REGULATORY FRAMEWORK

Our products are subject to regulatory controls governing pharmaceutical products and medical appliances and equipment. Thus we are subject to regulation and oversight by different levels of the food and drug administration in the PRC, in particular, the SFDA. The Law of the People's Republic of China on the Administration of Pharmaceuticals (《中華人民共和國藥品管理法》), as amended on 28 February 2001, together with its implementation regulations, provides the legal framework for the administration of the production and sale of pharmaceutical products in the PRC and covers the manufacturing, distributing, packaging, pricing and advertising of pharmaceutical products in the PRC.

We are also subject to other PRC laws and regulations that regulate the manufacturing, distribution of pharmaceutical products and medical devices, as well as commercial franchising activities.

Principal Administrative Authorities

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

MOH is a ministerial department under the direct supervision of the State Council. MOH focuses primarily on public healthcare matters that are not directly related to the pharmaceutical industry. MOH also performs a variety of regulatory roles in relation to drug administration, including, without limitation, carrying out healthcare system reform, formulating and implementing the National Essential Drugs System, formulating the National Drug Code and the National List of Essential Drugs, proposing pricing policies for National Essential Drugs, and supervising healthcare institutions. Meanwhile, MOH is responsible for supervising and overseeing the SFDA.

The Ministry of Commerce of PRC is the competent authority of the pharmaceutical wholesale sector in China. It is responsible for:

- formulating plans, policies and standards concerning the development of the pharmaceutical distribution industry;
- enhancing the structure readjustment of the pharmaceutical distribution industry;
- guiding the reform of the pharmaceutical distribution industry; and
- promoting the development of a modern pharmaceutical distribution industry in China.

The NDRC is responsible for the macro-guidance and management 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 management over the price of medicines and formulating the national unified retail price for certain drugs falling under the National Medical Insurance Drugs Catalog and for drugs the production and distribution of which are monopolized.

In accordance with the state laws, rules, regulations and policies relating to health and drugs and in light of the characteristics of the traditional Chinese medicine industry, the State Administration of Traditional Chinese Medicine 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.

MANUFACTURING OF PHARMACEUTICAL PRODUCTS

A manufacturer of pharmaceutical products must obtain a variety of special permits and licenses before commencing operations. These include a pharmaceutical manufacturing permit, a GMP certification(s) and a medicine approval document(s).

Pharmaceutical Manufacturing Permit

A manufacturer of pharmaceutical products must obtain a pharmaceutical manufacturing permit and a business license from the relevant provincial food and drug administration authority in the PRC. The grant of such permit is subject to an inspection of the manufacturing facilities, and a finding that their sanitary condition, quality assurance systems, management structure and equipment meet the required standards. According to the Regulations of Implementation of the Law of the People's Republic of China on the Administration of Pharmaceuticals (《中華人民共和國藥品管理法實施條例》), which became effective on 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》), which became effective on 5 August 2004, a pharmaceutical manufacturing permit 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.

Good Manufacturing Practices

A manufacturer of pharmaceutical products and pharmaceutical materials must obtain GMP certification for production of such products and materials in the PRC. GMP comprises a set of detailed guidelines on practices governing the production of pharmaceutical products. GMP certification criteria include those related to 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. A GMP certificate is generally valid for five years. The certificate may be renewed at least six months prior to the expiry date.

Formulated by the WHO, the guidelines embodied in GMP were designed to protect consumers by minimizing production errors and the possibility of contamination. The concept of GMP was introduced in the PRC in 1982 and was published in the Guidelines on the Implementation of GMP Standards (《藥品生產質量管理規範實施指南》) in 1985. In 1988, MOH promulgated the first version of GMP standards, which was subsequently amended in 1992, 1999 and 2010. On 17 January 2011, SFDA published the current version of GMP standards (2010 revised edition), which became effective on 1 March 2011.

Approval and Registration of Pharmaceutical Products

In accordance with the Measures for the Administration of Drug Registration (《藥品註冊管理辦法》), which became effective on 1 October 2007, a medicine must be registered with and approved by the SFDA before it can be manufactured. The registration and approval process requires the manufacturer to submit to the SFDA a registration application containing detailed information concerning the efficacy

and quality of the medicine and the manufacturing process and the production facilities the manufacturer expects to use for production of such medicine. This process generally takes at least a few months and could be longer, depending on the nature of the medicine under review, the quality of the data provided and the workload of the SFDA. To obtain SFDA registration and approval necessary for commencing production, the manufacturer is also required to conduct pre-clinical trials, apply to the SFDA for permission to conduct clinical trials, and, after the clinical trials are completed, file clinical data with the SFDA for approval. In January 2009, the SFDA issued the Provisions on Special Approval for the Registration of New Drugs (《新藥註冊特殊審批管理規定》) that created a fast track review process for the approval of certain new drugs.

If a medicine is approved by the SFDA as a new drug, the SFDA will issue a new drug certificate to the manufacturer and may impose a monitoring period of not more than five years. During the monitoring period, the SFDA will monitor the safety of the new drug, and will not accept new drug certificate registrations for an identical medicine by another pharmaceutical company, nor approve the production or import of an identical medicine by other pharmaceutical companies.

Continuing SFDA Regulation

A manufacturer of pharmaceutical products is subject to periodic inspection and safety monitoring by the SFDA to determine the manufacturer's compliance with regulatory requirements. The SFDA 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 referring non-compliance to the relevant authority for criminal investigation.

DISTRIBUTION OF PHARMACEUTICAL PRODUCTS

Pharmaceutical Operation Permit

The establishment of a wholesale pharmaceutical distribution company requires the approval of the food and drug administration of the people's government of the province, autonomous region or municipality directly under the PRC Central Government. Upon approval, the authority will grant a pharmaceutical operation permit. The establishment of a retail pharmacy requires the approval of the local food and drug administration at or above the county level. Upon approval, the authority will grant a pharmaceutical operation permit. Once these permits are received, the wholesale and retail pharmaceutical company shall be registered with the relevant administration for industry and commerce. The grant of such permit is subject to an inspection of the operator's facilities, warehouse, hygienic environment, quality control systems, personnel (including of whether pharmacists and other professionals have the relevant qualifications) and equipment. Under the Measures for the Administration of Pharmaceutical Operation Permit (《藥品經營許可證管理辦法》), which became effective on 1 April 2004, the pharmaceutical operation permit is valid for five years. Each operation permit holder must apply for an extension of the permit six months prior to its expiration, and extension is granted only after a re-examination of the permit holder by the authority which issued the permit. In addition, a pharmaceutical operator must obtain license from the relevant administration for industry and commerce prior to commencing its business.

