This section sets out summaries of certain aspects of the PRC laws and regulations, which are relevant to our Group's operation and business.

PROVISIONS ON FOREIGN INVESTMENT

The establishment, operation and management of corporate entities in the PRC are governed by the Company Law of the PRC (中華人民共和國公司法) (the "**Company law**"), which was promulgated by the Standing Committee of the National people's Congress on 29 December 1993 and became effective on 1 July 1994. It was subsequently amended on 25 December 1999, 28 August 2004 and 27 October 2005 respectively. The companies are classified into categories – limited liability companies and limited companies by shares. The Company Law shall also apply to foreign-invested limited liability companies. According to the Company Law, where laws on foreign investment have other stipulations, such stipulations shall apply.

The establishment procedures, verification and approval procedures, registered capital requirement, foreign exchange restriction, accounting practices, taxation and labour matters of a wholly foreign-owned enterprise are also regulated by the Wholly Foreign-owned Enterprise Law of the PRC (中華人民共和國外資企業法), which was promulgated on 12 April 1986 and amended on 31 October 2000, and the Implementation Regulation of the Wholly Foreign-owned Enterprise Law (中華人民共和國外資企業法實施細則), which was promulgated on 12 December 1990 and amended on 12 April 2001.

Investment in the PRC conducted by foreign investors and foreign-owned enterprises is governed by the Guidance Catalogue of Industries for Foreign Investment (外商投資產業指導目錄) (the "**Catalogue**"), which was promulgated by the Ministry of Commerce and the NDRC on 24 December 2011 and became effective on 30 January 2012. The Catalogue is a long-standing tool that PRC policymakers have used to manage and direct foreign investment. The Catalogue divides industries into three basic categories: encouraged industries, restricted industries and prohibited industries. Foreign investors and foreign-owned enterprises are not allowed to make investments which fall under the "prohibited" industry under the Catalogue. Industries not listed in the Catalogue are generally open to foreign investment unless specifically barred in other PRC regulations.

The "manufacturing of modern Chinese medicines with confidential proprietary formula" (中成藥保密處方產品的生產) is classified as "prohibited" under the Catalogue, but as advised by our PRC Legal Advisers and Jia Yuan Law Offices, the PRC legal advisers to the Underwriters, there is no clear definition of confidential proprietary formula under the Catalogue, and there is no provision under the Catalogue stating that foreign investors and foreign-owned enterprises are prohibited from manufacturing and sale of medicines with State Secret status. To clarify whether our uremic clearance granule's past State Secret status falls into the "prohibited" category, in November 2013, our PRC Legal Advisors and Jia Yuan Law Offices consulted the Bureau of Commerce of Inner Mongolia autonomous region (內蒙古自治區商務廳) (the "**Inner Mongolia DOC**"), which is a provincial branch of the Ministry of Commerce. Our PRC Legal Advisers and Jia Yuan Law Offices advised that the Ministry of Commerce, which promulgated the Catalogue jointly with the NDRC, is the major administrative body of the foreign investment matters in the PRC and it has the ultimate right to interpret the provisions under the Catalogue. Our PRC Legal Advisers and Jia Yuan Law Offices were directed by the Inner Mongolia DOC to consult the Department of Food and Drug Administration of Inner Mongolia autonomous region (內蒙古自治區食品藥品監督管理局) (the "**Inner Mongolia FDA**"). Accordingly, they consulted the Inner Mongolia FDA, a provincial branch of the CFDA which regulates medicines with confidential proprietary formula. The Inner Mongolia FDA verbally confirmed that only medicines which are recognised as class one (and not other classes) national Chinese medicine protection type by the CFDA qualify as having the confidential proprietary formula.

In addition, in November 2013, our PRC Legal Advisers and Jia Yuan Law Offices also consulted the Department of Science and Technology of Inner Mongolia autonomous region (內蒙古自治區科技廳) (the "**Inner Mongolia S&T**"), the provincial branch of Ministry of Science and Technology which granted the State Secret status to our uremic clearance granule jointly with the State Secrecy Bureau (國家保密局). The Inner Mongolia S&T verbally confirmed that medicines with State Secret status are regulated by the Ministry of Science and Technology while medicines with confidential proprietary formula are regulated by the CFDA and accordingly the two are different. Our PRC Legal Advisers and Jia Yuan Law Offices confirmed that the Ministry of Science and Technology or its branches has the right to interpret the Regulations on Protection of Scientific Technologies (科學技術保密規定) as it is the administrative authority of the application and renewal of the State Secret status, and that the State Secrecy Bureau should not override its interpretation.

Based on the confirmations from the Inner Mongolia S&T and the Inner Mongolia FDA:

(a) in view of the recognition of our uremic clearance granule as class two (but not class one) national Chinese medicine protection type by the CFDA, our PRC Legal Advisers and Jia Yuan Law Offices advised that our uremic clearance granule is not regarded as medicines with confidential proprietary formula (中成藥保密處方產品); and

(b) the commissioner of the foreign investments management (外商投資管理處處長) of the Inner Mongolia DOC agreed with the interpretation of the Inner Mongolia FDA. After consultation with the Ministry of Commerce of the PRC, he verbally confirmed that (i) our Group's manufacture and sale of uremic clearance granule since its production and sale do not fall under the prohibited category of the Catalogue, and have complied with the relevant PRC rules and regulations relating to foreign investments; (ii) our Group has not and will not be subject to any penalty under the relevant foreign investments rules and regulations due to our manufacture and sale of uremic clearance granule; and (iii) our Group is permitted to continue to manufacture and sell uremic clearance granule in the future.

The Development and Reform Commission of the Inner Mongolia autonomous region (內蒙古自治區發展和改革委員會), a provincial branch of the NDRC, also verbally confirmed that they agreed with the above confirmations from the Inner Mongolia DOC.

As confirmed by our PRC Legal Advisers and Jia Yuan Law Offices, we are in full compliance with the Catalogue and comply with all relevant PRC rules and regulations.

MEDICINE ADMINISTRATIVE REGULATORY FRAMEWORK

As a manufacturer and distributor of pharmaceutical products, we are subject to regulation and oversight by different levels of the food and medicine administration in the PRC, in particular, CFDA. Our products are subject to regulatory controls governing pharmaceutical products. The Law of the PRC on the Administration of Pharmaceuticals (中華人民共和國藥品管理法), which was promulgated by the Standing Committee of the National People's Congress on 20 September 1984 and came into effect on 1 July 1985, as amended on 28 February 2001 and came into effect on 1 December 2001, together with its implementation regulations, provides the legal framework for the administration of the production and sale of pharmaceutical products in the PRC which covers the manufacturing, distributing, registration, packaging, pricing and advertising of pharmaceutical products in the PRC.

We are also subject to other PRC laws and regulations that regulate the manufacturing and distribution of pharmaceutical products.

Principal administrative authorities

As the competent authority of the industry, the CFDA is responsible for administrative supervision and technical supervision over the research, production, circulation and usage of medicines, including Chinese medicines. The local medicine administrative authorities at the level of provinces, autonomous regions and municipalities directly under the PRC central government are responsible for supervision and administration of medicines within their respective administrative regions.

