OVERVIEW

The pharmaceutical industry is highly regulated in the PRC. We are subject to PRC laws and regulations that govern pharmaceutical products as well as those regulate the manufacturing, sales and distribution of pharmaceutical products. This section contains a summary of principal laws and regulations currently relevant to our Group's operation.

PRINCIPAL LAWS AND REGULATIONS

- Drug Administration Law of the PRC (《中華人民共和國藥品管理法》) (the "**Drug Administration Law**"), which was promulgated by the Standing Committee of the National People's Congress (中華人民共和國全國人民代表大會常務委員會) (the "**SCNPC**") of the PRC on 20 September 1984 and last amended on 24 April 2015, provides the basic legal framework for the administration of the manufacture and sale of pharmaceutical products in China and covers the aspects of manufacturing, distributing, packaging, pricing and advertising of pharmaceutical products;

- Regulations for Implementation of the Drug Administration Law of the PRC (《中華人民共和國藥品管理法實施條例》) (the "**Implementation Regulation**"), which was promulgated by the State Council on 4 August 2002 and effective on 15 September 2002, sets out detailed implementation rules with respect to the administration of pharmaceutical products in China.

PRINCIPAL ADMINISTRATIVE AUTHORITIES

- CFDA, which succeeded the State Food and Drug Administration ("**SFDA**") (國家食品藥品監督管理局), is responsible for the administrative supervision and technical supervision over the research, production, circulation and usage of drugs, including Chinese patent medicines in the PRC and organising the formulation and publication of the Chinese Pharmacopeia. The local administrative authorities at the level of provinces, autonomous regions and municipalities directly under the PRC central government are responsible for the supervision and administration of drugs within their respective administrative regions.

- NHFPC is responsible for multiple supervisions over drug regulation, including but not limited to, enforcing the healthcare system reform, establishing the National Essential Drugs System (國家基本藥物制度), implementing the National List of Essential Drugs, proposing the pricing policy of drugs within the National List of Essential Drugs and supervising medical institutions.

- State Administration of Traditional Chinese Medicine of the PRC (中華人民共和國國家中醫藥管理局) ("**SATCM**"), a bureau under the jurisdiction of NHFPC, is responsible for the regulation of traditional Chinese medicine industry in the PRC.

- NDRC is responsible for the macro-guidance and administration of the healthcare industry's development planning, technological upgrading, approval of investment programs and the economic operation status of the medical enterprises, the supervision and administration over the price of medicines and formulation of the national unified price for certain drugs.

MANUFACTURING OF PHARMACEUTICAL PRODUCTS

Manufacturing Licence

Each pharmaceutical manufacturing enterprise is required to obtain a Pharmaceutical Manufacturing Permit and a business licence (營業執照). The Pharmaceutical Manufacturing Permit is issued by the CFDA. This permit is issued only after the relevant production facilities have been inspected and their sanitary conditions, quality assurance systems, management structure and equipment standards have been found to fulfill the required standards. According to the Implementation Regulation, each Pharmaceutical Manufacturing Permit is valid for five years. The pharmaceutical manufacturing enterprise must apply for an extension six months prior to the licences expiration, and extension is only granted after reevaluation by the relevant authority.

Good Manufacturing Practice (GMP)

The Ministry of Health promulgated the Good Manufacturing Practice for Drugs (2010 version) ("**2010 GMP**") (《藥品生產質量管理規範》(2010年修訂)) on 17 January 2011 which became effective on 1 March 2011. Compared with the 1998 GMP, the 2010 GMP provides stricter requirements for a manufacturer of pharmaceutical products. For example, the 2010 GMP enhanced the requirement for the facilities and strengthened the requirement for the management standard. Besides, it also established some new systems under the newly introduced concept of risk management and emphasised the connection with other supervision aspects such as pharmaceutical products registration and drug recalls. According to the 2010 GMP, a manufacturer of pharmaceutical products and pharmaceutical materials must obtain GMP certification to produce pharmaceutical products and pharmaceutical materials in China. The 2010 GMP provides detailed guidelines on practices governing the production of pharmaceutical products. A GMP certification certifies that a manufacturer's factory has met certain criteria as set out in the 2010 GMP, which include institution and staff qualifications, production premises and facilities, equipment, hygiene conditions, production management, quality controls, product operation, maintenance of sales records and manner of handling customer complaints and adverse reaction reports. The appendix to the 2010 GMP (關於發布《藥品生產質量管理規範(2010年修訂)》中藥飲片等3個附錄的公告) promulgated by the CFDA on 27 June 2014 which became effective on 1 July 2014 specifies

requirements on staff qualifications, production premises and facilities, materials and products, equipment, validation, documentation management, production management, as well as quality control for the production of decoction pieces.

Pursuant to the Notice of the CFDA, the Ministry of Health, and the State Administration of Chinese Medicine on Strengthening the Supervision and Administration of Traditional Decoction Pieces* (《國家食品藥品監督管理局、衛生部、國家中醫藥管理局關於加強中藥飲片監督管理的通知》) issued on 5 January 2011, manufacturers of traditional decoction pieces shall obtain a Pharmaceutical Manufacturing Permit and a GMP certification.

Pursuant to the Administrative Measures for Drug Good Manufacturing Practice Certification* (《藥品生產質量管理規範認證管理辦法》) promulgated by the CFDA on 7 September 2005 which was subsequently amended on 2 August 2011, GMP certificates are valid for a term of five years, except in the case of a newly established pharmaceutical manufacturer, the GMP certificate of which is valid for one year. GMP certificates must be renewed no later than six months, and in the case of a newly established pharmaceutical manufacturer, three months prior to expiration upon re-examination by the relevant authority.

Research Specification

The Guangdong Institute for Food and Drug Control (廣東省食品藥品檢驗所), authorised by the GFDA, promulgated the Research Specification on Guangdong Province Quality Standard of Modern Decoction Pieces (for Trial Implementation)* (《廣東省中藥破壁飲片質量標準研究規範（試行）》) ("**Research Specification**"), pursuant to which all the research and development units and the inspection bodies of modern decoction pieces in Guangdong are required to follow the technical specification prescribed in the Research Specification.

Continuing regulation by the CFDA

A manufacturer of pharmaceutical products is subject to periodic inspection and safety monitoring by the CFDA to determine compliance with regulatory requirements. The CFDA has a variety of enforcement actions available to enforce its regulations and rules, such as fines and injunctions, recalls or seizure of products, imposition of operating restrictions, partial suspension or complete shutdown of production and transfer to the relevant authorities for criminal investigation.

