated by the MOH, the State Council Office for Correcting Illegitimate Industrial Practices (國務院糾正行業不正之風辦公室), the NDRC, the Ministry of Supervision of the PRC (中華人民共和國監察部), SAIC and the CFDA on December 17, 2012, state that high value medical consumables, such as orthopedic implants and pacemakers, may only be purchased by means of collective procurement by qualified not-for-profit medical institutions run by the government at the county-level or above or by state-owned enterprises. Such medical institutions must not purchase high value medical consumables outside the scope of medical consumables listed for collective procurement without the prior approval of relevant authorities.

Administrative Measures on Pricing of Medical Consumables

In accordance with the Administrative Measures for the Collective Procurement and Pricing of Medical Consumables in Beijing (For Trial Implementation) (北京市醫用耗材集中招標採購價格管理辦法(試行)), which was promulgated by the Beijing Price Bureau on November 6, 2002 and become effective on November 10, 2002, and the Notice on the Standardization and Cancellation of Fees for Certain Medical Consumables (關於規範和取消部分醫療服務項目收費的通知), which was promulgated by the Beijing Municipal Commission of Development and Reform and the Beijing Municipal Health Bureau on January 25, 2007 and become effective on March 1, 2007, the mark-up on the retail price of medical consumables must not exceed 10% for items priced RMB500 or less, or 5% for items priced over RMB500.

LEGAL SUPERVISION OVER FOREIGN INVESTMENT IN CHINA

Wholly Foreign-Owned Enterprise Law of the People's Republic of China and its implementation measures

The Wholly Foreign-Owned Enterprise Law of the People's Republic of China (中華人民共和國外資企業法), which was promulgated by the Standing Committee of the NPC on October 31, 2000 and came into effect on the same day, and the Implementation Measures for the Wholly Foreign-Owned Enterprise Law (中華人民共和國外資企業法實施細則), which were promulgated by the State Council on April 12, 2001 and came into effect on the same day, stipulate that foreign enterprises and other economic organizations or individuals may establish wholly foreign-owned enterprises ("WFOEs") in China. The application for the establishment of a WFOE is subject to the examination and approval by the competent commercial departments before an Approval Certificate is issued.

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

The Interim Provisions on Investment Made by Foreign-Invested Enterprises in China (關於外商投資企業境內投資的暫行規定), which were jointly promulgated by MOFCOM and the State Administration of Industry and Commerce on July 25, 2000, stipulate that the provisions of the Interim Provisions Guiding Foreign Investment Direction and the Industry Catalog for Guiding Foreign Investment will govern foreign-invested enterprises' investment in China. Foreign-invested enterprises are not permitted to invest in any sector prohibited to foreign investment. Where a foreign-invested enterprise makes investment in a restricted sector, the foreign-invested enterprise must file an application with the provincial commercial department of the place where the investee company is located. The relevant company registration authority will, in accordance with the relevant provisions of the Company Law and the Regulations on the Administration of Company Registration of the People's Republic China (中華人民共和國公司登記管理條例), decide whether to approve the registration or not. If the registration is approved, a Business License of an Enterprise Legal Person will be issued with the designation "Invested by a Foreign-Invested Enterprise" added. The foreign-invested enterprise is required to report the establishment of the investee company within 30 days of the date of its establishment to the original examination and approval authority for record-filing.

Notice on Further Encouraging and Guiding Private Capital to Invest in Medical Institutions

Pursuant to Order No. 58 (關於進一步鼓勵和引導社會資本舉辦醫療機構意見的通知), foreign investors are permitted to set up for-profit or not-for-profit medical institutions in China as foreign-invested projects. Overseas medical institutions, enterprises and other economic organizations are permitted to establish medical facilities together with domestic medical institutions, enterprises or other economic organizations in the form of equity or cooperative joint ventures, and the restrictions on equity proportion for foreign capital will be gradually removed. A pilot program will be introduced and gradually expanded to permit eligible foreign investors to set-up wholly foreign owned medical institutions.

The Industry Catalog for Guiding Foreign Investment and Interim Provisions Guiding Foreign Investment Direction

The current Industry Catalog for Guiding Foreign Investment (外商投資產業指導目錄) (the "Foreign Investment Catalog was jointly promulgated by the NDRC and MOFCOM on December 24, 2011 and came into effect on January 30, 2012, and the Interim Provisions Guiding Foreign Investment Direction (指導外商投資方向規定), which were promulgated by the State Council on February 11, 2002 and came into effect on April 1, 2002, classify all foreign investment projects into four categories: (1) encouraged projects, (2) permitted projects, (3) restricted projects, and (4) prohibited projects. If the industry in which the investment is to occur falls into the encouraged category, foreign investment, in certain cases, may enjoy preferential policies or benefits. If restricted, foreign investment may be conducted in accordance with applicable legal and regulatory restrictions. If prohibited, foreign investment of any kind is not allowed. Medical institutions and pharmaceutical wholesale industries were moved from the restricted industry category into permitted industry category with the promulgation of the Foreign Investment Catalog (2011).