In accordance with the state laws, rules, regulations and policies relating to health and medicines and in light of the characteristics of the traditional Chinese medicine industry, the State Administration of Traditional Chinese Medicine (國家中醫藥管理局) is responsible for the guidance and implementation of fundamental works such as guidelines, policies, development strategies, qualification management and techniques of the Chinese medicine industry.

The Ministry of Health is responsible for multiple supervisions over medicines regulation, including, but not limited to, enforcing the medical and health system reform, formulating and implementing the national essential medicines system (國家基本藥物制度), formulating the national medicines codes (國家藥品法典) and the National List of Essential Medicines, proposing the pricing policy of medicines within the National List of Essential Medicines and supervising medical institutions.

NDRC is responsible for the macro-guidance and management of the healthcare industry's development planning, and the supervision and management over the price of medicines.

MANUFACTURE

Research and development

Institutions engaging in research for applications for clinical trials and production of medicines are required to register in accordance with Pharmaceutical Product Research Institution Filing Procedures (Trial) (藥品研究機構登記備案管理辦法(試行)), which was promulgated on and effective from 15 October 1999 by the State Drug Supervision and Administration Bureau, the predecessor of the CFDA. Research institutions engaged in conducting clinical trials of medicines are required to carry out their clinical trials in accordance with the Administrative Standards of Pharmaceuticals Clinical Trials (藥物臨床試驗質量管理規範) promulgated by the CFDA on 6 August 2003 and effective from 1 September 2003, which apply to the design, organisation, implementation, supervision, recording, analysis and reporting of clinical trials conducted following approval from the CFDA. Research institutions engaged in conducting pre-clinical research are required to carry out their research activities in accordance with Administrative Standards of the Pharmaceuticals Non-Clinical Research (藥物非臨床研究質量管理規範) promulgated by the CFDA on 6 August 2003 and effective from 1 September 2003, which apply to research on, among others, synthetic techniques, extraction method, chemical nature and purity, forms of intake, production methods, examination methods, quality standards, stability, and toxicity studies of a medicine conducted prior to the submission of the application for clinical trials to the CFDA. If certain actions in the pre-clinical trial research and clinical research conducted for a clinical application trial, and/or in the application procedures for registration of medicines, are in violation of the relevant rules and regulations, the CFDA is authorised to handle such cases pursuant to the Measures regarding Noncompliance with Relevant Rules of Research and Application for Registration of Medicines (藥品研究和申報註冊違規處理辦法(試行)) promulgated on and effective from 1 September 1999.

Pharmaceutical products' manufacturing

Manufacturing licenses and approvals

Each pharmaceutical manufacturing enterprise is required to obtain a Medicine Manufacturing Permit and a business license. Pursuant to the Law of the PRC on the Administration of Pharmaceuticals, its implementation regulations (中華人民共和國藥品管理法實施條例), which was promulgated on 4 August 2002 by the State Council and effective from 15 September 2002, and the Measures on the Supervision and Administration of the Manufacture of Pharmaceuticals (藥品生產監督管理辦法) promulgated by the CFDA on 5 August 2004 and effective from 5 August 2004, the Medicine Manufacturing Permit is issued by local medicine administrative authorities at the provincial level. The grant of such permit is subject to an inspection of the manufacturing facilities, and a finding that their staff qualification, the surroundings, sanitary conditions, quality assurance systems, management structure and equipment meet the required standards. Each Medicine Manufacturing Permit is valid for five years and may be renewed at least six months prior to its expiration date upon re-examination by the relevant authority.

Good Manufacturing Practices (藥品生產質量管理規範) ("GMP")

A GMP certificate is required for the production of each dosage form of pharmaceutical products. And GMP, which was promulgated by the Ministry of Health on 17 January 2011 and became effective on 1 March 2011, is a set of detailed basic guidelines on manufacture and quality control of pharmaceutical products, with the propose of ensuring that products are consistently manufactured appropriate to their intended use and statutory registration requirements for the pharmaceutical products, by minimising the risks of contamination, cross contamination, mix-ups and/or errors during the manufacture processing.

GMP certification criteria include sections regarding quality control, institution and staff qualifications, hygiene requirements for the staff, production premises and facilities, equipment, material and products, recognition and inspection, documentation maintenance, manufacture management, quality control and quality assurance, contractual manufacture and contractual inspection for the products, product distribution and recalls and self-inspection.

Under the Administrative Measures for Certification of the Good Manufacturing Practices (藥品生產質量管理規範認證管理辦法) promulgated on and effective from 2 August 2011 by the CFDA, a new pharmaceutical manufacturer, or a pharmaceutical manufacturer that extends its manufacturing scope or establishes a new workshop shall apply for GMP certification, and where a pharmaceutical manufacturer rebuilds or extends its existing plants or production lines, it shall reapply for GMP certification. GMP certificates shall be renewed no later than six months before the expiry of its valid term. Such renewal shall be granted upon re-examination by the relevant authority.

Approval and registration

Registration of New Medicine Certificate

According to the Registration Measures, promulgated by the CFDA on 10 July 2007 and effective from 1 October 2007, New Medicines refer to those products which have never been launched in the PRC market previously. Pharmaceutical products taking different dosage forms or route of administration or having curative effects for additional diseases are treated as New Medicines.

New Medicines are registered under three different types: Chinese medicines and natural medicine, chemical pharmaceutical products and biochemical products, each of which are divided into different categories. Different requirements are applicable to the registration under different types.

All New Medicines must undergo four phases before the launching: pre-clinical research, application for clinical trials, clinical trials and approval of production.

Upon the completion of pre-clinical research, pharmaceutical product manufacturers are required to obtain approval from the CFDA prior to commencement of clinical trials of any New Medicine.

Clinical trials comprise four phases: phase I (preliminary pharmacology and human safety trials), phase II (preliminary assessment on therapeutic efficacy), phase III (confirmation of therapeutic efficacy) and phase IV (research on applications after launching of New Medicines). The number of tested cases of clinical trials shall accord with the aim of each phase of clinical trials and relevant statistical requirements, and shall not be less than the statuary minimum number of clinical trial cases, save for otherwise approved by CFDA in the case of rare diseases, special diseases and other exceptional circumstances.

Upon the completion of clinical trials, the applicant shall also apply for an approval to manufacture the New Medicines. If approved, the applicant will be granted a New Medicine Certificate and an approved pharmaceutical number. The manufacturer may then commence mass production of the New Medicine.

The CFDA may stipulate a monitoring period of up to five years in respect of any New Medicine approved for production to monitor the safety of such New Medicine on an ongoing basis. The CFDA will not approve the production, change and import of such New Medicine by other enterprises during the monitoring period. No applications for the registration of similar pharmaceutical products by other applicants shall be accepted after the commencement of the monitoring period for such New Medicine. Applications for the registration of pharmaceutical products of similar products by other applicants that have been accepted but have not been approved to begin clinical trials shall be returned. However, after a New Medicine enters the monitoring period, for other applications whose clinical trial have already been approved by CFDA, the on-going application shall continue in the regular review process, and CFDA may approve the production or import of that application in compliance with the requirements, as well as monitor the New Medicine produced by the pharmaceutical manufacturer within PRC. Upon the expiration of the monitoring period of New Medicine, applicants may file an application in respect of their Generic Medicines or for the import of similar pharmaceutical products.