REGISTRATION OF PHARMACEUTICAL PRODUCTS

In addition to compliance with qualification requirements evidenced by possession of relevant permits, licences and certificates, pharmaceutical manufacturers are required to register each of their products with the CFDA prior to commencement of production. The registration is valid for a term of five years which must be renewed within six months prior to expiration by submitting application required under PRC laws to the relevant authorities. The following sets forth the application requirements and procedures to register new pharmaceutical products in China.

Registration of new pharmaceutical products

According to the Measures on the Administration of Pharmaceutical Products Registration* (《藥品註冊管理辦法》) promulgated by the CFDA on 10 July 2007 which became effective on 1 October 2007, new pharmaceutical products refer to those that were not previously available in China. Pharmaceutical products taking different dosage, forms or route or having curative effects for additional diseases are treated as new pharmaceutical products.

All new pharmaceutical products must undergo four phases before the product launch: pre-clinical research, application for clinical trials, clinical trials and application for production. All new pharmaceuticals must undergo these four phrases and obtain the approval documents and meet quality standards issued by the CFDA before launching to the market. Clinical trials comprise of four phases: phase I (preliminary pharmacology and human safety trials), phase II (preliminary assessment on the efficacy), phase III (confirmation of efficacy) and phase IV (research on applications after launching of new pharmaceuticals).

Pharmaceutical manufacturers are required to obtain an approval from the CFDA prior to commencement of clinical trials of a new pharmaceutical product. Application materials, including relevant pre-clinical study information must first be submitted to the CFDA at the provincial level. Upon receipt of the application, the CFDA at the provincial level will review the applicant's submission and conduct production site visits to collect drug samples (three sets of samples are required for biological products only) for examination by the drug inspection institution appointed by the CFDA. The CFDA will organise an expert committee made up of pharmaceutical experts and other specialists to conduct technical assessment of the new pharmaceutical product to consider whether an approval for clinical trials should be granted.

Upon completion of clinical trials, the applicant must also apply for an approval to manufacture the new pharmaceutical product. Application materials, including relevant clinical trials information and raw material samples, must be submitted to the CFDA at the provincial level and relevant drug inspection institution. The CFDA at the provincial level will then review the application materials and conduct production site visits, which must comply with GMP standards. Three consecutive production batches of drug samples (except for biological products) will be collected from the applicant's production site for examination by the drug inspection institution. After their investigation and assessment of the application, the CFDA at the provincial level and the drug inspection institution will report to the CFDA, which will conduct a final assessment. If

technical assessment is passed, the assessment center of the CFDA would notify the applicant to apply for on-site examination of production and inform the certification center of the CFDA. The certification center will organise on-site inspection on the process of bulk production of samples and confirm the feasibility of the production process being assessed, while one set of sample (three sets of samples are required for biological products) will be delivered to the drug inspection center for examination to re-examine the standard of the pharmaceutical product, and the results will be reported to the pharmaceutical product assessment center of the CFDA. The pharmaceutical product assessment center will then conclude the result from the production site and the result of sample inspection to form an opinion to report to the CFDA for approval. The CFDA will consider whether an approval for registration of the new product should be granted. If approved, the applicant will be granted a certificate of new pharmaceutical product, and a drug approval number will also be granted at the same time if the applicant is also with Pharmaceutical Manufacturing Permit and productive conditions, and the manufacturer may commence mass production of the new pharmaceutical product.

Supplemental Application

Supplemental application refers to application for variation, addition, or cancellation of the items or contents approved in the original application for new pharmaceutical products. Where changes or modifications are proposed to a registered medicine in respect of, among others, its drug standard, curative effects or production technology, the pharmaceutical manufacturer which is the applicant or holder of relevant registration certificate for such medicine is required to apply to the competent drug administration authority.

Renewal

An approval number for pharmaceutical product issued by the CFDA is valid for five years and may be renewed at least six months prior to its expiration date upon a re-examination by the relevant authority. If the manufacturer plans to continue to produce or import such medicine after such expiration, it shall apply for the re-registration of such pharmaceutical product.

DISTRIBUTION OF PHARMACEUTICAL PRODUCTS

Pharmaceutical Operation Permit

In accordance with the Drug Administration Law, the Implementation Regulation, and the Administration of Pharmaceutical Operation Permit (《藥品經營許可證管理辦法》) issued by the CFDA on 4 February 2004 which became effective from 1 April 2004, the establishment of a wholesale pharmaceutical enterprise requires the approval from the provincial drug administrative authorities of the registered locality of such wholesale pharmaceutical enterprise. Upon approval, the competent authority will grant a pharmaceutical operation permit to such wholesale pharmaceutical enterprise. The establishment of a retail pharmaceutical enterprise requires the approval of the local drug administrative authorities at or above the county level. Upon approval, the competent authority will grant a pharmaceutical operation permit to such retail pharmaceutical

enterprise. The grant of such permit is subject to an inspection of the facilities, warehouse, hygiene environment, quality control systems, personnel (including whether pharmacists and other professionals have the relevant qualifications) and equipment of the pharmaceutical enterprise. The Pharmaceutical Operation Permit is valid for five years. Each Pharmaceutical Operation Permit holder must apply for an extension of its permit within six months prior to expiration, and extensions will be granted only after a re-examination by the authority which issued the permit. In addition, wholesale or retail pharmaceutical enterprise must obtain a business licence from the relevant administration for industry and commerce prior to commencing its business.

Good Supply Practices (GSP)

Under the Drug Administration Law, the Implementation Regulation, the Good Supply Practice for Pharmaceutical Products (《藥品經營質量管理規範》) ("**GSP (2013)**") effective from 1 July 2000 which was subsequently amended on 1 June 2013, and the Administrative Measures for Certification of the Good Manufacturing Practice* (《藥品經營質量管理規範認證管理辦法》) promulgated on and effective from 24 April 2003, each wholesale or retail operator of pharmaceutical products is required to obtain a GSP certificate from the provincial drug administrative authorities of the registered locality of such wholesale or retail operator. The GSP certificate is valid for five years and may be renewed three months prior to its expiration upon a re-examination by the relevant authority.