Good Supply Practices

Each retail or wholesale operator of pharmaceutical products is required to obtain a GSP certificate from relevant food and drug administration prior to commencing its business. GSP standards, which comprise a set of quality guidelines for operations related to pharmaceutical products, regulate pharmaceutical wholesale and retail operators to ensure the quality of pharmaceutical products in the PRC. The current applicable GSP standards require pharmaceutical operators to implement strict controls on the 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》) issued on 24 April 2003 by SFDA, the GSP certificate is valid for five years and may be extended three months' prior to its expiration upon a re-examination by the relevant authority.

Supervision and Management of Drug Distribution

To strengthen drug supervision and management, and maintain orderly circulation and qualities, the SFDA issued the Method of Supervision and Management of Drug Distribution (《藥品流通監督管理辦法》) on 31 January 2007, which became effective from 1 May 2007. Detailed provisions are imposed on a variety of matters 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.

Distance between retail pharmacies

The PRC central government has not published rules on the distance between the retail pharmacies. However, for reasonable arrangement of pharmacy resources, the local governments have published some local regulations and guidance on the distance between the retail pharmacies. The following are examples of the relevant rules of the major locations of our retail pharmacies.

Beijing

Under article 5 of the Regulation Regarding Opening Retail Pharmacies in Beijing (《北京市開辦藥品零售企業暫行規定》), the opening of retail pharmacies should be in accordance with the principle of "reasonable layout and convenience to the masses".

The newly opened retail pharmacies should keep a traveling distance above 350 meters with existing pharmacies:

(1) There is no distance restriction on the directly operated retail pharmacies which are not legal persons and are operated by the same chain enterprise.

(2) There is neither distance restriction on, while opened in the same shopping mall, the directly operated retail pharmacies which are not legal persons, nor the retail enterprises which focus on type B non-prescription drugs.

Shanghai

Under article 3 of Shanghai's Guidance For Administrative Licensing of Drug Retail Enterprises 2011 Edition (《上海市藥品零售企業行政許可指南》(2011版)), the opening of retail pharmacies should be in accordance with the principle of "reasonable layout and convenience to the masses". And it should also meets the requirements for commercial network layout and development plan in the area where the

pharmacies are located. The law prevents new retail pharmacies gathering together in the city which its population is concentrated, but encourage the new retail pharmacies open in newly established residential areas, remote suburban and rural areas.

The newly opened (include relocation) retail pharmacies should keep a distance of more than 300 meters (include 300 meters) with existing pharmacies. The regulation cannot be changed even the retail pharmacy reach an agreement of the distance with the adjacent retail store.

For newly opened retail pharmacies, if there are more than 7,000 (include 7,000) residents (including household population and floating population) in this area, then there should be at least one retail pharmacy. But this is not applicable in rural areas.

Tianjin
Under article 6 of Tianjin's Regulation Of Implementation Of Business License For Drug Retail Enterprises (《天津市藥品零售企業藥品經營許可證管理實施細則》), the opening of retail pharmacies should be in accordance with the principle of "reasonable layout and convenience to the masses". The newly opened retail pharmacies should keep a distance of more than 100 meters with existing pharmacies.

EXPORT OF APIS AND INTERMEDIATE PRODUCTS TO OVERSEAS MARKETS

The APIs and intermediate products exported to overseas markets must be registered with and approved by both the SFDA and the local food and drug administrative authorities of the importing countries. In order to register with the local food and drug administrative authorities of the importing countries, (i) the APIs and the intermediate products are generally required to meet the quality standards of those countries, such as those set out in the United States Pharmacopeia and the European Pharmacopoeia; (ii) the production facilities are required to pass the GMP on-site inspection; and (iii) the samples extracted during the on-site inspection are required to pass the inspection as well. In addition to the above, the exported APIs and intermediate products are also subject to the import tariff related regulations of the importing countries. The developed economies that import our APIs, such as the U.S. and the European Union, have implemented the WTO agreement on pharmaceutical products in 1993, which eliminated import tariffs for finished products, active ingredients and some chemical intermediates, and in many countries tariffs are zero or close to zero. However, certain major developing economies, such as China, India, Russia, and the ASEAN countries still have import tariffs for active ingredients and finished products. Normally the importers of our API products bear all taxes and fees that arise after the goods reached the port of the importing countries. Products that are exported to the U.S. must meet the regulatory requirements under the U.S. Food and Drug Administration, while the product specification and standards are based on the customers' specific requirements. Products that are exported to the European Union must meet the regulatory requirements under the GMP standards.

COMMERCIAL FRANCHISE REGULATIONS

The PRC State Council promulgated the Regulations on the Administration of Commercial Franchises (《商業特許經營管理條例》) (the "Franchise Regulations") on 6 February 2007. The Franchise Regulations, which became effective on 1 May 2007, are intended to further liberalize the regime governing commercial franchising activities in the PRC. In addition to the Franchise Regulations, the Ministry of Commerce has promulgated two implementing regulations, namely, the Administrative Measures for Archival Filing of Commercial Franchises (《商業特許經營備案管理辦法》) (the "Archival Filing Measures"), which was amended on 12 December 2011, and the Administrative Measures on

Information Disclosure Requirements for Commercial Franchises (《商業特許經營信息披露管理辦法》) (the "Disclosure Measures") which was amended on 23 February 2012. The Franchise Regulations, Archival Filing Measures and Disclosure Measures form the basic legal framework for the regulation of PRC franchise operations, and address the requirements, fees, qualifications, administrative reporting and compliance procedures, and other issues related to commercial franchising.

MANUFACTURING AND DISTRIBUTION OF MEDICAL DEVICES

Medical Devices Manufacturing Permit

In accordance with the Regulations on the Supervision and Administration of Medical Devices (《醫療器械監督管理條例》), which became effective on 1 April 2000, manufacturing of class II and/or class III medical devices is subject to inspection and approval by the local drug administrative authority of the provinces, autonomous regions and municipalities and the manufacturer of such medical devices is required to obtain the Medical Device Manufacturing Enterprise License (《醫療器械生產企業許可證》). The list of each class of medical devices is set forth in the Medical Device Product Catalog (《醫療器械分類目錄》), which is promulgated and updated by the SFDA from time to time. The term of the validity of the Medical Device Manufacturing Enterprise License is five years. Re-inspection is required for the renewal of the license.