LEGAL SUPERVISION OVER THE LABOR PROTECTION IN CHINA

Labor Law of the People's Republic of China

The Labor Law (中華人民共和國勞動法), which was promulgated by the Standing Committee of the NPC on July 5, 1994, came into effect on January 1, 1995, and was amended on August 27, 2009, provides that an employer shall develop and improve its rules and regulations to safeguard the rights of its workers. An employer shall develop and improve its labor safety and health system, stringently implement national protocols and standards on labor safety and health, conduct labor safety and health education for workers, guard against labor accidents and reduce occupational hazards. Labor safety and health facilities must comply with relevant national standards. An employer must provide workers with the necessary labor protection equipment that complies with labor safety and health conditions stipulated under national regulations, as well as provide regular health checks for workers that are engaged in operations with occupational hazards. Workers engaged in special operations shall have received specialized training and obtained the pertinent qualifications. An employer must develop a vocational training system. Vocational training funds must be set aside and used in accordance with national regulations and vocational training for workers must be carried out systematically based on the actual conditions of the company.

Labor Contract Law of the People's Republic of China and its implementation regulations

The Labor Contract Law (中華人民共和國勞動合同法), which was promulgated by the Standing Committee of the NPC on June 29, 2007, came into effect on January 1, 2008, and was amended on December 28, 2012, and the Implementation Regulations on Labor Contract Law (勞動合同法實施條例) which were promulgated on September 18, 2008 and came into effect on the same day, regulate employer and the employee relations and contain specific provisions involving the terms of the labor contract. Labor contracts must be made in writing and may, after reaching agreement upon due negotiations, be for a fixed-term, an un-fixed term, or conclude upon the completion of certain work assignments. An employer may legally terminate a labor contract and dismiss its employees after reaching an agreement upon due negotiations with the employee or by fulfilling the statutory conditions.

Laws and Regulations on the Supervision over the Social Security and Housing Funds

According to the Temporary Regulations on the Collection and Payment of Social Insurance Premium (社會保險費徵繳暫行條例), the Regulations on Work Injury Insurance (工傷保險條例), the Regulations on Unemployment Insurance (失業保險條例) and the Trial Measures on Employee Maternity Insurance of Enterprises (企業職工生育保險試行辦法), enterprises in China must provide benefit plans for their employees, which include basic pension insurance, unemployment insurance, maternity insurance, work injury insurance and medical insurance. An enterprise must provide social insurance by processing social insurance registration with local social insurance agencies, and must pay or withhold relevant social insurance premiums for or on behalf of employees. The Law on Social Insurance (中華人民共和國社會保險法), which was promulgated on October 28, 2010 and came into effect on July 1, 2011, regulate basic pension insurance, unemployment insurance, maternity insurance, work injury insurance and medical insurance, and has elaborated in detail the legal obligations and liabilities of employers who do not comply with relevant laws and regulations on social insurance.

The Regulations on the Administration of Housing Provident Fund (住房公積金管理條例), which were promulgated and came into effective on April 3, 1999, and were amended on March 24, 2002, stipulate that housing provident fund contributions paid by an individual employee and housing provident fund contributions paid by his or her employer all belong to the individual employee.

LEGAL SUPERVISION OVER TAXATION IN CHINA

Enterprise Income Tax

According to the Enterprise Income Tax Law (中華人民共和國企業所得税法) (the "EIT Law"), which was promulgated by the NPC on March 16, 2007 and came into effect on January 1, 2008, and the Implementation Regulations on the EIT Law (企業所得税法實施條例), which were promulgated by the State Council on December 6, 2007 and came into effect on January 1, 2008, a uniform income tax rate of 25% will be applied to domestic enterprises, foreign-invested enterprises and foreign enterprises that have established production and operation facilities in China. These enterprises are classified as either resident enterprises or non-resident enterprises.

Resident enterprises refer to enterprises that are established in accordance with PRC laws, or that are established in accordance with the laws of foreign countries but whose actual or de facto control is administered from within the PRC. Non-resident enterprises refer to enterprises that are set up in accordance with the laws of foreign countries and whose actual administration is conducted outside the PRC, but who (whether or not through the establishment of institutions in the PRC) derive income from the PRC. Under the EIT Law and relevant implementing regulations, a uniform corporate income tax rate of 25% is applicable. However, if non-resident enterprises have not established institutions in the PRC, or if they have established institutions in the PRC but there is no actual relationship between the relevant income derived in the PRC and the institutions set up by them, enterprise income tax is set at the rate of 10%.