Pursuant to the GSP (2013), the legal representative or person in charge of an enterprise shall have the qualification of licensed pharmacist. An enterprise shall, in accordance with the relevant provisions of the State, have licensed pharmacists to be responsible for the audit of prescriptions and guidance of the rational use of drugs. According to the Notice of CFDA on Implementation of the GSP (2013)* (國家食品藥品監督管理總局關於貫徹實施新修訂《藥品經營質量管理規範》(2013年版)的通知) promulgated by the CFDA which became effective on 24 June 2013, and the Guiding Opinions concerning Implementation of the GSP (2013)* (關於貫徹實施新修訂《藥品經營質量管理規範》(2013年版)的指導意見) promulgated by the Zhongshan Food and Drug Administration which became effective on 12 July 2013, all pharmaceutical operation enterprises must meet the requirements of the GSP (2013) before 31 December 2015, regardless of the expiration of their pharmaceutical operation permit and GSP certificate. Starting from 1 January 2016, pharmaceutical operation enterprises who do not meet the requirements of the GSP (2013) are not allowed to continue their pharmaceutical operating activities.

Medical Devices Operation Permit

According to the Administrative Measures for the Operation Supervision of Medical Equipment* (《醫療器械經營監督管理辦法》) promulgated by the CFDA on 30 July 2014 which became effective on 1 October 2014, enterprises engaging in Category II medical equipment business shall be administrated by archival filing, and devices engaging in Category III medical devices business shall hold a medical devices operation permit (醫療器械經營許可證).

Provisions for Supervision of Pharmaceutical Distribution

To strengthen drug supervision and administration, and maintain orderly circulation and qualities, the CFDA issued the Provisions for Supervision of Pharmaceutical Distribution* (《藥品流通監督管理辦法》) on 31 January 2007, which became effective from 1 May 2007. The relevant provisions are imposed on various aspects such as the purchase, sale and storage of medicines by pharmaceutical production and operation enterprises as well as the purchase and storage of medicines by pharmaceutical institutions.

Provisions for Supervision of Online Sales

Pursuant to the Measures Regarding the Administration of Pharmaceutical Information Service over the Internet* (《互聯網藥品信息服務管理辦法》) promulgated by the CFDA which became effective on 8 July 2004, the CFDA shall implement the supervision and administration of such websites which provide drug information service over the internet. According to the said Measures Regarding the Administration of Pharmaceutical Information Service over the internet, whoever is engaged in providing drug information services over the internet shall obtain internet pharmaceutical information service certificate (互聯網藥品信息服務資格證書). According to the Interim Provisions on the Approval of Pharmaceutical Dealership over the internet* (《互聯網藥品交易服務審批暫行規定》) promulgated by the CFDA which became effective on 1 December 2005, whoever is engaged in the drug dealership over the internet shall obtain an internet medicine dealership certificate (互聯網藥品交易服務資格證書).

According to the Notice Regarding the Implementation of Pharmaceutical Electronic Supervision* (《關於實施藥品電子監管工作有關問題的通知》) promulgated by the CFDA which became effective on 10 April 2008, the CFDA shall establish the national unified drug electronic supervision network and implement the supervision and administration pursuant to the classification of the drugs. Whoever is engaged in the manufacturing or operation of the drugs which are in the Catalogue of Pharmaceutical in the Network* (《入網藥品目錄》) shall join the drug electronic supervision network within the prescribed period of time. All the drugs in the said Catalogue of Pharmaceutical in the Network shall be labelled with the drug electronic supervision code on the minimum packaging of the products before the drugs are launched on the market.

Prescription Medicines and Over-the-Counter Medicines

In order to promote safety, efficacy and convenience in the use of pharmaceutical products, the State Drug Administration, the predecessor of the SFDA, 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)》) in June 1999, which became effective on 1 January 2000. These administrative measures divide drugs according to their type, specification, the relevant disease or ailment which they are designed to treat, dosage and method of administration. Prescription medicines relate to those of which prescription, purchase and intake require prescription by qualified medical practitioners. Over-the-counter medicines relate to those of which prescription, purchase and intake do not require prescription by qualified medical practitioners.

The SFDA is responsible for the selection, approval, publication and revision of the State Over-the-Counter Medicine Catalogue* (《國家非處方藥目錄》). Depending on the safety of the relevant drug, over-the-counter medicines are further subdivided into type A and type B and are administered separately. Wholesalers of prescription medicines and over-the-counter medicines and retailers selling prescription medicines and type A over-the-counter medicines are required to obtain a Medicine Operation Certificate. Retailers selling type B over-the-counter medicines require approval from the provincial food and drug administration or other designated authorities. In addition, retailers 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.

ADVERTISING RESTRICTION OF PHARMACEUTICAL PRODUCTS

Pursuant to the Drug Administration Law, the Implementation Regulation, and the Provisions for Drug Advertisement Examination (《藥品廣告審查辦法》) jointly issued by the CFDA and SAIC on 13 March 2007 which became effective from 1 May 2007, a pharmaceutical operation seeking to advertise its pharmaceutical products must apply for an advertising approval code, of which the validity term is one year, from the provincial drug administrative authority.

Pursuant to the Advertising Law of the PRC (《中華人民共和國廣告法》), promulgated by the SCNPC on 27 October 1994 and which became effective on 1 February 1995, an advertisement for medicines or medical devices should not in any way contain the following:

- any unscientific assertions or assurances in terms of efficiency or uses;
- treatment efficiency or curative rate;
- comparisons with other medicines or medical apparatuses in efficacy or safety;
- titles or images of medical research institutes, academic institutions, medical organisations or experts, doctors or patients; and
- other contents that are prohibited by laws and administrative decrees.

The contents of an advertisement for a medicine should be based on the indications approved by the public health administrative department of the State Council or by the public health administrative department of a province, autonomous region or municipality directly under the PRC government. For advertisements which are subject to examination according to the Advertising Law of the PRC before publication and acts of advertising without approval by advertisement examination organisations, the advertising supervision and administrative organisations shall order the responsible advertisers, advertising agents or advertisement publishers to stop publications, confiscate the advertising expenses and concurrently impose a fine ranging from the amount equal to the advertising expenses to five times the amount of the advertising expenses.

Pursuant to the Drug Administration Law, pharmaceutical products advertisement shall be subject to approval by the drug regulatory department of the province, autonomous region or municipality directly under the PRC government where the enterprise is located, and once approved a pharmaceutical products advertisement shall be given an approval number. No one may launch pharmaceutical products advertisements without an approval number. Prescription medicine may be introduced in the medical or pharmaceutical professional publications jointly designated by the administrative department for health and the drug regulatory department under the State Council, but their advertisements may not be released by mass media or disseminated to the general public by other means. Any violation of the provision of this law related to the control over pharmaceutical products advertising shall be punished pursuant to the provisions of the Advertising Law of the PRC, and the relevant drug regulatory department that issued the advertisement approval number shall withdraw it and shall, within one year, reject any application for approval of advertising for the drug in question.