Registration of Medical Devices Manufacturing

In accordance with the Regulations on the Supervision and Administration of Medical Devices (《醫療器械監督管理條例》), a product registration system for manufacturing medical devices was implemented. Under this product registration system, class I medical devices shall be inspected, approved and issued a registration certificate by the local drug administrative authority, class II medical devices shall be inspected, approved and issued registration certificates by the drug regulatory agency of provinces, autonomous regions and municipalities, and class III medical devices shall be inspected, approved and issued registration certificates by the drug regulatory agency directly under the State Council. The term of validity for the registration certificate of medical devices is four years, which must be renewed within six months prior to expiration. The registration certificate shall be invalidated if the production has been terminated for more than two consecutive years.

Medical Device Operation Permit

In accordance with the Regulations on the Supervision and Administration of Medical Devices (《醫療器械監督管理條例》), which became effective on 1 April 2000, and the Measures for the Administration of Permits for Medical Devices Operation Enterprises (《醫療器械經營企業許可證管理辦法》), which became effective on 9 August 2004, an enterprise engaged in wholesale or retail of medical devices must obtain an operation permit from the provincial level food and drug administration before commencing the distribution of class II and class III medical devices. An exemption from this requirement exists in the case of a distributor of a small number of Class II medical devices where the distributor is able to guarantee the safety and effectiveness of the medical devices. An operation permit is valid for five years and is renewable upon expiration. To renew an operation permit, a distributor needs to submit an application to the provincial level food and drug administration, along with required information six months before the expiration of the permit.

In December 2008, the SFDA and MOH jointly released the Measures on Monitoring and Re-Evaluation of the Adverse Events Involving Medical Devices (Trial) (《醫療器械不良事件監測和再評價管理辦法(試行)》), which specify the process and timeline for reporting, monitoring and investigating adverse incidents involving medical devices.

REGISTRATION OF NEW PHARMACEUTICAL PRODUCTS

According to the Measures on the Administration of Pharmaceutical Products Registration (《藥品註冊管理辦法》), which was promulgated by the SFDA in 2007, new pharmaceutical products refer to those products which have not been launched in the PRC market. Pharmaceutical products taking different dosage forms or route of administration or having curative effects for additional diseases are treated as new pharmaceutical products. All new pharmaceutical products 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 SFDA prior to commencement of clinical trials of any new pharmaceutical product. Application materials, including relevant pre-clinical research information, must first be submitted to the provincial drug administrative authorities. The provincial drug administrative authorities will conduct production site visits. For biological products, the SFDA will collect three sets of drug samples for examination. The SFDA will consolidate the review opinions, on-site inspection report, drug inspection report (if any) and pre-clinical research information from the provincial authorities, and then organize an expert committee made up of pharmaceutical experts and other specialists to conduct technical assessments of the new pharmaceutical product to consider whether an approval for clinical trials should be granted.

Pharmaceutical manufacturers may conduct clinical trials after obtaining approval to do so. Clinical trials comprise four phases: phase I (preliminary pharmacology and human safety trials), phase II (preliminary assessment on efficacy), phase III (confirmation of efficacy) and phase IV (research on applications after launching of new pharmaceutical products). 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 minimum number of clinical trial cases set forth in the Measures on the Administration of Pharmaceutical Products Registration. In the case of rare diseases, special diseases and other exceptional circumstances, application for reducing the number of clinical trial cases or exemption from clinical trials may be submitted to SFDA for approval. Upon the completion of clinical trials, the applicant must also apply for an approval to manufacture the new pharmaceutical product. Application materials, including relevant clinical trial information and raw material samples, must be submitted to the provincial drug administrative authorities and the drug inspection bureau. The provincial SFDA will then review the application materials and conduct production site visits. Three consecutive production batches of drug samples will be collected from the applicant's production site for examination by the drug inspection bureau. After their investigation and assessment of the application, the provincial drug administrative authorities and the drug inspection bureau will report to the assessment center of the SFDA, which will conduct a final assessment.

If the new pharmaceutical product passes the technical assessment, the assessment center of the SFDA would notify the applicant to apply for on-site examination of production and inform the certification center of the SFDA. The certification center of the SFDA will conduct an on-site inspection, within 30 days after receipt of the application, on the process of bulk production of samples and confirm the feasibility of the assessed production process. One set of samples will be delivered to another drug inspection bureau to re-examine the standard of the pharmaceutical product, and the results will be

reported to the assessment center of the SDFA. The assessment center will then consolidate the results from the on-site examination and sample examination to form an opinion to report to the SDFA. The SDFA will then consider whether an approval for registration of the new product should be granted. If approved, the applicant will be granted a certificate of new drug and an approved pharmaceutical number. The manufacturer may then commence mass production of the new pharmaceutical product. The SFDA may stipulate a monitoring period of up to five years in respect of any new pharmaceutical product approved for production to monitor the safety of such new pharmaceutical product on an ongoing basis. The SFDA will not approve the production, change and import of such new pharmaceutical product 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 pharmaceutical product. 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. Upon the expiration of the monitoring period of such new pharmaceutical products, applicants may file an application in respect of their generic pharmaceutical products or for the import of similar pharmaceutical products.

According to the Measures on the Administration of Pharmaceutical Products Registration (藥品註冊管理辦法), the approval number for medicine approved by SFDA, the certificate of imported medicines and registration certificate of medicines are valid for five years. The certificates should be renewed within six months prior to expiration.

On 7 January 2009, the SFDA promulgated the Administrative Measures on the Special Examination and Approval of New Pharmaceutical Products Registration (《新藥註冊特殊審批管理規定》), which provided that certain types of new pharmaceutical products may apply to go through the special examination and approval process when submitting the application for clinical trials or the application of production. Under the special examination and approval process, the new pharmaceutical products which fulfil the prescribed criteria will enjoy priorities such as accelerated approval and additional supplementary information submission channels with respect to the registration.

CHINESE MEDICINE PROTECTION

According to the Regulations on the Protection of Chinese Medicines (《中藥品種保護條例》), which was promulgated by the State Council on 14 October 1992 and became effective from 1 January 1993, for the purposes of improving the quality and promoting the development of traditional Chinese medicines, as well as protecting their manufacturers' legitimate rights and interests, protections are granted with respect to a variety of domestically manufactured traditional Chinese medicines which have fulfilled national medicine standards ingredients. 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 SDA, 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 were implemented with effect from 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 whose

prescription, purchase and intake require prescription by practicing doctors or assistant doctors. Over-the-counter medicines relate to those whose prescription, purchase and intake do not require prescription by practicing doctors or assistant doctors.