Under the Administrative Measures on the Special Examination and Approval of New Medicine Registration (新藥註冊特殊審批管理規定), which was promulgated and implemented since 7 January 2009 by the CFDA, certain types of New Medicines may apply to go through the special examination and approval process when submitting the application for clinical trials or the application of production.

Registration of Generic Medicines

Generic Medicines are those that have already been launched in the PRC market and are in compliance with applicable national standards set by the PRC government.

For Generic Medicines, the applicants need to go through at least two processes, which are pre-clinical research and the application of production; and clinical trials could be required where the CFDA deem necessary. All the applicants shall begin the manufacture after obtaining the production approval by the CFDA.

Immediate packaging materials and containers of medicines

According to the Law of the PRC on the Administration of Pharmaceuticals (中華人民共和國藥品管理法), together with its implementation regulations, and Administrative Provisions on Immediate Packaging Materials and Containers (直接接觸藥品的包裝材料和容器管理辦法), which was promulgated by CFDA on 20 July 2004, immediate packaging materials and containers shall meet the requirements for medicinal use and the standards for ensuring human health and safety. CFDA shall promulgate the registered immediate packaging materials and containers catalog and implement registration management to the products of the catalog.

Pharmaceutical gelatin capsules and capsule medicines

According to Circular on Strict Implementation of Batch Testing regarding the Pharmaceutical Gelatin Capsules and Capsule Medicines (關於嚴格實施藥用明膠膠囊和膠囊劑藥品批批檢的公告), which was promulgated by CFDA on 27 April 2012, and Notice on Strengthening the Quality Administration of the Capsule Medicines and Relevant Products (關於加強膠囊劑藥品及相關產品品質管理工作的通知), which was promulgated by CFDA on 28 April 2012 and came into effect on 1 May 2012, together with a series of following notices promulgated by CFDA, the manufacturers of capsule medicine shall purchase pharmaceutical capsules from the enterprise with a production qualification approval number for such pharmaceutical capsules, and the pharmaceutical capsules, as well as the capsule medicines, shall be tested by batch by the pharmaceutical manufacturing enterprise.

Pharmaceutical directions and labels

According to the Law of the PRC on the Administration of Pharmaceuticals (中華人民共和國藥品管理法), together with its implementation regulations, and Administrative Provisions on Pharmaceutical Directions and Labels (藥品說明書和標籤管理規定), which was promulgated by CFDA on 15 March 2006 and came into effect on 1 June 2006, a label shall be printed or stuck on the drug package, which shall indicate the adopted name of the drug used in PRC, its ingredients specification, manufacturer, approval number, product batch number, production date, date of expiry, indications or functions, usage, dosage, contraindications, adverse drug reactions, and precautions. The smallest packages produced by a pharmaceutical manufacturing enterprise for sale on the market must be attached with directions. The pharmaceutical directions shall include important scientific data, conclusion and information on its safety and effectiveness, so as to guide the safe and reasonable usage of the medicine.

DISTRIBUTION

Medicine Operation Certificate

The establishment of a wholesale pharmaceutical distribution company requires the approval of the provincial medicine administrative authorities. Upon approval, the authority will grant a Medicine Operation Certificate in respect of the wholesale pharmaceutical product distribution company. The establishment of a retail pharmacy store requires the approval of the local medicine administrative authorities at or above the county level. Upon approval, the authority will grant a Medicine Operation Certificate in respect of the retail pharmacy store. Once these permits are received, the wholesale or retail pharmaceutical company (as the case may be) shall be registered with the relevant local branch of SAIC.

Under the Measures for the Administration of Pharmaceutical Operation Permit (藥品經營許可證管理辦法) promulgated by the CFDA on 4 February 2004 and effective from 1 April 2004, a Medicine Operation Certificate is valid for five years. Each holder of the Medicine Operation Certificate must apply for an extension of its permit six months prior to expiration.

Good Supply Practices (藥品經營質量管理規範) ("GSP")

Each retail or wholesale operator of pharmaceutical products is required to obtain a GSP certificate from the relevant medicine administrative authorities prior to commencing its business. GSP constitutes the basic standards in management of operation quality of medicines and shall apply to enterprises exclusively or concurrently engaged in medicine operation within the PRC. The current applicable GSP standards require pharmaceutical operators to implement strict controls on its operation of pharmaceutical products, including standards regarding staff qualifications, premises, warehouses, inspection equipment and facilities, management and quality control. Under the Administrative Measures for Certification of Good Supply Practices (藥品經營質量管理規範認證管理辦法) promulgated on and effective from 24 April 2003 by the CFDA, the GSP certificate is generally valid for five years and may be extended three months prior to its expiry of its valid term.

Supervision and management of medicine distribution

Under Method of Supervision and Management of Drug Distribution (藥品流通監督管理辦法), which was issued by the CFDA on 31 January 2007 and came into effect on 1 May 2007, detailed provisions are imposed on aspects such as the purchase, sale, transportation and storage of medicines by pharmaceutical production and operation enterprises as well as the purchase and storage of medicines by pharmaceutical institutions.

Online pharmaceutical information service permit

The Measures regarding the Administration of Drug Information Service Over the Internet (互聯網藥品信息服務管理辦法), promulgated and implemented since 8 July 2004 by the CFDA, define the delivery of free publicly available medicine information services over the Internet as a non-profit online medicine information service. This service requires a qualification certificate from the relevant provincial medicine administrative authorities. The qualification certificate is valid for five years and may be renewed by filing for a renewal at least six months prior to its expiration date and undergoing re-examination by the relevant authority.

Statutory tender process requirements for hospital procurement of medicines

Pursuant to The Guiding Opinions concerning the Urban Medical and Health System Reform (關於城鎮醫藥衛生體制改革的指導意見) promulgated on 16 January 2000 by the State Commission for Restructuring Economic Systems and seven other ministries and commissions in the PRC, medical institutions shall be divided into two catalogues, i.e. non- profit medical institutions and profitable medical institutions. The Opinions also state that the Ministry of Health and other relevant authorities shall implement the pilot program of the centralised tender system for the procurement of pharmaceutical products in accordance with the Tendering and Bidding Law of the PRC.

According to Implementing Rules of the Urban Medical Institution Classified Administration (關於城鎮醫療機構分類管理的實施意見), which was jointly promulgated by the Ministry of Health and the other three governmental departments on 18 July 2000 and came into effect on 1 September 2000, medical institutions shall be divided into two catalogues, i.e. non-profit medical institutions and profitable medical institutions. Non-profit medical institutions are established for the public service purpose,and the earnings shall be used for the maintenance and development of such

institutions; while profitable medical institutions are established for investment returns by their investors, and the PRC government will not establish profitable medical institutions. A medical institutional shall be classified as non-profit or profitable when it is established.