PACKAGING OF PHARMACEUTICAL PRODUCTS

According to the Measures for The Administration of Pharmaceutical Packaging* (《藥品包裝管理辦法》) effective on 1 September 1988, pharmaceutical packaging must comply with the provisions of the national standard and professional standard. If there are no such standards, the enterprise can formulate its own standard after obtaining the approval from the provincial level food and drug administration. The enterprise shall reapply to the relevant authorities if it needs to change the packaging standard. Drugs without packing must not be sold in PRC (except for drugs needed by the army).

PHARMACEUTICAL DIRECTIONS AND LABELS

Pursuant to the Administrative Provisions on Pharmaceutical Directions and Labels* (《藥品說明書和標籤管理規定》) effective on 1 June 2006, pharmaceutical directions and labels shall be subject to the ratification of the CFDA. The labels of a pharmaceutical shall be based on its directions, and the contents thereof shall not exceed the scope of the directions, and may not be printed with any word or mark that implies the curative effect, misleads the usage or inappropriately advertises the product. The package of a pharmaceutical must be printed or affixed with the label according to the provisions, and shall not carry other literal or video materials or other information that advertises the product or the enterprise. The smallest packages produced by a pharmaceutical manufacturing enterprise for sale on the market must be attached with directions. The pharmaceutical directions, the interior labels and exterior labels as well as names shall comply with the relevant provisions.

CATALOGUE AND PRICE CONTROLS OF PHARMACEUTICAL PRODUCTS

The National Medical Insurance Programme

The national medical insurance programme was adopted pursuant to the Decision of the State Council on the Establishment of the Urban Employee Basic Medical Insurance Programme* (《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, under which all employers in urban cities are required to enroll their employees in the national medical insurance programme and the insurance premium is jointly contributed by the employers and employees. The State Council promulgated Guiding Opinions of the State Council about the Pilot Urban Resident Basic Medical Insurance* (《國務院關於開展城鎮居民基本醫療保險試點的指導意見》) on 10 July 2007, under which urban residents of the pilot district, rather than urban employees, may voluntarily join the Urban Resident Basic Medical Insurance.

Participants of the national medical insurance programme and their employers, where relevant, are required to contribute to the payment of insurance premium on a monthly basis. Programme participants are eligible for full or partial reimbursement of the cost of medicines included in the National Medical Insurance Drugs Catalogue and Provincial Medical Insurance Drugs Catalogue. The Notice Regarding the Tentative Measures for the Administration of the Scope of Medical Insurance Coverage for Pharmaceutical Products for Urban Employee* (《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 Labour and Social Security of the PRC ("**Ministry of Labour and Social Security**") (中華人民共和國勞動和社會保障部) and the MOF, among others, on 12 May 1999, provides that a pharmaceutical product listed in the National Medical Insurance Drugs Catalogue and Provincial Medical Insurance Drugs Catalogue must be clinically needed, safe, effective, reasonably priced, easy to use, available in sufficient quantity, and must meet the following requirements: it is set forth in the Chinese Pharmacopoeia; it meets the standards promulgated by the CFDA; and if imported, it is approved by the CFDA for import.

The Ministry of Labour and Social Security, together with other government authorities, has the power to determine the medicines included in the National Medical Insurance Drugs Catalogue, which is divided into two parts, Part A and Part B. Provincial governments are required to include all Part A medicines listed on the National Medical Insurance Drugs Catalogue in their Provincial Medical Insurance Drugs Catalogue, but have the discretion to adjust upwards or downwards by no more than 15% from the number of Part B medicines listed in the National Medical Insurance Drugs Catalogue. As a result, the contents of Part B of the Provincial Medical Insurance Drugs Catalogue may differ from region to region in the PRC.

Participants purchasing medicines included in Part A of the National Medical Insurance Drugs Catalogue and Provincial Medical Insurance Drugs Catalogue are entitled to reimbursement of the entire amount of the purchase price. Participants purchasing medicines included in Part B of the National Medical Insurance Drugs Catalogue and Provincial Medical Insurance Drugs Catalogue are

required to pay a certain percentage of the purchase price and obtain reimbursement for the remainder of the purchase price. The percentage of reimbursement for Part B medicines differs from region to region in the PRC.

The total amount of reimbursement for the cost of medicines, in addition to other medical expenses, for an individual participant under the national medical insurance programme in a calendar year is capped at the amounts in such participant's individual account under such programme. The amount in a participant's account varies, depending on the amount of contributions from the participants and his/her employer.

National List of Essential Drugs

On 18 August 2009, the Ministry of Health and eight other ministries and commissions in the PRC issued the Regulation for National Essential Drugs List (Provisional) (《國家基本藥物目錄管理辦法(暫行)》) and the Guidelines on the Establishment of the National Essential Drugs 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 drugs contained in the National List of Essential Drugs. On 13 March 2013, the Ministry of Health issued the National List of Essential Drugs (2012 Edition) (《國家基本藥物目錄(2012年版)》) which came into effect as from 1 May 2013. According to these regulations, basic healthcare institutions funded by the PRC government, which primarily include county-level hospitals, county-level Chinese medicine hospitals, rural clinics and community clinics, shall store up and use drugs listed in National List of Essential Drugs. The drugs listed in National List of Essential Drugs shall be purchased by centralised tender process and shall be subject to the price control by the NDRC. Pursuant to the Drug Pricing Reform Notice, price controls on all pharmaceutical products, except for anesthetics and some types of psychiatric drugs, were lifted from 1 June 2015. Medical drugs in the National List of Essential Drugs are all listed in the National Medical Insurance Drugs Catalogue and Provincial Medical Insurance Drugs Catalogue and the entire amount of the purchase price of such drugs is entitled to reimbursement.

Price Controls

Pursuant to the Drug Administration Law, the Implementation Regulation, and the Circular on Price-controlled Pharmaceutical Products List of the NDRC* (《國家發展改革委定價藥品目錄》) issued by the NDRC on 27 June 2005 which was subsequently amended on 5 March 2010, prices of pharmaceutical products are either determined by the PRC government or by market conditions. The prices of certain pharmaceutical products sold in the PRC, primarily those included in the National Medical Insurance Drugs Catalogue and Provincial Medical Insurance Drugs Catalogue, are subject to price controls mainly in the form of fixed prices or price ceilings. Manufacturers and operators are not allowed to set the actual price for any price-controlled product above the price ceiling or deviate from the fixed price imposed by the PRC government. The prices of medicines that are not subject to price controls are determined freely at the discretion of the respective

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

The NDRC directly regulates the pricing of all prescription medicines on the National Medical Insurance Drugs Catalogue and Provincial Medical Insurance Drugs Catalogue and all medicines on the National List of Essential Drugs, and delegates to provincial and regional price control authorities the authority to regulate the pricing of non-prescription medicines on the National Medical Insurance Drugs Catalogue and Provincial Medical Insurance Drugs Catalogue.