The SFDA is responsible for the selection, approval, publication and revision of the State Non-Prescription Medicine Catalog (《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 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 drugs. Retailers and wholesalers of prescription medicines and over-the-counter medicines and retail outlets selling 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 food and drug administration or other designated authorities. 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. Retail outlets are required to source their drugs from qualified manufacturers and operators holding the requisite permits and approvals.

NATIONAL LIST OF ESSENTIAL DRUGS

On 18 August 2009, MOH and other eight ministries and commissions in the PRC issued the Provisional Measures on the Administration of National List of Essential Drugs (《國家基本藥物目錄管理辦法(暫行)》), or the Measures, and the Guidelines on the Implementation of the National List of Essential Drugs System (《關於建立國家基本藥物制度的實施意見》), or the Essential Drugs Guidelines, that aim to promote essential medicines sold to consumers at fair prices in the PRC and ensure that the general public in the PRC have equal access to the drugs contained in the National List of Essential Drugs. On the same day, MOH promulgated the National List of Essential Drugs (Catalog for the Basic Healthcare Institutions) (2009 Edition) (《國家基本藥物目錄(基層醫療衛生機構配備使用部分)》(2009版)), which applies only to basic healthcare institutions.

Basic healthcare institutions primarily include county-level hospitals, county-level Chinese medicine hospitals, rural clinics and community clinics. Pharmaceutical sales from basic healthcare institutions account for a small portion of the pharmaceutical market in the PRC.

PRICE CONTROLS

Pursuant to the Opinion of the Bureau of State Planning Commission regarding Reforms on Price Administration of Pharmaceutical Products (《國家計委關於改革藥品價格管理的意見》) issued by Bureau of State Planning Commission, the predecessor of the National Development and Reform Commission, on 20 July 2000, and the Circular of the National Development and Reform Commission on Issue of Price-controlled Pharmaceutical Products Catalog of National Development and Reform Commission (《國家發展改革委員會關於印發〈國家發展改革委定價藥品目錄〉的通知》), which became effective on 1 August 2005, prices of pharmaceutical products are either determined by the PRC government or based on market conditions. On 5 March 2010, the NDRC issued the Circular of the National Development and Reform Commission on adjustment of Price-controlled Pharmaceutical Products Catalog of National Development and Reform Commission (《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》), which has adjusted the Price-controlled Pharmaceutical Products Catalog issued in 2005. The prices of certain pharmaceutical products sold in the PRC, primarily those included in the national and Provincial Medical Insurance Drugs Catalogs are subject to price controls mainly in the form

of fixed prices or price ceilings. Manufacturers and operators cannot set the actual price for any given price-controlled product above the price ceiling or deviate from the fixed price imposed by the government. The prices of medicines that are not subject to price controls are determined freely at the discretion of the relevant pharmaceutical companies. Sales of pharmaceutical products by pharmaceutical manufacturers in the PRC to overseas markets are not subject to any price control by the PRC government.

NDRC issued the Notice on the Guiding Retail Price of National Essential Drugs (《國家發展改革委關於公佈國家基本藥物零售指導價格的通知》) in September 2009, which sets ceiling prices for the national essential drugs. As a result, all kinds of medical institutions, retail pharmacies and other pharmaceutical manufacturers and distributors at all levels should not sell the national essential drugs at the prices which exceed the prices listed in this notice.

The 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. On 5 March 2010, the NDRC promulgated the Circular of the National Development and Reform Commission on adjustment of Price-controlled Pharmaceutical Products Catalog of National Development and Reform Commission (《國家發展改革委員會關於調整〈國家發展改革委定價藥品目錄〉等有關問題的通知》), which revised the Catalog of Medicines subject to NDRC Price Control issued in 2005 (國家發改委定價藥品目錄). The latest price reductions occurred in September 2012 when the NDRC promulgated the Notice for Adjustment of the Prices of Medicines for certain immunomodulating agents, oncology and blood systems medications, setting out the ceiling prices for certain medicines within these therapeutic areas.

Fixed prices and price ceilings on medicines are determined based on profit margins that the relevant government authorities deem reasonable, the type and quality of the medicine, 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.

Further, pursuant to the Notice Regarding Further Improvement of the Order of Market Price of Pharmaceutical Products and Medical Services (《關於進一步整頓藥品和醫療服務市場價格秩序的意見》) jointly issued by the NDRC, the State Council Legislative Affairs Office and the State Council Office for Rectifying, the MOH, the SFDA, the Ministry of Commerce, the Ministry of Finance and the Ministry of Labor and Social Security on 19 May 2006, the PRC government exercises price control over pharmaceutical products included in the National Medical Insurance Drugs Catalog and Provincial Medical Insurance Drugs Catalog, and made an overall adjustment of their prices by reducing the retail price of certain overpriced pharmaceutical products and increased the retail price of certain underpriced pharmaceutical products in demand for clinical use but that have not been produced in large quantities by manufacturers due to their low retail price levels. In particular, the retail price charged by hospitals at the county level or above may not exceed 115% of the procurement cost of the relevant pharmaceutical products or 125% for certain Chinese medicine products.

On 9 November 2009, the NDRC, the MOH and the Ministry of Human Resources 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 drugs included in the National Medical Insurance Drugs

Catalog, Provincial Medical Insurance Drugs Catalog and certain drugs whose production or trading tend to create monopolies, drugs listed in the National List of Essential Drugs are subject to PRC government price control. The prices of other drugs are determined by the market conditions and are not subject to PRC government price control.

The manufacturer of a medicine or the distributor of an imported medicine may apply for an increase in the price of the medicine and it must either apply to the provincial price control authorities in the province where it is incorporated, if the medicine is provincially regulated, or to the NDRC, if the medicine is regulated at the central government level. For a provincially regulated medicine, in cases where provincial price control authorities approve an application, the provincial price control authorities must file the new approved price with the NDRC for record and make an announcement to the public through designated media.

In addition, 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 for an approval for separate pricing, subject to approval of NDRC.