According to the Notice on Issuing Certain Regulations on the Trial Implementation of Centralised Procurement of Pharmaceutical Products by Medical Organisations (關於印發醫療機構藥品集中招標採購試點工作若干規定的通知) promulgated on 7 July 2000 by the Ministry of Health and four other ministries and commissions and the Notice on Further Improvement on the Implementation of Centralised Procurement of Pharmaceutical Products by Medical Organisations (關於進一步做好醫療機構藥品集中招標採購工作的通知) promulgated on 23 July 2001 by the Ministry of Health and five other ministries and commissions, non-profit medical institutions established by the PRC government at the county level or higher are required to implement a centralised tender system for the procurement of pharmaceutical products. And the non-profit medical institutions belonging to the PRC government at the county level or above shall comply with the centralised tender process requirements when purchasing medicines in the National Medical Insurance Medicines Catalogue and medicines that are consumed in large volumes and commonly prescribed for clinical uses. In principal, the tender process shall be operated and organised by the public offer purchasing agencies.

On 12 November 2001, the Ministry of Health and five other ministries and commissions jointly promulgated the Working Regulations of Medical Institutions for Procurement of Medicines by Centralised and Price Negotiations (Trial) (醫療機構藥品集中招標採購工作規範(試行)) (the "**Working Regulations (Trial)**"), which was repealed on 7 July 2010, to implement the tender process requirements and ensure the requirements are followed uniformly throughout the country.

In November 2001, the Ministry of Health also promulgated the Sample Document for Medical Institutions for Procurement of Medicines by Centralised and Price Negotiations (Trial) (醫療機構藥品集中招標採購和集中議價採購文件範本(試行)) (the "**Sample Document**") as the operational document of the Working Regulations (Trial). The Working Regulations (Trial) and the Sample Document provide rules for the tender process and negotiations of the prices of pharmaceutical products, operational procedures, a code of conduct, and standards or measures for evaluating bids and negotiating prices.

According to the Working Regulations (Trial), the centralised tender system for the procurement of pharmaceutical products shall be participated by both the pharmaceutical manufacturers and the wholesale pharmaceutical distribution companies.

On 23 September 2004, the Ministry of Health and the other relevant PRC government authorities promulgated the Provisions on Further Regulating Procurement of Medicines by Medical Institutions through Centralised Tendering (關於進一步規範醫療機構藥品集中招標採購的若干規定) to modify and perfect the tender process system.

On 17 January 2009 and 7 July 2010, the Ministry of Health and other relevant PRC government authorities promulgated the Opinions concerning Further Regulating Centralised Procurement of Medicines 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) and the Working Regulations of Medical Institutions for Centralised Procurement of Medicines (醫療機構藥品集中採購工作規範) (the "**Working Regulations**"), and replaced the Working Regulations (Trial) at the same time. Under the Working Regulations, save for otherwise described in the working Regulations, all the non-profit medical institutions at the county level or higher established and/or controlled by the PRC government shall implement a centralised procurement of pharmaceutical products, the methods of which include open tender, invited tender and direct procurement. And the provincial governmental authorities shall determine the method of

centralised procurement of pharmaceutical products based on the actual situation. In addition, profitable medical institutions are not required to implement a centralised procurement of pharmaceutical products under PRC laws.

According to the Working Regulations, the centralised procurement of pharmaceutical products shall be solely participated by pharmaceutical manufacturers as well as the companies that could be deemed as pharmaceutical manufacturers. And either the bidders themselves, or wholesale pharmaceutical distribution companies as engaged by such bidders, could distribute the medicines to the medical institutions.

OTHER RELATED REGULATIONS IN THE PRC PHARMACEUTICAL INDUSTRY

National medicine standard

National medicine standard refers to the quality standards, inspection methods and manufacturing techniques established to ensure the quality of medicines, which include such standards as these included in the Medicine Standards of the Ministry of Health of the PRC (中華人民共和國衛生部藥品標準), Pharmacopoeia of the PRC (中華人民共和國藥典) and National Medicine Standard of CFDA (國家食品藥品監督管理局國家藥品標準). Prepared slices of Chinese crude medicines shall generally be processed in conformity with the national medicine standards,save for the ones which are not covered by the national medicine standards and shall be produced according to the processing procedures formulated by the medicine regulatory department of the provincial governments.

Chinese medicine protection

According to the Regulations on the Protection of Chinese Medicines (中藥品種保護條例) promulgated by the State Council on 14 October 1992 and effective from 1 January 1993, for the purposes of improving the quality and promoting the development of traditional Chinese medicines, protections are granted to a variety of domestically manufactured traditional Chinese medicines, which shall be within the list of national medicine standards ingredients and meet certain statuary requirements. Different provisions have been stipulated for the prescription composition, production techniques and their overseas transfers.

Prescription medicines and over-the-counter medicines

In order to promote safety, efficacy and convenience in the use of pharmaceutical products, the SFDA, the predecessor of the CFDA, published the Trial Administrative Measures regarding the Classification of Prescription Medicines and Over-the-Counter Medicines (處方藥與非處方藥分類管理辦法(試行)) on 18 June 1999 with effect from 1 January 2000. These administrative measures divide medicines according to their type, specification, the relevant disease or ailment which they are designed to treat, dosage and method of administration. Prescription medicines are those whose prescription, purchase and intake require prescription by practicing doctors or assistant doctors. Over-the-counter medicines are those whose prescription, purchase and intake do not require prescription by practicing doctors or assistant doctors.

The CFDA is responsible for the selection, approval, publication, and revision of the State Non-Prescription Medicine Catalogue (國家非處方藥目錄) depending on the safety of the relevant medicine, over-the-counter medicines are further subdivided into type A and type B and administered separately. Manufacturers of both prescription and over-the-counter medicines are required to obtain a pharmaceutical manufacturing permit and to obtain production approvals for the relevant medicines: (i) wholesalers of prescription medicines and over-the-counter medicines

and (ii) retailers of prescription medicines and type A over-the-counter medicines are required to obtain a pharmaceutical operation permit. Retail outlets selling type B over-the-counter medicines require approval from the provincial bureau of the CFDA or the authorised bureau. In addition, retail outlets selling type B over-the-counter medicines are required to have professionally trained and suitably qualified staff before engaging in the sale of type B over-the-counter medicines.

National List of Essential Medicines

On 18 August 2009, the Ministry of Health and eight other ministries and commissions in the PRC issued the Provisional Measures on the Administration of the National List of Essential Medicines (國家基本藥物目錄管理辦法(暫行)), and the Guidelines on the Implementation of the National List of Essential Medicines System (關於建立國家基本藥物制度的實施意見), which aim to promote essential medicines sold to consumers at fair prices in the PRC and ensure that the general public in the PRC has equal access to the medicines contained in the National List of Essential Medicines.