Pursuant to the Drug Pricing Reform Notice, price controls on all pharmaceutical products, except for anesthetics and some types of psychiatric drugs, were lifted from 1 June 2015. After the Drug Pricing Reform Notice has come into effect, in case there are any previous policy or provision related to the administration of drug prices that is inconsistent with the Drug Pricing Reform Notice, the Drug Pricing Reform Notice shall prevail.

COLLECTIVE TENDERING SYSTEM FOR PROCUREMENT OF PHARMACEUTICAL PRODUCTS BY MEDICAL ORGANISATIONS

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》) which was promulgated on 21 February 2000, aims to regulate the purchasing process of pharmaceutical products by medical institutions. The Ministry of Health and other relevant government authorities have promulgated a series of regulations and releases in order to implement the tender requirements.

According to the Notice on Issuing Certain Regulations on the Trial Implementation of centralised Tender Procurement of Drugs by Medical Institutions* (《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 and the Notice on Further Improvement on the Implementation of centralised Tender Procurement of Drugs by Medical Institutions* (《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 8 August 2001 (collectively, the "**Centralised Tender Regulations**"), medical institutions established by PRC government at county level or above are required to implement centralised tender procurement of drugs.

The Ministry of Health promulgated the Working Regulations of Medical Institutions for Procurement of Drugs by centralised Tender and Price Negotiations (for Trial Implementation)* ("**Centralised Procurement Regulations**") 《醫療機構藥品集中招標採購和集中議價採購工作規範(試行)》) on 13 March 2002, and promulgated Sample Document for Medical Institutions for Procurement of Drugs by centralised Tender and Price Negotiations (for Trial Implementation)* ("**Centralised Tender Sample Document**") (《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)》) in November 2001, to implement the tender process requirements and ensure the requirements are followed uniformly throughout the country. The Centralised Tender Regulations

and the Centralised Tender Sample Document provide rules for the tender process and negotiations of the prices of drugs, operational procedures, a code of conduct and standards or measures of evaluating bids and negotiating prices.

The Notice Regarding the Measures for Guangdong Province Pharmaceutical Dealership of Medical Institutions* (《關於印發廣東省醫療機構藥品交易相關辦法的通知》) (the "**Notice**") issued on 11 September 2013 contains several appendices. In Appendix I, the Trial Measures of Guangdong Province on Medical Institutions Transaction of Non-essential Drugs* (《廣東省醫療機構非基本藥物交易辦法(試行)》), and Appendix II, the Trial Measures of Guangdong Province on Medical Institutions Transaction of Essential Drugs* (《廣東省醫療機構基本藥物交易辦法(試行)》), the price of non-essential drugs and essential drugs are set by the medical administrative authorities. As for the same products from the same manufacturers, comparing with the average tender price of the five lowest ones in other provinces (or the average tender price of the three lowest ones in other provinces when concerning the products of exclusive production after grouping) and the current purchase price in the Guangdong province, it shall take the lower one as the market price. In Appendix III, the Trial Measures for Guangdong Province Procurement and Distribution of Medical Institutions* (《廣東省醫療機構藥品採購與配送辦法(試行)》), pharmaceutical manufacturing enterprises shall designate their own distribution enterprises, and the number of distribution enterprises is unlimited in each region. Medical institutions shall select the distribution enterprises designated by the pharmaceutical manufacturing enterprises, or by the method of random election.

Pursuant to the Detailed Rules of Guangdong Province on Pharmaceutical Dealership Bargaining of Medical Institutions* (《關於廣東省醫療機構藥品交易議價的管理細則》) promulgated on 12 February 2014 and effective on 20 March 2014, medical institutions and pharmaceutical manufacturing enterprises can trade pharmaceutical products through the centralised drug procurement platform of Guangdong province. The medical institutions can, through this centralised drug procurement platform, make an offer to the pharmaceutical manufacturing enterprises, including the pharmaceutical product specification, quantity, price, period of procurement, etc. On the other hand, pharmaceutical manufacturing enterprises can bargain for another price, accept or refuse the offer.

According to the Notice Regarding the Extension of Trial Period of Guangdong Province Pharmaceutical Dealership of Medical Institutions* (《關於延長廣東省醫療機構藥品交易相關辦法試行期的通知》) issued on 13 February 2015, the Notice will continue to be effective until the date of promulgation and implementation of new measures.

On 9 February 2015, the General Office of the State Council issued the Guiding Opinions on Enhancing Centralised Procurement of Pharmaceutical Products by Public Hospitals* (《國務院辦公廳關於完善公立醫院藥品集中採購工作的指導意見》) (the "**Guiding Opinions**"), which became effective on the same date. Pursuant to the Guiding Opinions, all drugs used by public hospitals, except for decoction pieces, shall be procured through the provincial centralised drug procurement platform. Hospitals are encouraged to directly settle the payment for drugs with pharmaceutical manufacturing enterprises, whereas pharmaceutical manufacturing enterprises are encouraged to

directly settle the distribution expenses with distribution enterprises. In addition, the Guiding Opinions also made it clear that pharmaceutical manufacturing enterprises are primarily liable for guaranteeing the drug quality and supply and may distribute drugs to the designated hospital directly or by a qualified drug operator with distribution capabilities.

MANUFACTURING AND DISTRIBUTION OF FOOD PRODUCTS

The Food Safety Law of the PRC (《中華人民共和國食品安全法》), which became effective on 1 June 2009, provides the basic legal framework for the administration of the manufacturing and distribution of food products in China and covers the manufacturing, distributing, packaging and advertising of food products. Its implementation regulations set out detailed implementation rules with respect to the administration of food products in China.

Food Production Licence

Pursuant to the Food Safety Law of the PRC and the Measures for the Administration of Food Production Licences* (《食品生產許可管理辦法》) promulgated by the State Administration of Quality Supervision, Inspection and Quarantine ("**AQSIQ**") (國家質量監督檢驗檢疫總局) on 7 April 2010 and became effective on 1 June 2010, each enterprise engaging in food production activities is required to obtain a food production licence (食品生產許可證) and a business licence. This licence is issued only after the relevant food safety standards are fulfilled. Each food production licence is valid for three years. The food manufacturing enterprise must apply for an extension six months prior to the licence expiration.