With respect to pharmaceutical products whose prices are determined by market conditions, the pharmaceutical manufacturers are able to determine the retail price of their products based on their production cost and market demand and supply for the relevant product. Wholesalers and retailers of such products are permitted to determine the actual retail price to the end customers, provided that such price does not exceed the retail price determined by the manufacturers. The pharmaceutical manufacturers are required to adjust the retail prices from time to time based on their production cost and the market demand and supply for the relevant product.

Under the Measures on the Investigation of Ex-Factory Prices of Drugs (Trial Implementation) 《藥品出廠價格調查辦法(試行)》) issued on 9 November 2011 and the Notice on Enforcement of Investigation and Survey of Ex-Factory Prices of Drugs (《國家發展改革委辦公廳關於加強藥品出廠價格調查和監測工作的通知》) issued on 26 March 2012 by NDRC, the government will have the authority to conduct investigation on the ex-factory prices on medicines produced in China or imported from overseas but distributed in China. The pharmaceutical manufacturers should provide certain documents required by NDRC. The investigators are required to check the retail prices of these pharmaceutical products according to the pricing documents issued by the price authority or the pharmaceutical manufacturers. Once the measures are implemented, the government will be able to use the results of the investigation to set the ex-factory prices for the pharmaceutical products.

According to the Notice of Investigation of Ex-factory Prices on Certain Medicines issued by NDRC (《國家發展改革委辦公廳關於對部分藥品進行出廠價格調查的通知》) on 1 July 2010, a survey of the wholesale prices of approximately 900 pharmaceutical products and the operations of the relevant pharmaceutical manufacturers will be conducted to understand the pricing structure of the selected pharmaceutical products, which may lead to further downward adjustments in the maximum retail prices of these pharmaceutical products based on the results of the survey.

According to the Notice on Inspection of National Medical Healthy Service (《關於開展全國醫藥衛生服務價格大檢查的通知》) which was issued in March 2011, NDRC and other related authorities will inspect the rates of medical institutions, disease control and prevention centers, blood stations, medical organizations which conduct centralized procurement, and units engaged in medical service as at 1 January 2010.

Under the Circular of Regulating the Price of Medical Service and Related Items (《關於規範醫療服務價格管理及有關問題的通知》) issued on 4 May 2012, NDRC, MOH and National Administration of Traditional Chinese Medicine revised the Standard of National Price for Medical Service 2012 (《全國醫療服務價格項目規範（二零一二年版）》). The newly revised Standard of National Price for Medical Service 2012 comprehensively standardizes the prices of medical services, and strictly controls the prices of newly added medical services. Prices fixed for medical services published in the national standard are basis for charges of medical services in non-profit hospitals at various levels. The fee charging items which not listed in the national standard should be canceled in principle. The items which need to be preserved, should be submitted to the NDRC and MOH for approval before the end of May 2013. The charging items can exist during the approval period.

ENCOURAGEMENT ON THE ENTRY OF PRIVATE INVESTMENT INTO THE HEALTHCARE INDUSTRY

Under the Guiding Opinions of the State Council On Encouraging and Guiding the Healthy Development of the Private Investment (《國務院關於鼓勵和引導民間投資健康發展的若干意見》) issued on 7 May 2010, and the Circular of the State Council on Issue of the Cooperation of the Departments to Encourage and Guide the Healthy Development of the Private Investment (《國務院辦公廳關於鼓勵和引導民間投資健康發展重點工作分工的通知》) issued on 22 July 2010, the State Council requests the governments at all levels to promote the healthcare reform by encouraging and guiding the private investment to participate in the development of the healthcare industry. The PRC government should guide the private investment as an important supplement to the investment by the government, and speed up the establishment of a public healthcare service system in which the government investment plays a dominant role and the private investment plays an ancillary role. The government should support the private investment to operate hospitals, community healthcare service centers, nursing homes, outpatient department and clinics. It should also support the private investment to take part in the establishment of public hospitals. The private medical institutions are encouraged to provide public health service, basic healthcare service and specified service of medical insurance. The State Council requires the government at all levels to provide a favourable environment to the private investment in the healthcare industry with governmental financial support, financial institutions' financing and simplified procedures for government approvals.

Under the Opinions of Priority Areas of Work on Deepening the Economic System Reform in 2012 (《關於2012年深化經濟體制改革重點工作意見的通知》) approved by State Council on 18 March 2012, the State Council requires the governments at all levels to advance pilot reforms of public hospitals at the county level and urban public hospital, and speed up to form an open, diversified medical service model to deepen healthcare system reform.

REIMBURSEMENT UNDER THE NATIONAL MEDICAL INSURANCE PROGRAM

Urban Resident Program

Pharmaceutical products listed in the National Medical Insurance Drugs Catalog, are covered by the national medical insurance program. The national medical insurance program was adopted pursuant to the Decision of the State Council on the Establishment of Basic Medical Insurance System for Urban Employees (《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 basic medical insurance program and the insurance premium is jointly contributed by the employers and employees.

Participants of the national medical insurance program and their employers are required to contribute to the payment of insurance premium on a monthly basis. The Notice Regarding the Tentative Measures for the Administration of the Scope of 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 Drugs Catalog must be clinically needed, safe, effective, reasonably priced, user-friendly and available in the market and must also meet the following requirements:

- it is set forth in the Pharmacopoeia of the PRC;
- it meets standards promulgated by the State Drug Administration (the predecessor of SFDA); and
- it is approved by the State Drug Administration for import.

The national medical insurance drugs, industrial injury insurance drugs and maternity insurance drugs catalog

On 27 November 2009, the Ministry of Human Resources and Social Security of the PRC published the Circuit of the National Medical Insurance Drugs, Industrial Injury Insurance Drugs and Maternity Insurance Drugs Catalog (《國家基本醫療保險、工傷保險和生育保險藥品目錄 (二零零九年版)》) to renew the National Medical Insurance Drugs Catalog, and requested the provinces, autonomous regions and municipalities throughout the PRC to issue the provincial catalogs on 31 March 2010. More medical products were included in this Catalog. The Catalog will be modified from time to time.

The Catalog can be divided into three types: western medicine, traditional Chinese medicine patent prescription and Chinese herbal pieces. When the patients who take part in the insurance purchase the western medicine, traditional Chinese medicine patent prescription which are included in the Catalog and Chinese herbal pieces which are not included in the Catalog, they will get reimbursement according to the rules of national medical insurance drugs, industrial injury insurance drugs and maternity insurance drugs insurance funds.