National Medical Insurance Medicines Catalogue and basic medical insurance system for urban worker

Pursuant to the Decision of the State Council on the Establishment of the Urban Worker Basic Medical Insurance Program (國務院關於建立城鎮職工基本醫療保險制度的決定) issued by the State Council on 14 December 1998, all employers in urban cities are required to enroll their employees in a basic medical insurance program with the payable insurance premium jointly contributed by the employers and employees. Participants in the national medical insurance program and their employees are required to contribute to the payment of insurance premiums on a monthly basis. The Notice Regarding the Provisional Measures for the Administration of the Scope of Basic Medical Insurance Coverage for Pharmaceutical Products for Urban Worker (關於印發城鎮職工基本醫療保險用藥範圍管理暫行辦法的通知), jointly issued by several authorities including the Ministry of Labor and Social Security and the Ministry of Finance, among others, on 12 May 1999, further requires that a pharmaceutical product included in the National Medical Insurance Medicines Catalogue must be clinically needed, safe, effective, reasonably priced, user-friendly, available in the market and must meet at least one of the following requirements:

- it is set forth in the Pharmacopoeia of the PRC;
- it meets standards promulgated by the CFDA; and
- it is approved by the CFDA for import.

The National Medical Insurance Medicines Catalogue is divided into two parts, Part A and Part B. The medicines included in Part A are determined by the PRC government for general application and local authorities may not alter the list of medicines in Part A. The medicines in Part B are determined by the PRC government, and local authorities at the provincial level may, based on local economic development, medical demand and medical treatment habit, alter up to 15% of the total number of Part B medicines.

As a result, the contents of Part B in the National Medical Insurance Medicines Catalogue may differ from region to region in the PRC. Patients purchasing medicines included in Part A of the National Medical Insurance Medicines Catalogue are entitled to reimbursement of the entire amount of the purchase price while patients purchasing medicines included in Part B of the National Medical Insurance Medicines Catalogue are required to pay a deductible and obtain reimbursement for the remainder of the purchase price. The amount of the deductible differs from region to region in the PRC.

Advertising restriction

Pursuant to the Law on the Administration of Pharmaceuticals Products of the PRC (中華人民共和國藥品管理法) promulgated on 28 February 2001 and effective from 1 December 2001 and the Measures on the Examination of Pharmaceuticals Products Advertisement (藥品廣告審查辦法) promulgated on 13 March 2007 and effective from 1 May 2007, an enterprise seeking to advertise its pharmaceutical products must apply for an advertising approval code number. The code number is issued by the relevant local administrative authority.

Healthcare fraud and abuse

According to Anti Unfair Competition Law of the PRC (中華人民共和國反不正當競爭法) (effective on 1 December 1993), business operator bribery by giving properties or using any other method in order to sell or purchase the commodities and violate the Criminal Law, shall be investigated in accordance with the Criminal Law; if the acts as first mentioned do not violate the Criminal Law, the supervisor may fine an amount from more than RMB10,000 to less than RMB200,000 in accordance with the facts and confiscate the illegal income.

The Interim Provisions on Banning Commercial Bribery (the "**Interim Provisions**") (關於禁止商業賄賂行為的暫行規定) (effective on 15 November 1996) provides a detailed scope of "properties or using any other method," the term "property" refers to cash and material objects, including property given by a business operator to another entity or individual in the name of promotion fee, publicity fee, sponsorship fee, scientific research fee, service charge, consulting fee, commissions, reimbursed expenses, etc., in order to sell or purchase commodities, and the term "other means" refers to any means other than giving property, such as offering domestic or international tours or surveys in various names. In addition, the Interim Provisions also made it clear that commercial bribery committed by any employee of a business operator for selling or purchasing commodities for the operator shall be regarded as the operator's act.

According to Criminal Law of the PRC (中華人民共和國刑法) (effective on 1 October 1997), as amended on 25 December 1999, 31 August 2001, 29 December 2001, 28 December 2002, 28 February 2005, 29 June 2006, 28 February 2009 and 25 February 2011, and the Opinions of the Supreme People's Court and the Supreme People's Procuratorate on Issues Concerning the Application of Law in the Handling of Criminal Cases of Commercial Briberies (最高人民法院、最高人民檢察院關於辦理商業賄賂刑事案件適用法律若干問題的意見) (effective on 20 November 2008), business operators in the healthcare industry may be prosecuted with several charges due to commercial briberies, and these charges include: crime of acceptance of bribes by a non-state functionary, crime of offering bribes to a non-state functionary, crime of acceptance of bribes, crime of acceptance of bribes by an entity, crime of offering bribes, crime of offering bribes to an entity, crime of bribing as an intermediary and crime of offering bribes by an entity. If found guilty, such operator may be punished by term sentence, life sentence or even death sentence.

PRICE CONTROLS

Pursuant to the Announcement of the Opinion of the Bureau of State Planning Commission regarding Reforms on Price Administration of Pharmaceutical Products (國家計委印發關於改革藥品價格管理的意見的通知) issued by the Bureau of State Planning Commission, the predecessor of the NDRC, on 20 July 2000 and the Price-controlled Pharmaceutical Products Catalogue of the NDRC (國家發展改革委定價藥品目錄) which was promulgated on 27 June 2005, amended on 5 March 2010 and effective from 1 April 2010, retail prices of pharmaceutical products are either determined by the PRC government or by market conditions. The retail prices of certain pharmaceutical products sold in the PRC, primarily those included in the National Medical Insurance Medicines Catalogue,

are subject to price controls mainly in the form of fixed retail prices or maximum retail prices. Manufacturers and operators are not allowed to set the actual retail price for any price-controlled product above the maximum retail prices or deviate from the fixed retail price imposed by the government. The retail prices of medicines that are not subject to price controls are determined freely at the discretion of the respective pharmaceutical product companies.

Sales of pharmaceutical products by pharmaceutical product manufacturers in the PRC to overseas markets are not subject to any price control by the PRC government.

The retail prices of medicines that are subject to price controls are administered by the NDRC and provincial and regional price control authorities. From time to time, the NDRC publishes and updates a list of medicines that are subject to price controls.

Pursuant to the Circular of the National Development Planning Commission on Printing and Distributing the Measures for Pricing of Medicines by Government (國家計委關於印發藥品政府定價辦法的通知) promulgated on 21 November 2000 and effective from 25 December 2000, fixed prices and maximum retail prices on medicines are determined based on profit margins that the relevant government authorities deem reasonable, the type and quality of the medicine, its average production costs, and the prices of substitute medicines. The NDRC directly regulates the price of a portion of the medicines on the list, and delegates to provincial and regional price control authorities the authority to regulate the pricing of the rest of the medicines on the list.

On 9 November 2009, the NDRC, the Ministry of Health and the Ministry of Labor and Social Security jointly promulgated the Notice on Issuing Opinions on Reforming the Price Formation System of Medicine and Medical Services (關於印發改革藥品和醫療服務價格形成機制的意見的通知). According to this Notice, in addition to medicines included in the National Medical Insurance Medicines Catalogue, Provincial Medical Insurance Medicines Catalogue and certain medicines whose production or trading tend to create monopolies, medicines listed in the National List of Essential Medicines are subject to PRC government price control. The prices of other medicines are determined by the market conditions and are not subject to PRC government price control.