Production Licence for Industrial Products

Pursuant to the Regulation of the PRC on the Administration of Production Licence for Industrial Products (《中華人民共和國工業產品生產許可證管理條例》) promulgated by the State Council on 9 July 2005 and became effective on 1 September 2005, and the Measures for the Implementation of the Regulation of the PRC on the Administration of Production Licence for Industrial Products* (《中華人民共和國工業產品生產許可證管理條例實施辦法》) promulgated by the AQSIQ on 21 April 2014 and became effective on 1 August 2014, the enterprises which produce important industrial products listed in the Catalogue of the Industrial Products (工業產品目錄) are required to obtain a production licence for industrial products (工業產品生產許可證). This licence is issued only after the relevant conditions are met. The period of validity of a production licence shall be five years, but the period of validity of the production license for food processing enterprises shall be three years. The enterprise must apply for an extension six months prior to the licence expiration.

Food Circulation Permit

Pursuant to the Food Safety Law of the PRC and the Measures for the Administration of Food Circulation Permits (《食品流通許可管理辦法》) promulgated by the SAIC and became effective on 30 July 2009, an enterprise engaged in food distribution shall obtain a business licence and a food

circulation permit (食品流通許可證) from the local administration for industry and commerce at county level or above. Each food circulation permit is valid for three years. The food operating enterprise must apply for an extension thirty days prior to the permit expiration. The hygiene permits or food hygiene permits issued before the effectiveness of this law remain valid until expiration.

LABELING OF FOOD PRODUCTS

According to the Administrative Provisions on Food Labeling (2009 Revision)* (《食品標籤管理規定》(2009修訂)) promulgated by the AQSIQ on 27 August 2007 and was amended on 22 October 2009, the labeling of food produced (sub-packaged) and distributed must comply with these provisions. Food products or their packages shall be attached with labels, unless it is otherwise provided by any law or administrative regulation. The contents of a food label shall be authentic, accurate, exoteric, easy to understand, scientific and legal.

ANTI-BRIBERY, ANTI-CORRUPTION AND ANTI-UNFAIR COMPETITION

According to the Anti Unfair Competition Law of the PRC (《中華人民共和國反不正當競爭法》), which became effective on 1 December 1993, a business operator who bribes by giving property or using any other method in order to sell or purchase the commodities in violation of the Criminal Law of the PRC (《中華人民共和國刑法》) which became effective on 1 October 1997, shall be investigated in accordance with the Criminal Law of the PRC; even if the acts mentioned above do not constitute violation of the Criminal Law of the PRC, such business operator may be subject to a fine in the range of RMB10,000 to RMB200,000 in accordance with the facts and the illegal income shall be confiscated.

The Interim Provisions on Banning Commercial Bribery* (《關於禁止商業賄賂行為的暫行規定》) ("**Interim Provisions**"), which became effective on 15 November 1996 provides a detailed scope of "property or using any other method". As defined in the Interim Provisions, the term "property" refers to cash and material objects, including property given by a business operator to another entity or individual in the form of promotion fees, publicity fees, sponsorship fees, research fees, service charges, consulting fees, commissions or reimbursements, in order to sell or purchase commodities, and the term "other method" refers to any means other than giving property, such as offering domestic or international tours or site visits in various forms. 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 business operator shall be regarded as the business operator's act.

Medical production and operation enterprises involved in criminal, investigation or administrative procedure for commercial bribery shall be listed in the Adverse Records of Commercial Briberies by provincial health and family planning administrative department. Pursuant to the Provisions on the Establishment of Adverse Records of Commercial Briberies in the Medicine Purchase and Sales Industry* (《關於建立醫藥購銷領域商業賄賂不良記錄的規定》) enforced on 1 March 2014 by the NHFPC, if a pharmaceutical production and operation enterprise

is listed on the Adverse Records of Commercial Briberies for the first time, its products shall not be purchased by public medical institutions and a pharmaceutical and health institutions receiving financial subsidies in local province in two years from the publication of the record, and public medical institution and medical and health institutions receiving financial subsidies in other province shall lower their rating in bidding or purchasing process. If a pharmaceutical production and operation enterprise is listed on the Adverse Records of Commercial Briberies for two times or more in five years, its products shall not be purchased by public medical institutions, and medical and health institutions receiving financial subsidies nationwide in two years from the publication of the record.

As advised by our PRC Legal Advisors, from a PRC law perspective, a pharmaceutical enterprise will not be penalised by the relevant PRC government authorities merely by virtue of having contractual relationships with distributors or third party promoters who are engaged in bribery activities, so long as such pharmaceutical enterprise and its employees are not utilising the distributors or third party promoters for the implementation of, or acting in conjunction with them in, the prohibited bribery activities. In addition, a pharmaceutical enterprise is under no legal obligation to monitor the operating activities of its distributors and third party promoters, and will not be subject to penalties or sanctions by relevant PRC government authorities as a result of failure to monitor their operating activities.

PRODUCT LIABILITY

In accordance with the Product Quality Law of the PRC (《中華人民共和國產品質量法》) (as promulgated on 22 February 1993 by the SCNPC, effective from 1 September 1993, amended on 8 July 2000 and 27 August 2009 respectively) and the Tort Liability Law of the PRC (《中華人民共和國侵權責任法》) (promulgated on 26 December 2009 by the SCNPC and effective from 1 July 2010), where a product with any defect caused by the fault of the seller causes any harm to another person, the seller shall assume the tort liability. If a seller can neither specify the manufacturer nor specify the suppliers of a defective product, the seller shall assume the tort liability caused by such defective product.

Where any harm is caused by a defective product, the victim may require compensation to be made by the manufacturer or the seller of such defective product. If the defect of the product is caused by the manufacturer and the seller has made the compensation for the defect, the seller shall be entitled to be reimbursed by the manufacturer; if the defect of the product is caused by the fault of the seller and the manufacturer has made the compensation for the defect, the manufacturer shall be entitled to be reimbursed by the seller. But if there are relevant provisions in the contracts between manufacturers, sellers or between manufacturers and sellers, the parties to the contracts shall implement the provisions of the contracts.