The medical insurance drugs catalog is divided into two parts, namely Part A and Part B. The National Essential Drugs are all included in part A of the Catalog. And Industrial Injury Insurance and Maternity Insurance are not divided into any parts. The drugs included in Part A are determined by the PRC government for general application and local authorities may not alter the list of drugs in Part A. Patients purchasing drugs included in Part A of the Catalog are entitled to reimbursement of the entire amount of the purchase price.

The drugs 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, the number of Part B drugs, but the total number altered may not exceed 243 kinds of drugs. As a result, the contents of Part B in the Catalog may differ from region to region in the PRC. Patients purchasing drugs included in Part B of the National Medical Insurance Drugs Catalog 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.

Medical Subsidy to Residents in Rural Areas

As part of the medical treatment and healthcare reform, the PRC central government has implemented plans for the PRC central and local governments to share the costs of subsidizing the medical expenses of rural residents since 2003. On 13 January 2004, the State Council circulated the Guiding Opinions regarding the Further Improvement of Cooperative Medical Care in New Type Rural Areas on a Trial Basis (《國務院辦公廳轉發衛生部等部門關於進一步做好新型農村合作醫療試點工作指導意見的通知》), which was formulated by ten PRC government agencies including MOH, pursuant to which every rural resident in the middle and western regions of the PRC participating in this new rural cooperative medical care plan on a voluntary basis receives medical subsidies in the amount of RMB10.0 (equivalent to approximately US$1.5) per year from the PRC central government. In addition, local governments in the middle and western regions of the PRC are required to subsidize no less than RMB10.0 per person per year and those in the eastern regions of the PRC are encouraged to aim to subsidize up to RMB20.0 (equivalent to approximately US$3.0) per person per year. The actual amount of subsidy contributed by local governments is dependent on the financial condition of the relevant local government.

The PRC central government further increased the amount of subsidy in 2006. On 10 January 2006, MOH, NDRC and five other ministries and bureaus jointly promulgated the Notice Regarding Acceleration of Implementation of Cooperative Medical Care in New Type Rural Areas on a Trial Basis (《關於加快推進新型農村合作醫療試點工作的通知》), pursuant to which the PRC central government increased the amount of subsidy for the rural residents in middle and western regions of the PRC, from RMB10.0 per person per year to RMB20.0 per person per year. In addition, local governments were required to increase the amount of subsidy by an additional RMB10.0 per person per year.

Urban Residents Basic Medical Insurance

Pursuant to the Guiding Opinion of the State Council on Developing Pilot Programs of Urban Residents 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》), promulgated by the State Council on 10 July 2007, in order to achieve the objective of establishing a medical security system basically covering all urban and rural residents, the State Council has decided to launch pilot programs of urban resident basic medical insurance, so as to cover the unemployed urban residents who have not been covered by any arrangements under the medical security system. The opinion provides that urban resident basic medical insurance premiums shall be mainly paid by households with appropriate subsidies of governments. The urban resident basic medical insurance fund will first be used for payment of the inpatient fees and outpatient fees of participating residents who have serious illness.

Safety and Credibility Rating

In order to increase the awareness of pharmaceutical product manufacturers and research institutions about the safety and credibility of pharmaceutical products and medical equipment, the SFDA promulgated the Tentative Regulations Regarding the Safety and Credibility Rating of Pharmaceutical Products (《藥品安全信用分類管理暫行規定》) on 13 September 2004, pursuant to which the SFDA at the county level or above regulates the safety and credibility rating of the pharmaceutical product manufacturers and research institutions in their jurisdiction by establishment of an information system through which the relevant pharmaceutical product manufacturers and research institutions may be rated and rewarded accordingly.

TENDERING REQUIREMENTS FOR HOSPITAL PURCHASES OF MEDICINES

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 by the State Commission for Restructuring Economic Systems and seven other ministries and commissions in the PRC, require public hospitals and healthcare institutions to purchase medicines through a centralized tendering process. MOH and other relevant government authorities have promulgated a series of regulations and releases in order to implement the tendering requirements. On 12 November 2001, MOH and five other ministries and commissions jointly promulgated the Working Regulations of Medical Institutions for Purchase of Medicines by Centralized Tendering and Price Negotiations (Trial) (《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)》), or the Working Regulations, to implement the tendering process requirements and ensure the requirements are followed uniformly throughout the country. In November 2001, MOH also promulgated the Sample Document for Medical Institutions for Purchase of Medicines by Centralized Tendering and Price Negotiations (Trial) (《醫療機構藥品集中採購和集中議價採購文件範本(試行)》), or the Sample Document, as the operational document of the Working Regulations. The Working Regulations and the Sample Document provide rules for the tendering process and negotiations of the prices of pharmaceutical products, operational procedures, a code of conduct and standards or measures of evaluating bids and negotiating prices. On 23 September 2004 and 17 January 2009, MOH and the other relevant government authorities promulgated the Provisions on Further Regulating Purchase of Medicines by Medical Institutions through Centralized 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》) and the Opinions concerning Further Regulating Purchase of Medicines by Medical Institutions through Centralized Tendering (《關於進一步規範醫療機構藥品集中採購工作的意見》), respectively, to modify and improve the tendering process system.

In accordance with Notice on Issuing Certain Regulations on the Trial Implementation of Centralized Procurement of Pharmaceutical Products by Medical Organizations (《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 Centralized Procurement of Pharmaceutical Products by Medical Organizations (《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, non-profit medical institutions established by the PRC government at the county level or above are required to implement a centralized tender system for the procurement of pharmaceutical products. Public hospitals and healthcare institutions at the county level or above must comply with the centralized tendering process requirements. The tendering process is operated and organized by provincial and municipal government agencies such as provincial or municipal health departments. The centralized tendering process is conducted at most twice every year in the relevant province or city in the PRC. With the exception of medicines included in the National List of Essential Drugs and certain other special medicines, public hospitals and healthcare institutions that participate in the tendering process in principle shall use medicines included in the provincial medicine purchasing catalogs, as formulated by the relevant provincial and municipal government authorities. These public hospitals and healthcare institutions must only purchase these medicines through a public tender, online price bids, centralized price negotiations and direct online price listings, including through implementation of government-mandated price controls. The Sample Document must be included in the tendering documents prepared in relation to the centralized tendering process and may not be modified. To increase the transparency of medicine purchases, public hospitals and healthcare institutions are required to make their purchases of medicines through an online platform established by each provincial and municipal government authority.