Pursuant to the Notice on Adjusting the Catalogue of Medicines Priced by the National Development and Reform Commission and Relevant Questions (Fa Gai Jia Ge [2010] No. 429) (國家發展改革委關於調整《國家發展改革委定價藥品目錄》等有關問題的通知(發改價格[2010]429號)) promulgated by the NDRC on 5 March 2010, if the maximum retail price or fixed price of a medicine being sold in the market which price should be set by the NDRC has not yet been determined by the NDRC, the manufacturer of such medicine is entitled to set the manufacturer suggested retail price of such medicine. This notice took effect on 1 April 2010 and prevails over the prior relevant provisions.

The manufacturer of a medicine may make suggestions to the relevant authorities for the increase in the price of the medicines. In addition, pursuant to the Announcement of the Opinion of the Bureau of State Planning Commission regarding Reforms on Price Administration of Pharmaceutical Products, if a particular pharmaceutical product is significantly superior to comparable products in terms of effectiveness, safety, treatment cycle and costs of treatment, its manufacturer or operator may apply to the NDRC for approval for separate pricing.

The Guangdong Pricing Bureau promulgated the Measures on Management of Differentiated Pricing of Medicine (廣東省物價局關於關於藥品差別定價的管理辦法) on 11 September 2012. The measures were made after Guangdong province has been approved by the State Development and Reform Commission as the trial area for reform of pricing management of medical services and medicine. The measures stipulate that higher period expense rates and profit rates shall apply to

patented or innovatory medicines, and a relatively loose control over period expense rates and profit rates shall apply to protect Chinese medicine, state secret technologies, confidential prescriptions or medicines encouraged by the State.

The differentiated pricing treatment policy is approved by the NDRC in compliance with the national rules and regulations relating to price controls and it normally will not be revoked once such differentiated pricing treatment is granted unless any of the following circumstances occurs: (i) the production approval, GMP certificate or other approval documents obtained by the relevant manufacturer is revoked or suspended; (ii) the relevant pharmaceutical product is subject to investigation or warning due to quality or pricing issues; (iii) the patent or protection of the relevant pharmaceutical product has expired; (iv) any pharmaceutical product manufactured by the relevant manufacturer causes serious accidents; (v) the relevant pharmaceutical manufacturer submits false materials or bribes when applying for such differentiated pricing treatment; or (vi) other misconducts of the relevant pharmaceutical manufacturer that cause severe adverse effects.

TAXATION

Income tax

According to PRC EIT Law which was promulgated by the National People's Congress on 16 March 2007 and became effective on 1 January 2008, the income tax rate for both domestic and foreign-invested enterprises is 25% commencing 1 January 2008.

Under the PRC EIT Law, high and new technology Enterprises that require key state support are subject to the applicable enterprise income tax rate with a reduction of 15%.

Value-added tax

Pursuant to the Provisional Regulations on Value-added Tax of the PRC (中華人民共和國增值税暫行條例), which was promulgated by the State Council on 13 December 1993 and amended on 10 November 2008 and which became effective on 1 January 2009, all entities or individuals in the PRC engaged in the sale of goods, processing services, repair and replacement services, and the importation of goods are required to pay value-added tax ("**VAT**"). VAT payable is calculated as "output VAT" minus "input VAT", and the rate of VAT is 17% or in certain limited circumstances, 13%, depending on the products.

Value-added tax in lieu of business tax

Pursuant to the Circular on Printing and Distributing the Pilot Proposals for the Collection of Value-Added Tax in Lieu of Business Tax (《關於印發 <營業税改徵增值税試點方案 >的通知》)(Cai Shui [2011] No.110) ("the Cai Shui Notice No. 110") promulgated on 16 November 2011 jointly by State Administration of Taxation and Ministry of Finance, the pilot program of the collection of VAT in lieu of Business Tax (the "BT") has been carried out since 1 January 2012 in the pilot industries within the pilot regions. According to the Cai Shui Notice No. 110, the tax rate of 6% shall be applicable to other modern service industries.

Pursuant to Circular of the Ministry of Finance and the State Administration of Taxation on Launching the Pilot Collection of Value Added Tax in lieu of Business Tax in Transportation and Certain Areas of Modern Services Industries in 8 Provinces and Municipalities Including Beijing (《財政部 國家税務總局關於在北京等 8省市開展交通運輸業和部分現代服務業營業税改徵增值税試點的通知》) (Cai Shui [2012] No. 71)) (the "Cai Shui Notice No 71") promulgated on 31 July 2012 jointly by State Administration of Taxation and Ministry of Finance, Guangdong province and the other seven provinces shall be included into the pilot regions.

Pursuant to Circular of the Ministry of Finance and the State Administration of Taxation on Tax Policies in the Nationwide Pilot Collection of Value Added Tax in Lieu of Business Tax in the Transportation Industry and Certain Modern Services Industries (《財政部、國家税務總局關於在全國開展交通運輸業和部分現代服務業營業税改徵增值税試點税收政策的通知》)(Cai Shui [2013] No. 37) (the "**Cai Shui Notice No. 37**") and its appendixes promulgated on 24 May 2013 and to be effective on 1 August 2013 jointly by State Administration of Taxation and Ministry of Finance, the nationwide pilot BT to VAT in certain modern services industries has been approved by the State Council, and will be carried out on 1 August 2013; and the Cai Shui Notice No. 71 and the relevant regulations shall be abolished since 1 August 2013. According to the Cai Shui Notice No. 37, taxpayers providing services of certain modern service industries shall pay VAT, and will no longer pay BT; and for the taxpayers who provide services in modern services industry (with the exception of leasing services of tangible personal property), the tax rate shall be 6%.

Business tax

Pursuant to the Provisional Regulations of the PRC on Business Tax (中華人民共和國營業税暫行條例) effective from 1 January 1994, as amended on 10 November 2008, and its implementation rules, all institutions and individuals providing taxable services, transferring intangible assets or selling real estate within the PRC must pay business tax. The items and rates of business tax shall be implemented in accordance with the List of Items and Rates of Business Tax (營業税税目税率表) attached to the regulation.

PROTECTION OF PHARMACEUTICAL PRODUCTS IN THE PRC

Patent law

Under the PRC Patent Law (中華人民共和國專利法), which was promulgated by the Standing Committee of the National People's Congress on 12 March 1984 and effective from 1 April 1985, as amended on 4 September 1992, 25 August 2000 and 27 December 2008, the period of patents relating to inventions are 20 years from the initial date the patent application was filed and the patent becomes effective upon the authorisation announcement is published by SIPO. The period of patents relating to utility model patents and design patents are ten years from the initial date the patent application was filed and the patent becomes effective upon the authorisation announcement is published by SIPO. Any persons and entities using the patent in the absence of authorisation from the patent owner or conducting other activities which infringe upon patent rights will be held liable for compensation to the patent owner, subject to fines charged by relevant administrative authorities and may include criminal liabilities, as the case may be.

Trademark law

Under the PRC Trademark Law (中華人民共和國商標法), which was promulgated by the Standing Committee of the National People's Congress on 23 August 1982 and became effective from March 1, 1983, as amended on 22 February 1993 and 27 October 2001, the Trademark Office of State Administration of Industry and Commerce is responsible for the registration and administration of trademarks throughout the country. The period of validity of a registered trademark is ten years from the date of registration; renewal is allowed thereafter and the period of validity of each renewal of registration is ten years. Any persons and entities using the registered trademark in the absence of authorisation from the registered trademark holder or conducting other activities which infringe upon registered trademark rights will be held liable for compensation to the registered trademark holder, subject to fines charged by relevant administrative authorities and may include criminal liabilities, as the case may be.