Withholding Tax and International Tax Treaties

According to the Treaty on the Avoidance of Double Taxation and Tax Evasion between Mainland and Hong Kong (內地和香港特別行政區關於對所得避免雙重徵税和防止偷漏税的安排) (the "Tax Treaty"), if the non-PRC parent company of a PRC enterprise is a Hong Kong resident which beneficially owns a 25% or more interest in the PRC enterprise, the 10% withholding tax rate applicable under the EIT Law may be lowered to 5% for dividends and 7% for interest payments once approvals have been obtained from the relevant tax authorities. The determination of beneficial ownership is clarified under the Notice on Understanding and Determining Beneficial Owners (國家税務總局關於如何理解和認定税收協定中「受益所有人」的通知) issued by the SAT on October 27, 2009, which expressly excludes from the definition of a beneficial owner any company not engaged in actual operations such as manufacturing, sales or management but that is established for the purpose of avoiding or reducing tax obligations or transferring or accumulating profits.

Pursuant to the Notice on the Several Issues of the Implementation of Tax Treaty (國家税務總局關於執行税收協定股息條款有關問題的通知), which was promulgated by the SAT and came into effect on February 20, 2009, the non-resident taxpayer or the withholding agent is required to obtain and keep sufficient documentary evidence proving that the recipient of the dividends meets the relevant requirements for enjoying a lower withholding tax rate under a tax treaty if the main purpose of an offshore transaction or arrangement is to obtain a preferential tax treatment.

Pursuant to the Trial Administrative Measures on Non-residents to Enjoy the Treatment Under Tax Treaties (非居民享受税收協議待遇管理辦法(試行)的通知), which were promulgated by the SAT on August 24, 2009 and came into effect on October 1, 2009, and the Supplemental Notice on Several Issues of the Trail Administrative Measures on Non-residents to Enjoy the Treatment Under Tax Treaties (關於「非居民享受税收協定待遇管理辦法(試行)」有關問題的補充通知), which was promulgated by on June 21, 2010, a non-resident enterprise subject to taxation is required to obtain approval from the relevant tax administration department before it may enjoy a tax reduction or exemption under the dividend provision of a tax treaty.

Business Tax

The Temporary Regulations on Business Tax (營業税暫行條例), which were promulgated by the State Council on December 13, 1993, became effective on January 1, 1994, and amended on November 10, 2008 and came into effect on January 1, 2009, provide that entities and individuals must pay business tax if they are engaged in the provision of services with respect to the industries of transportation, construction, finance and insurance, post and telecommunication, culture and sports, entertainments and service prescribed in Temporary Regulations on Business Tax, or transfer of intangible assets or sale of real estate within China's territory. Healthcare services provided by hospitals, clinics and other medical institutions are exempt from business tax.

Value-added Tax

The Temporary Regulations on Value-added Tax (增值税暫行條例), which were promulgated by the State Council on December 13, 1993, came into effect on January 1, 1994, and amended on November 10, 2008, and the Detailed Implementing Rules of the Temporary Regulations on Value-added Tax (增值税暫行條例實施細則), which were promulgated by the MOF and became effective on December 25, 1993, and were amended on December 15, 2008 and October 28, 2011, set out that all taxpayers selling goods or providing processing, repairing or replacement services and importing goods in China shall pay a value-added tax. A tax rate of 17% shall be levied on general taxpayers selling or importing various goods and on taxpayers providing processing, repairing or replacement service; the applicable rate for the export of goods by taxpayers shall be nil, unless otherwise stipulated.

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

LEGAL SUPERVISION OVER FOREIGN EXCHANGE IN CHINA

The Regulations on the Control of Foreign Exchange (外匯管理條例), which were promulgated by the State Council on January 29, 1996, came into effect on April 1, 1996, and amended on January 14, 1997 and August 5, 2008, set out that foreign exchange receipts of domestic institutions or individuals may be transferred to China or deposited abroad and that SAFE shall specify the conditions for transfer to China or overseas and other requirements in accordance with the international receipts, payments status and requirements of foreign

exchange control. Foreign exchange receipts for current account transactions may be retained or sold to financial institutions engaged in the settlement or sale of foreign exchange. Domestic institutions or individuals that make direct investments abroad or are engaged in the distribution or sale of valuable securities or derivative products overseas should register according to SAFE regulations. Such institutions or individuals subject to prior approval or record-filing with other competent authorities shall complete the required approval or record-filing prior to foreign exchange registration. The exchange rate for RMB follows a managed floating exchange rate system based on market demand and supply.

The Regulations on the Administration of the Settlement, Sale and Payment of Foreign Exchange (結匯、售匯及付匯管理規定), which were promulgated by the PBOC on June 20, 1996 and came into effect on July 1, 1996, provide that foreign exchange receipts under the current account of foreign-invested enterprises may be retained to the fullest extent specified by the foreign exchange bureau. Any portion in excess of such amount shall be sold to a designated foreign exchange bank or through a foreign exchange swap center.