The manufacturers of medicines that are on the medical institutions' formularies and are otherwise in demand by these hospitals are invited to bid and participate in the centralized tender process, which they must do directly by themselves. These manufacturers may, however, be advised by pharmaceutical distribution companies and they may use pharmaceutical distribution companies to distribute the medicines to the hospitals and healthcare institutions. A duly organized bid-evaluation committee, which is composed of pharmaceutical experts and clinical medical experts who will be randomly selected from a database of experts established by the relevant competent government authority, is responsible for bid evaluations. The selection is based on a number of factors, including bid price, quality, clinical effectiveness, and manufacturer's reputation and service quality.

ADVERTISING RESTRICTIONS

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》), which was promulgated on 28 February 2001 and became effective from 1 December 2001, and the Measures on the Examination of Pharmaceutical Products Advertisement (《藥品廣告審查辦法》), which was promulgated on 13 March 2007 and became effective from 1 May 2007, an enterprise seeking to advertise its pharmaceutical products must apply for an advertising approval code. The code is issued by the relevant local administrative authority.

HEALTHCARE FRAUD AND ABUSE

According to Anti Unfair Competition Law of the People's Republic of China (中華人民共和國反不正當競爭法) (effective on 1 December 1993), business operator who bribes by giving properties or using any other method in order to sell or purchase the commodities in violation of the Criminal Law of PRC, shall be investigated in accordance with the Criminal Law; even if the acts mentioned above do not constitute violation of the Criminal Law, the business operator may be subject to a fine in an amount from more than RMB10,000 to less than RMB200,000 in accordance with the facts and the illegal income should 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") (effective on 15 November 1996) provides a detailed scope of "properties 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 means" 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 operator shall be regarded as the operator's act. According to Criminal Law of the People's Republic of China (effective on 1 October 1997) 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-governmental functionary, crime of offering bribes to a non-governmental 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 sentence of a fixed term of imprisonment, life sentence or even death sentence.

CLASSIFICATION OF HOSPITALS

According to the Interim Measures of Assessment of Hospitals (《醫院評審暫行辦法》) promulgated by the MOH on 21 September 2011 and the Measures for Hospitals Classification (Trial) (《醫院分級管理辦法(試行)》) promulgated by the MOH on 29 November 1989, hospitals in the PRC are classified into three classes according to competent authorities' assessment. Each of the three classes is further divided. The highest class and rank is Rank I of Class III.

MOH regulates and is responsible for the assessment of all hospitals. The MOH and its Hospital Assessment Committee are responsible for conducting all hospital assessments in the PRC. Under the MOH, each healthcare administrative department at the provincial level has hospital assessment teams to assess hospitals in its jurisdiction.

MOH had also promulgated a number of regulations with regard to hospitals assessments, including the Standard of Assessment of Class III General Hospitals 2011 (《三級綜合醫院評審標準(2011年版)》) and the Standard of Assessment of Class II General Hospitals 2012 (《二級綜合醫院評審標準(2012年版)》).

Under the relevant regulations, each hospital is assessed once in every four years. Based on the assessment results, the hospital may be classified as Rank I or Rank II within its class, with Rank I being the highest, or it may be demoted to a lower class.

ENVIRONMENTAL PROTECTION

The Ministry of Environmental Protection of the PRC is responsible for overall supervision and control of environmental protection in the PRC. It formulates national environmental quality and discharge standards and monitors China'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 People's Republic of China (《中華人民共和國環境保護法》), or the Environmental Protection Law, which was promulgated and became effective on 26 December 1989, the environmental protection department of the State Council is in charge of promulgating national standards for environmental protection. The provincial governments and the local governments in autonomous regions and municipalities directly under the PRC Central Government may also promulgate local standards for environmental protection on matters not specified under national standards, provided that local governments must report such standards to the relevant department of environmental protection administration under the State Council for record.

Pursuant to the Law on Environmental Impact Evaluation of the People's Republic of China (《中華人民共和國環境影響評價法》), which was promulgated on 28 October 2002 and became effective on 1 September 2003, 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 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.

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. Such system shall include effective measures to control and properly dispose of waste gases, waste water, waste residue, dust or other waste materials. Any entity that discharges pollutants 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. Any entity undertaking a construction project that fails to install pollution prevention and control facilities in compliance with environmental standards for a construction project may be ordered to suspend production or operations and may be fined. Criminal liability may be imposed for a material violation of environmental laws and regulations that causes loss of property or personal injuries or death.

Pursuant to the Air Pollution Prevention Law of the PRC (《中華人民共和國大氣污染防治法》), which was promulgated by the National People's Congress on 5 September 1987, and most recently amended on 29 April 2000 and became effective from 1 September 2000, the environmental protection authorities above the county level are in charge of unified supervision and administration of prevention and control of air pollution. Manufacturers discharging polluted air must comply with applicable national and local standards and pay polluted air discharging fees. If a manufacturer emits polluted air at a level exceeding national or local standards, it must take correction actions during a prescribed period of time and 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》), which was promulgated by the National People's Congress on 11 May 1984, and amended on 15 May 1996 and 28 February 2008 and became 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 pollution, treatment fees. In addition, the environmental protection authority has the power 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 by the end of the stipulated period, the environmental protection authority may, subject to approval by the relevant level of the PRC government, shut down the facilities of the manufacturer.

OCCUPATIONAL HEALTH AND SAFETY

Pursuant to the Labor Law of the People's Republic of China (《中華人民共和國勞動法》) effective on 1 January 1995, 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 People's Republic of China (《中華人民共和國安全生產法》), which became effective on 1 November 2002, manufacturers must establish a comprehensive management system to ensure manufacturing safety in accordance with applicable laws and regulations. Manufacturers not meeting relevant legal requirements are not permitted to commence their manufacturing activities.

Pursuant to the Labor Contract Law of the PRC (《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, employers are required, when employing labor, 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 Labor Contract Law of the PRC.

Pursuant to the Administrative Measures Governing the Production Quality of Pharmaceutical Products (2010 revised edition) (《藥品生產質量管理規範(二零一零年修訂)》), effective from 1 March 2011 manufacturers of pharmaceutical products are required to establish production safety and labor protection measures in connection with the operation of their manufacturing equipment and manufacturing process.

PRODUCT LIABILITY AND PROTECTION OF CONSUMERS

Product liability claims may arise if the products sold have any harmful effect on consumers. The injured party can claim for damages or compensation. The General Principles of the Civil Law of the People's Republic of China (《中華人民共和國民法通則》), which became effective on 1 January 1987, states that manufacturers and sellers of defective products causing property damage or injury shall bear civil liabilities.