State Secret

According to the Law on Guarding of the State Secrets of the PRC (中華人民共和國保守國家秘密法) promulgated on 5 September 1988 and amended on 29 April 2010, the State Secrets are protected by laws, and all State organisations, armed forces, political parties, social associations, enterprises, working units and citizens shall fulfill their obligations of protecting the State Secrets. The State Secrets shall be classified into three categories: top secret (絕密), confidential (機密) and secret (秘密), and the protection periods respectively shall not exceed 30 years, 20 years and 10 years. The State Secrets shall be declassified automatically if the protection period of the secrets expires. If an organisation or unit violates the law and involves in significant secret divulgation, the persons in charge shall be punished by the relevant organisations or units. Pursuant to the Regulations on Protection of Scientific Technologies (科學技術保密規定) promulgated on 6 January 1995, the administrative governments of science and technologies may decide to prolong the period of secrets if they deem necessary. Although the Administration Provisions on Pharmaceutical Directions and Labels require that a label of medicine shall indicate all the ingredients, the Law of Protection of the State Secrets stipulates an obligation of protecting the State Secrets of all enterprises and citizens. The Company does not list all the ingredients of uremic clearance granule in its product label, as uremic clearance granule has been recognised by the relevant governmental authorities as a State Secret. As advised by our PRC Legal Advisers, such labelling does not violate the relevant PRC laws.

Formula and technologies which are recognised as State Secret(s) enjoy the highest level of confidentiality protection as (i) no other person is allowed to copy, record or keep such State Secret; (ii) any prohibited use or disclosure of such State Secret will be subject to penalties or criminal liabilities; and (iii) CFDA will suspend the examination of applications or registration of any pharmaceutical product if its formula or production technologies are the same as or similar to an existing State Secret.

ENVIRONMENTAL PROTECTION

The Ministry of Environmental Protection of the PRC (中華人民共和國環境保護部) is responsible for the uniform supervision and control of environmental protection in the PRC. It formulates national environmental quality and discharge standards and monitors the PRC's environmental system. Environmental protection bureaus at the county level and above are responsible for environmental protection within their areas of jurisdiction.

Pursuant to the Environmental Protection Law of the PRC (中華人民共和國環境保護法) (the "**Environmental Protection Law**"), promulgated on and effective from 26 December 1989, by the Standing Committee of the National People's Congress, the environmental protection department of the State Council is in charge of promulgating national standards for environmental protection. The Environmental Protection Law requires any facility that produces pollutants or other hazards to incorporate environmental protection measures in its operations and establish an environmental protection responsibility system. Any entity that discharges pollution must register with the relevant environmental protection authority. Remedial measures for breaches of the Environmental Protection Law include a warning, payment of damages or imposition of a fine. Criminal liability may be imposed for a material violation of environmental laws and regulations that causes loss of property, personal injuries or death.

Pursuant to the Law on Environmental Impact Evaluation of the PRC (中華人民共和國環境影響評價法) promulgated on 28 October 2002 and effective from 1 September 2003, by the Standing Committee of the National People's Congress, manufacturers must prepare and file an environmental impact report setting forth the impact that the proposed construction project may

have on the environment and the measures to prevent or mitigate the impact for approval by the relevant PRC government authority prior to commencement of construction of the relevant project. New facilities built pursuant to this approval are not permitted to operate until the relevant environmental bureau has performed an inspection and is satisfied that the facilities are in compliance with environmental standards.

Pursuant to the Air Pollution Prevention Law of the PRC (中華人民共和國大氣污染防治法) promulgated by the Standing Committee of the National People's Congress on 5 September 1987, last amended on 29 April 2000 and effective from 1 September 2000, the environmental protection authorities above the county level are in charge of exercising unified supervision and administration of prevention and control of air pollution. Manufacturers discharging polluted air must comply with applicable national and local standards. Manufacturers discharging polluted air must pay polluted air discharging fees. If a manufacturer emits polluted air exceeding national or local standards, it must correct its action during a prescribed period of time and the manufacturer may be subject to penalties.

Pursuant to the Water Pollution Prevention Law of the PRC (中華人民共和國水污染防治法) promulgated by the Standing Committee of the National People's Congress on 11 May 1984, amended on 15 May 1996 and 28 February 2008, and effective from 1 June 2008, manufacturers must discharge water pollutants in accordance with national and local standards. If the water pollutants discharged exceed national or local standards, the manufacturer would be subject to fines amounting to two to five times the water pollutants treatment fees. In addition, the environmental protection authority has the right to order such manufacturer to correct their actions by reducing the amount of discharge during a stipulated period of time by restricting or suspending their operations. If the manufacturer fails to correct its action at the expiration of the stipulated period, the environmental protection authority may, subject to approval by the relevant level of the PRC government, shut down the manufacturer.

According to the Law of the PRC on Prevention and Control of Environmental Pollution by Noise (中華人民共和國環境噪聲污染防治法) promulgated on 29 October 1996 and effective as of 1 March 1997, new construction project, expansion, or reconstruction project that discharges pollutants into air shall be subject to the state regulations on environmental protection of construction projects. Industrial enterprises that discharge noise during industrial production with fixed facilities shall report to the local environmental protection department categories and quantities of their existing facilities for discharging noise, and the noise volume of noise discharged under their normal operation conditions as well as treating facilities against noise, and also submit to the same department technical information with regard to the prevention and control of noise pollution. Units discharge noise exceeding the relevant standards shall pay the discharge fee subject to the regulations.

OCCUPATIONAL HEALTH AND SAFETY

Pursuant to the Labour Law of the PRC (中華人民共和國勞動法) promulgated by the Standing Committee of the National People's Congress on 5 July 1994 and effective from 1 January 1995, as amended on 27 August 2009, employers must establish a comprehensive management system to protect the rights of their employees, including a system governing occupational health and safety to provide employees with occupational training to prevent occupational injury.

Pursuant to the Law of Manufacturing Safety of the PRC (中華人民共和國安全生產法) promulgated by the Standing Committee of the National People's Congress on 29 June 2002 and effective from 1 November 2002, as amended on 27 August 2009, manufacturers must establish a comprehensive management system to ensure manufacturing safety in accordance with applicable laws and regulations. Manufacturers who do not meet relevant legal requirements are not permitted to commence manufacturing activities.

Pursuant to the PRC Labour Contract Law (中華人民共和國勞動合同法) promulgated by the Standing Committee of the National People's Congress on 29 June 2007 and effective from 1 January 2008, as amended on 28 December 2012 and came into effect on 1 July 2013, employers are required, when employing labour, to truthfully inform prospective employees of the job description, working conditions, location, occupational hazards and status of safe production as well as remuneration and other conditions as requested by the PRC Labour Contract Law.