If any product defect is found after such product has been put into circulation, the manufacturer or seller shall take such remedial measures as warning and recall in a timely manner. The manufacturer or seller, who fails to take remedial measures in a timely manner or take sufficient and effective measures and has caused any harm, shall assume the tort liability. In the

case that a manufacturer or seller knowing any defect of a product continues to manufacture or sells the product and the defect causes a death or any serious damage to the health of another person, the victim shall be entitled to require the corresponding punitive compensation. In addition, operators who sell defective products may be subject to confiscation of earnings from such sales, revocation of business licences and imposition of fines, and in severe circumstances, may be subject to criminal liability.

PROTECTION OF CONSUMERS

The Law of the PRC on Protection of Consumer Rights and Interests (《中華人民共和國消費者權益保護法》) was promulgated by the SAIC on 31 October 1993 and was amended on 25 October 2013 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/or provide services to customers.

According to the said law on Protection of Consumer Rights and Interests, consumers whose lawful rights and interests are infringed upon in purchasing or using commodities may claim compensation from the sellers, which shall, after paying compensation, have the right to be reimbursed by the liable manufacturers or other sellers supplying the commodities to them. Consumers or other victims suffering personal injuries or property damage from defects of commodities may claim compensation from the sellers and manufacturers. If the manufacturers are liable, the sellers shall, after paying compensation, have the right to be reimbursed by the manufacturers. If the sellers are liable, the manufacturers shall, after paying compensation, have the right to be reimbursed by the sellers. In extreme situations, pharmaceutical 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.

PROTECTION OF PHARMACEUTICAL PRODUCTS IN CHINA

Protection under patent law

According to the Patent Law of the PRC (《中華人民共和國專利法》) last amended on 27 December 2008, patent protection is divided into three categories: invention patent (發明專利), utility model patent (實用新型專利) and design patent (外觀設計專利). Invention patent (發明專利) is intended to protect new technology or measures for a product, method or its improvement. Utility model patent (實用新型專利) is intended to protect new technology or measures to increase the utility of a product shape, structure or its combination. Design patent (外觀設計專利) is intended to protect new designs by combination of product shape, graphic or color with aesthetic and industrial application value. Patents relating to pharmaceutical inventions are effective for 20 years from the initial date the patent application was filed.

Under the said Patent Law of the PRC, the term of patent protection starts from the date the patent application was filed, instead of the date it was registered. Patents relating to utility-models and designs are effective for ten years from the initial date the patent application was filed. Existing

patents can become invalid or unenforceable due to a number of factors, including known or unknown prior art, deficiencies in patent application, and lack of originality in technology. 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.

Protection under trademark law

The Trademark Law of the PRC (《中華人民共和國商標法》) was promulgated on 23 August 1982 (last amended on 30 August 2013) and the Implementing Regulations of the Trademark Law of the PRC (《中華人民共和國商標法實施條例》) was promulgated on 3 August 2002 (last amended on 29 April 2014). These laws provide the basic legal framework for the regulation of trademarks in China. The PRC Trademark Office is responsible for the registration and administration of trademarks throughout the country. Like patents, the PRC has adopted a "first-to-file" principle with respect to trademarks. 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. The SAIC has the power to investigate and handle any act of infringement of the exclusive right to use a registered trademark according to law; where the case is so serious as to constitute a crime, it shall be transferred to the judicial authority for handling.

PRC LAWS AND REGULATIONS RELATING TO FOREIGN INVESTMENT

Foreign-invested enterprises in China must follow applicable PRC laws and regulations and must not engage in activities detrimental to China's public interest.

The Foreign Investment Catalogue

The Foreign Investment Catalogue jointly promulgated by the NDRC and the MOFCOM on 10 March 2015, became effective on 10 April 2015 and replaced the Catalogue of Industries for Guiding Foreign Investment (2011 version) (《外商投資產業指導目錄(2011年版)》) which was effective on 30 January 2012. Both versions of the Foreign Investment Catalogue divide foreign investments in the PRC into three categories: encouraged, restricted or prohibited. Encouraged foreign investments are eligible to receive certain benefits and incentives from the PRC government, which may change from time to time; restricted foreign investments are permitted subject to restrictions; and prohibited foreign investments are not allowed. According to the Foreign Investment Catalogue, application of processing techniques such as steaming, stir-frying, moxibustion and calcination for making decoction pieces and production of traditional Chinese patent medicines of secret prescriptions are prohibited from foreign investment.

Foreign Currency Exchange

The principal regulations governing foreign currency exchange in China are the Regulations on Foreign Exchange of the PRC (《中華人民共和國外匯管理條例》) which were promulgated by the State Council on 29 January 1996 and last amended on 5 August 2008 and the Regulations on the Administration of Foreign Exchange Settlement, Sale and Payment (《結匯、售匯及付匯管理規定》) promulgated by the People's Bank of China on 20 June 1996 which became effective on 1 July 1996. Under these regulations and other PRC rules and regulations on currency conversion, RMB is freely convertible for payments of current account items, such as trade and service-related foreign exchange transactions and divided payments, but not freely convertible for capital account items, such as direct investment, loan or investment in securities outside China unless prior approval of the State Administration of Foreign Exchange (國家外匯管理局) (the "**SAFE**") or its local counterparts is obtained. Foreign investment enterprises ("the **FIEs**") in the PRC may purchase foreign exchange without the approval of SAFE for paying dividends by providing certain supporting documents (such as board resolutions), or for trade and service-related foreign exchange transactions by providing commercial documents evidencing such transactions. They are also allowed to retain their recurrent exchange earnings according to their needs of operation and the sums retained may be deposited into foreign exchange bank accounts maintained with the designated banks in the PRC. In addition, foreign exchange transactions involving overseas direct investment or investment and exchange in securities, derivative products abroad are subject to registration with SAFE and approval form or filling with the relevant PRC government authorities (if necessary).

The Circular of the SAFE on Relevant Business Operations Issues Concerning Improving the Administration of the Payment and Settlement of Foreign Exchange Capital of Foreign-Funded Enterprises (《關於完善外商投資企業外匯資本金支付結匯管理有關業務操作問題的通知》) was promulgated and became effective on 29 August 2008. It regulates the conversion by a FIE of foreign currency into RMB by restricting how the converted RMB may be used. It requires that RMB converted from the foreign currency denominated capital of a FIE may only be used for purposes within the business scope approved by the relevant governmental authorities and may not be used for equity investments within the PRC unless otherwise specifically provided. Further, it cannot be used to repay RMB loans if the proceeds of such loans have not yet been used.