The Product Quality Law of the People's Republic of China (《中華人民共和國產品質量法》), which was enacted in 1993 and amended in 2000, aims 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 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 People's Republic of China 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》), which was promulgated on 31 October 1993 and became effective from 1 January 1994, protects 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. 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.

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. 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.

PRC PATENT LAW

The PRC government first provided proprietary rights with patent protection as set forth in the People's Republic of China Patent Law, or Patent Law, (《中華人民共和國專利法》), which became effective in 1985 and most lately amended on 27 December 2008. Pharmaceutical inventions became patentable after the Patent Law was amended on 1 January 1993. Patents relating to pharmaceutical inventions are effective for 20 years from the initial date the patent application was filed. Patents relating to utility model patents and design patents are effective for ten years from the initial date the patent application was filed.

Patent Prosecution

The patent system in the PRC, like most countries other than the United States, adopts the principle of "first to file". This means that, where more than one person files a patent application for the same invention, a patent will be granted to the person who first filed the application. The United States uses a principle of first to invent to determine the granting of patents. In the PRC, a patent must possess novelty, innovation and practical application. Under the Patent Law, novelty means that before a patent application is filed, no identical invention or utility model has been publicly disclosed in any publication in the PRC or abroad or has been publicly used or made known to the public by any other means, whether in or outside of China, nor has any other person filed with the patent authority an application which describes an identical invention or utility model and is published after the filing date. Patents issued in the PRC are not enforceable in Hong Kong, Taiwan or Macao, each of which has independent patent system. Patents in the PRC are filed at the SIPO in Beijing. Normally, the SIPO publishes an application for a pharmaceutical invention 18 months after the application is filed, which may be shortened upon request by the applicant. The applicant shall apply to the SIPO for a substantive examination within three years from the date the application is filed.

Patent Enforcement

When a dispute arises as a result of infringement of the patent holder's patent right, PRC law requires that the parties first attempt to settle the dispute through consultation between the respective parties. However, if the dispute cannot be settled through consultation, the patent holder or an interested party who believes the patent is being infringed may either file a civil legal suit or file an administrative complaint with the relevant patent administration authority under the SIPO. A PRC court may issue a preliminary injunction upon the patent holder's or an interested party's request before instituting any legal proceedings or during the proceedings. Damages for infringement are calculated as either the loss suffered by the patent holder arising from the infringement or the benefit gained by the infringer from the infringement. If it is difficult to ascertain damages in this manner, damages may be determined by using a reasonable multiple of the license fee under a contractual license. As in other jurisdictions, with one notable exception, the patent holder in the PRC has the burden of proving that the patent is being infringed. However, if the holder of a manufacturing process patent alleges infringement of such patent, the alleged infringing party has the burden of proving that there has been no infringement.

Compulsory License

According to the Patent Law, the SIPO may grant a person who is not the patent holder a compulsory license under certain circumstances, where, for example, a person possesses the means to utilize a patented technology, but such person cannot obtain a license from the patent holder on reasonable terms and in a reasonable period of time, or where a national emergency or any extraordinary state of affairs occurs or where the public interest so requires.

International Patent Treaties

The PRC is also a signatory to all major intellectual property conventions, including the Paris Convention for the Protection of Industrial Property, Madrid Agreement concerning the International Registration of Marks and Madrid Protocol, Patent Cooperation Treaty, Budapest Treaty on the International Recognition of the Deposit of Microorganisms for the Purposes of Patent Procedure and the Agreement on Trade-Related Aspects of Intellectual Property Rights.

Although patent rights are national rights, there is also a large degree of international co-operation under the Patent Cooperation Treaty, to which China is a signatory. Under the Patent Cooperation Treaty, applicants in one country can seek patent protection for an invention simultaneously in a number of other member countries by filing a single international patent application. The fact that a patent application is pending is no guarantee that a patent will be granted, and even if granted, the scope of a patent may not be as broad as the subject of the initial application.

TRADEMARKS

The People's Republic of China Trademark Law (《中華人民共和國商標法》) was promulgated in 1982 (later amended on 27 October 2001) and the People's Republic of China Trademark Implementing Regulations (《中華人民共和國商標法實施條例》) was promulgated on 3 August 2002. These laws provide the basic legal framework for the regulation of trademarks in the PRC. The 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.

PRC law provides that the following acts constitute infringement of the exclusive right to use a registered trademark:

- use of a trademark that is identical with or similar to a registered trademark in respect of the same kind of or similar commodities without the authorization of the trademark registrant;
- sale of commodities infringing upon the exclusive right to use the registered trademark;
- counterfeiting or making, without authorization, representations of a registered trademark of another person, or sale of such representations of a registered trademark;
- changing a registered trademark and selling products on which the changed registered trademark is used without the consent of the trademark registrant; and
- otherwise infringing upon the exclusive right of another person to use a registered trademark.

In the PRC, a registered trademark owner who believes the registered trademark is being infringed has three options:

- The registered trademark owner can provide his trademark registration certificate and other relevant evidence to the administration for industry and commerce at the central or local government level, which can, at its discretion, launch an investigation. The Administration for Industry and Commerce may take various actions, such as ordering the infringer to immediately cease the infringing actions, seizing and destroying any infringing products and trademark in question, closing down the facilities used to manufacture the infringing products or imposing a fine. If the registered trademark owner is dissatisfied with the Administration for Industry and Commerce's decision, he may, within 15 days of receiving the Administration for Industry and Commerce's decision, institute administrative proceedings in court.

- The registered trademark owner may institute civil proceedings directly in court. Civil redress for trademark infringement includes:

  — injunctions;

  — requiring the infringer to take steps to mitigate the damage (i.e., print notices in newspapers); and

  — damages (i.e. compensation for the economic loss and injury to reputation as a result of trademark infringement suffered by the trademark holder).

  The amount of compensation is calculated according to either the gains acquired by the infringer from the infringement during the infringement, or the loss suffered by the registered trademark owner, including expenses incurred by the trademark holder to deter such infringement. If it is difficult to determine the gains acquired by the infringer from the infringement, or the loss suffered by the trademark owner, the court may elect to award compensation of not more than RMB500,000.

- If a crime is suspected to be committed, the case shall be promptly referred to the judicial departments for handling according to law.