PRODUCT LIABILITY AND PROTECTION OF CONSUMERS

Product liability claims may arise if the products sold have any harmful effects on consumers. The injured party may file claims for damages or compensation. The General Principles of the Civil Law of the PRC (中華人民共和國民法通則), which was promulgated by the National People's Congress on 12 April 1986 and became effective from January 1, 1987, as amended on 27 August 2009, states that manufacturers and sellers of defective products causing property damage or injury shall incur civil liabilities.

The Product Quality Law of the PRC (中華人民共和國產品質量法) was promulgated on 22 February 1993 and effective from 1 September 1993 by the Standing Committee of the National People's Congress, as amended on 8 July 2000 and 27 August 2009, to strengthen quality control of products and protect consumers' rights. Under this law, manufacturers and operators who produce and sell defective products may be subject to the confiscation of earnings from such sales, the revocation of business licenses and imposition of fines, and in severe circumstances, may be subject to criminal liability.

The Law of the PRC on the Protection of the Rights and Interests of Consumers (中華人民共和國消費者權益保護法) was promulgated by the Standing Committee of the National People's Congress on 31 October 1993 and effective from 1 January 1994 to protect consumers' rights when they purchase or use goods and accept services. All business operators must comply with this law when they manufacture or sell goods and provide services to customers. In extreme situations, pharmaceutical product manufacturers and operators may be subject to criminal liability if their goods or services lead to the death or injuries of customers or other third parties.

On 26 December 2009, the Standing Committee of the National People's Congress of the PRC promulgated the PRC Tort Liability Law (中華人民共和國侵權責任法), which became effective from 1 July 2010. Producers shall bear liability for damage caused to others by their defective products, and for such damage, the injured party may seek compensation from either the producer or the seller. Where the product defect is caused by the producer, the seller may, after paying

compensation, claim the same from the producer. Where the product defect is caused by the seller, the producer may, after paying compensation, claim the same from the seller. With respect to the environment, the PRC Tort Liability Law highlighted the principle that polluters are to assume liability in respect of harm caused by their environmental pollution, irrespective of whether they have breached national environmental protection regulations.

PROVISIONS RELATING TO FOREIGN EXCHANGE

The Foreign Exchange Administrative Regulations of the PRC (中華人民共和國外匯管理條例) (the "**Foreign Exchange Administrative Regulations**"), which was promulgated and implemented since 1 April 1996 and was amended with effect from 5 August 2008, forms an important legal basis for the PRC authorities to supervise and regulate foreign exchange.

According to Foreign Exchange Administrative Regulations, Renminbi is generally freely convertible for payments of current account items, such as trade and service-related foreign exchange transactions and dividend payments, but not freely convertible for capital account items, such as capital transfer, direct investment, investment in securities, derivative products or loans unless prior approval of the SAFE is obtained.

Foreign-invested enterprises in the PRC may purchase foreign exchange without the approval of SAFE for paying dividends by providing certain evidencing documents (board resolutions, tax certificates, etc.), or for trade and services-related foreign exchange.

In accordance with the Notice on Relevant Issues of Foreign Exchange Control on Domestic Residents regarding Corporate Financing and Round-trip Investment through Offshore Special Purpose Vehicles《關於境內居民通過境外特殊目的公司融資及返程投資外匯管理有關問題的通知》("SAFE Notice No. 75") promulgated on 21 October 2005 and effective on 1 November 2005, a "special purpose vehicle" means an offshore enterprise directly established or indirectly controlled by PRC domestic residents (companies or individuals) for the purpose of carrying out offshore equity financing with the assets or equity interests they hold in domestic enterprises. And the PRC domestic residents who intend to carry out offshore equity financing shall file applications with, and obtain the records from, the foreign exchange administrative authorities.

LABOUR AND INSURANCE

The relevant labour laws in the PRC include the PRC Labour Law (中華人民共和國勞動法) (the "**Labour Law**") (effective from 1 January 1995), the PRC Labour Contract Law (中華人民共和國勞動合同法) (effective from 1 January 2008), the Social Insurance Law of the PRC (中華人民共和國社會保險法) (effective from 1 July 2011), the Regulation of Insurance for Work-Related Injury (工傷保險條例) (effective from 1 January 2011), the Provisional Measures on Insurance for Maternity of Employees (企業職工生育保險試行辦法) (effective from 1 January 1995), the Interim Regulation on the Collection and Payment of Social Insurance Premiums (社會保險費徵繳暫行條例) (effective from 22 January 1999), the Interim Provisions on Registration of Social Insurance (社會保險登記管理暫行辦法) (effective from 19 March 1999), the Regulations on the Administration of Housing Accumulation Funds (住房公積金管理條例) (effective from 24 March 2002), and other related law and regulations issued by relevant governmental authorities from time to time in the PRC.

The Labour Law was promulgated by the Standing Committee of the National People's Congress on 5 July 1994. According to the Labour Law, employees are entitled to have equal opportunities in employment, selection of occupations, receiving wages and remuneration, rest days and holidays, protection of occupational safety and health, the rights to social insurance and welfare, etc. An employee shall not work for more than eight hours a day and no more than 44 hours

a week on average. The employers must establish and improve the system for occupational safety and health, provide education on occupational safety and health to employees, and comply with the State and/or local regulations of occupational safety and health as well as provide the necessary labour protective measures to employees.

On 29 June 2007, the PRC Labour Contract Law, another important law concerning employees, was adopted by the Standing Committee of the National People's Congress and came into effect on 1 January 2008 and was amended on 28 December 2012. According to the PRC Labour Contract Law, labour contracts must be executed in order to establish a labour relationship between an employer and employees. When an employer is recruiting employees, it should inform the employees truthfully the content of work, working conditions, place of work, occupational hazards, safe production conditions, labour remuneration and other circumstances requested to be notified by the employees. An employer and an employee shall fully perform their respective obligations in accordance with the terms set forth in the labour contract. An employer must make payment for employee remuneration timely and in full amount in accordance with the contract terms, must strictly abide by the fixed standard of labour work, and must not force or threaten an employee in disguise to work overtime. After the labour contract is released or terminated, the employer should issue a proof of release or termination of the labour contract to the employee, and complete the filing procedure and transfer of social insurance relationship for the employee within 15 days.

Under the Social Insurance Law, the Regulation of Insurance for Work-Related Injury, the Provisional Measures on Insurance for Maternity of Employees, the Interim Regulation on the Collection and Payment of Social Insurance Premiums, and the Interim Provisions on Registration of Social Insurance, an employer is required to contribute the social insurance for its employees, including the basic pension insurance, basic medical insurance, unemployment insurance, maternity insurance and injury insurance.

Under the Regulations on the Administration of Housing Accumulation Funds, promulgated by the State Council on 3 April 1999 and as amended on 24 March 2002, employers are required to make contributions to a housing accumulation fund for their employees.

M&A RULES

Under the M&A Rules, mergers and acquisitions of domestic enterprises by foreign investors must be reviewed and approved by the MOFCOM or its provincial branches. Particularly, the M&A Rules require special purpose offshore companies formed for overseas listing purposes and controlled directly or indirectly by PRC companies or individuals to obtain the approval of the CSRC prior to publicly listing their securities on an overseas stock exchange.