Pursuant to the Circular of the SAFE on Further Improving and Adjusting Foreign Exchange Administration Policies for Direct Investment (《國家外匯管理局關於進一步改進和調整直接投資外匯管理政策的通知》) promulgated by SAFE on 19 November 2012 and became effective on 17 December 2012, approval is not required for the opening of an account entry in foreign exchange accounts under direct investment, for domestic transfer of the foreign exchange under direct investment. This Circular also simplified the capital verification and confirmation formalities for the FIEs; the foreign capital and foreign exchange registration formalities required for the foreign investors to acquire equities; the foreign exchange registration formalities required for the foreign investors to acquire the equities of Chinese party; and further improve the administration on exchange settlement of foreign exchange capital of FIEs.

On 4 July 2014, SAFE promulgated the Circular on Relevant Issues Concerning Foreign Exchange Administration for PRC Residents Engaging in Overseas Investment and Financing and Roundtrip Investments via Special Purpose Vehicles* (《國家外匯管理局關於境內居民通過特殊目的公司境外投融資及返程投資外匯管理有關問題的通知》), effective from 4 July 2014, which requires PRC residents (including PRC institutions and PRC individual residents) to register with SAFE for foreign exchange registration of overseas investments before contributing the domestic and overseas lawful assets or interests to a special purpose vehicle, and to update such registration in the event of any change of basic information of the registered special purpose vehicle or major change in capital, including increases and decreases of capital, share transfers, share swaps, mergers or divisions.

The M&A Rules

On 8 August 2006, six authorities including without limitation MOFCOM issued the Provisions on Mergers and Acquisitions of Domestic Enterprises by Foreign Investors (《關於外國投資者併購境內企業的規定》), which became effective on 8 September 2006 and amended on 22 June 2009. Such Rules provide that an offshore special purpose vehicle established for listing purposes, and controlled directly or indirectly by PRC companies or individuals shall obtain the approval of the China Securities Regulatory Commission prior to the listing and trading of such special purpose vehicle's securities on an overseas stock exchange.

Restrictions Relating to Dividend Distribution

The principal regulations governing distribution of dividends of foreign holding companies include the Company Law of the PRC (《中華人民共和國公司法》) promulgated by the SCNPC on 29 December 1993 and last amended on 28 December 2013, the Law of the PRC on Foreign-Funded Enterprises (《中華人民共和國外資企業法》) promulgated by the SCNPC on 12 April 1986 and amended on 31 October 2000, and the Administrative Rules under the Foreign Investment Enterprise Law* (《外資企業法實施細則》) promulgated by the State Council on 12 December 1990 and amended on 12 April 2001 and 19 February 2014.

According to the Company Law of the PRC, where a company distributes its after-tax profits for the current financial year, it shall draw 10% of its profits as the company's statutory common reserve, provided that a company with an aggregate common reserve of more than 50% of the company's registered capital may elect not to draw any statutory common reserve any more. Where the aggregate balance of the company's statutory common reserve is insufficient to cover any loss the company made in the previous financial year, the current financial year's profits shall first be used to cover the loss before any statutory common reserve is drawn.

EMPLOYEES' HEALTH AND SAFETY

Pursuant to the Interim Measures for the Pharmaceutical Industry Production Safety Management* (《醫藥行業安全生產管理暫行辦法》) promulgated and effective on 20 November 1987, in order to improve the production safety management and protect the health and safety of

the employees of pharmaceutical companies, all the pharmaceutical companies and their employees are required to satisfy the specified requirements, including the requirements on premises and facilities, sanitation, safety education, safety precautions, safety inspection, accident management, etc. Any violation of the provision of this law which leads to the damage of the state's or people's properties or lives shall be subject to the administrative sanctions, financial penalties or criminal liability.

ENVIRONMENTAL PROTECTION

Pursuant to the Discharge Standard of Water Pollutants for Pharmaceutical Industry Chinese Medicine Category (《中藥類製藥工業水污染物排放標準》) ("**Discharge Standard**") promulgated on 25 June 2008 and effective on 1 August 2008, the discharge of water pollutants control of each pharmaceutical enterprise manufacturing Chinese medicine is required to carry out according to the Discharge Standard.

THE RECOGNITION AND REVIEW OF HIGH AND NEW TECHNOLOGY ENTERPRISES

Pursuant to the Administrative Measures for the Recognition of High and New Technology Enterprises (《高新技術企業認定管理辦法》), promulgated by the Ministry of Science and Technology of the PRC (中華人民共和國科學技術部), MOF and the SAT on 14 April 2008, high and new technology enterprises refer to the PRC resident enterprises that are incessantly devoted to the research and development as well as transformation of technological achievements in the "High and New Technology Areas Entitled to the Key Support of the State", have formed their own independent core intellectual property rights and are carrying out business activities on this basis, and have been registered for at least one year within the territory of China (excluding Hong Kong, Macau and Taiwan regions).

An enterprise must satisfy the following requirements simultaneously in order to be recognised as a high and new technology enterprise: (1) it must be an enterprise that is registered within the territory of China (excluding Hong Kong, Macau and Taiwan regions) and possess independent intellectual property rights of the core technologies in its major products (services) by way of independent research and development, acceptance of transfer, donation or merger during the immediately preceding three years or through exclusive licensing for a minimum period of five years; (2) its products (services) fall within the range prescribed in the "High and New Technology Areas Entitled to the Key Support of the State"; (3) the proportion of scientific and technological personnel and research and development personnel in its employment with a minimum educational background of junior college graduation reaches the required percentage; (4) the enterprise has been conducting continuous research and development activities, and the proportion of its total research and development expenditure and its total sales revenue during the immediately preceding three accounting years meets the requirements; (5) the revenue from high and new technology products (services) accounts for at least 60 percent of the total revenue of the enterprise during the current year; and (6) the enterprise's level of organisation and management of research and development, capacity of transformation of scientific and technological achievements, the number of independent

intellectual property rights, growth in sales and total assets as well as other indicators conform to the requirements mentioned in the Guidelines on the Administration of Recognition of High and New Technology Enterprises (《高新技術企業認定管理工作指引》).

The validity period of the high and new technology enterprise qualification shall be three years from the date of issuance of the certificate of high and new technology enterprise. The enterprise shall file an application for review within three months prior to the expiration of the validity period. The review shall focus on the conformity with requirement no. 4 above, i.e. the continuity of research and development activities of the enterprise and the proportion of its total research and development expenditure and its total sales revenue. Therefore, for the review, the enterprise shall submit a report on research and development activities and other technological innovation activities conducted during the immediately preceding three years, statements on the research and development expenditure of the enterprise during the immediately preceding three financial years and special audit report on the revenue from high and new technology products (services) during the immediately preceding one financial year attested by a qualified intermediary agency.