REGULATION

REGULATORY FRAMEWORK

Our products are subject to regulatory controls governing pharmaceutical products and medical appliances and equipment. As a distributor, retailer and manufacturer of pharmaceutical products, we are subject to regulation and oversight by different levels of the food and drug administration in China, 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, provides the basic legal framework for the administration of the production and sale of pharmaceutical products in China and covers the manufacturing, distributing, packaging, pricing and advertising of pharmaceutical products in China. Its implementation regulations set out detailed implementation rules with respect to the administration of pharmaceutical products in China.

We are also subject to other PRC laws and regulations that are applicable to manufacturing, retail and distribution, as well as PRC laws and regulations applicable to chemical reagents and logistics.

Principal Administrative Authorities

Two administrative agencies, the SFDA and the Ministry of Health, have principal regulatory authority over the pharmaceutical industry.

In the PRC, the SFDA is the authority that monitors and supervises the administration of pharmaceutical products and medical appliances and equipment as well as consumer food products and cosmetics. The SFDA's predecessor, the State Drug Administration, or the SDA, was established in August 1998 as an organization under the State Council to assume the responsibilities previously handled by the Ministry of Health, the State Pharmaceutical Administration Bureau of the People's Republic of China and the State Administration of Traditional Chinese Medicine of the People's Republic of China. The SFDA was founded in March 2003 to replace the SDA.

The primary responsibilities of the SFDA include but are not limited to:

- monitoring and supervising the security administration of drugs, medical supplies, consumer food safety and cosmetics in the PRC;
- formulating administrative rules and policies concerning the supervision and administration of drugs, medical supplies, consumer food products and cosmetics;
- formulating and monitoring quality standards for the research and development, manufacture, distributing and utilization of drugs and medical supplies;
- supervising and monitoring registration of drugs and medical supplies, participating in the formulation of the National List of Essential Drugs, implementing the classification and administration of prescription drugs and over-the-counter drugs; and
- inspecting illegal activities in relation to consumer food safety, and the research and development, manufacture, distribution and utilization of drugs, medical supplies and cosmetics.

The Ministry of Health is a ministerial department under the direct supervision of the State Council. Prior to the formation of the SFDA, the Ministry of Health shared responsibility for monitoring and supervising the pharmaceutical industry and promulgating rules and formulating policies to regulate the industry. Since the establishment of the SFDA, the Ministry of Health has focused primarily on public healthcare matters that are not directly related to the pharmaceutical industry. The Ministry of Health 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. The Ministry of Health is responsible for supervising and overseeing the SFDA.

DISTRIBUTION OF PHARMACEUTICAL PRODUCTS

Pharmaceutical Operation Permit and Business License

The establishment of a wholesale pharmaceutical distribution company requires the approval of the local 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, hygiene 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) effective on 1 April 2004, the pharmaceutical operation permit is valid for five years. Each operation permit holder must apply for an extension of its permit six months prior to expiration, and extensions are granted only after a reexamination of the permit holder by the authority which issued the permit. In addition, a pharmaceutical operator must obtain a business license from the relevant administration for industry and commerce prior to commencing its business.

As of the Latest Practicable Date, we had obtained 665 pharmaceutical operation permits for our entities engaged in the retail and wholesale operation of pharmaceutical products each of which is currently valid, and one permit is in the process of being renewed. We do not believe it would be difficult for us to renew these certifications.

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 China. 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) announced on 24 April 2003, the GSP certificate is valid for five years and may be extended three months' prior to its expiration upon a reexamination by the relevant authority.

As of the Latest Practicable Date, we had obtained 48 GSP certificates for our subsidiaries engaged in the retail or wholesale operations related to pharmaceutical products, of which two are subject to renewal. We do not believe it would be difficult for us to renew these certificates.

REGULATION

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) that became effective on 1 April 2000 and *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) that became effective on 9 August 2004, an enterprise engaged in the 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 to the provincial level food and drug administration an application to renew the operation permit, along with required information six months before the expiration date of the permit.

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

As of the Latest Practicable Date, we had obtained 363 operation permits of medical devices for our subsidiaries engaged in the retail or wholesale operations related to medical devices, each of which is currently valid. We do not believe it will be difficult for us to renew these operation permits.

Anesthetics and Anti-Psychotic Drugs

China regulates the distribution of anesthetics and anti-psychotic drugs pursuant to the *Regulations on the Administration of Anesthetics and Anti-Psychotic Drugs* (麻醉藥品和精神藥品管理條例), which became effective on 1 November 2005. In China, anti-psychotic drugs are classified into two different categories, category I and category II, with category I being subject to the highest level of regulation. Under these regulations, an enterprise engaged in the wholesale distribution of anesthetics and category I anti-psychotic drugs across a province, autonomous region or municipality directly under the PRC Central Government (a national wholesale enterprise) must obtain the prior approval of the SFDA. An enterprise engaged in the wholesale distribution of anesthetics and category I anti-psychotic drugs entirely within its own province, autonomous region or municipality directly under the PRC Central Government (a regional wholesale enterprise) must obtain the prior approval of the provincial food and drug administration. An enterprise engaged in the wholesale distribution of category II anti-psychotic drugs, whether or not across provincial boundaries, must obtain the prior approval of the provincial food and drug administration. National wholesale enterprises and regional wholesale enterprises may engage in the wholesale distribution of category II anti-psychotic drugs. A national wholesale enterprise may sell anesthetics and category I anti-psychotic drugs to regional wholesale enterprises, or to the hospitals and other medical institutions that have obtained the appropriate qualification for prescribing anesthetics and anti-psychotic drugs under an approval of the provincial food and drug administration in the jurisdiction where the hospital or other medical institution is located, or to such other organizations as permitted under applicable law.

As of the Latest Practicable Date, National Medicines, our subsidiary, was one of three national wholesale enterprises engaged in the wholesale distribution of anesthetics and category I anti-psychotic drugs.

REGULATION

Manufacture and Distribution of Substances Regulated by the Anti-Doping Regulations

China strictly regulates the manufacture and distribution of substances banned by the World Anti-Doping Agency and other sport bodies. These include anabolic steroids, peptide hormones, stimulants and other anabolic agents. The *Anti-Doping Regulations* (反興奮劑條例), which became effective on 1 March 2004, gives the State authority to regulate banned substances and authorizes the State Council department in charge of sports to formulate, revise and make public a catalog of banned substances in cooperation with the SFDA, the Ministry of Health, the Ministry of Commerce and the General Administration of Customs. Under the *Anti-Doping Regulations*, a pharmaceutical distributor must obtain the prior approval of the provincial food and drug administration before commencing the distribution of anabolic steroids and peptide hormones contained in the list of banned substances. The distributor may only distribute the banned substances to hospitals and other healthcare institutions, manufacturers of such products and other pharmaceutical distributors of such products.

As of the Latest Practicable Date, 12 of our subsidiaries had obtained distribution permits for the distribution of anabolic steroids and peptide hormones contained in the catalog of banned substances.

Online Pharmaceutical Operation Permit

The *Interim Regulations on the Examination and Approval of Providing Drug Transaction Services on the Internet* (《互聯網藥品交易服務審批暫行規定》), which became effective on 1 December 2005, define providing drug transaction services on the Internet as online drug transactions between a wholesale pharmaceutical distribution company and unrelated third parties using the website of the distribution company. These transactions are subject to inspection by, and the pharmaceutical distribution company must obtain a qualification certificate from, the provincial food and drug administration. The qualification certificate is valid for five years and may be renewed by filing for an extension at least six months prior to its expiration date and undergoing a reexamination by the relevant authority.

Sinopharm Henan, a subsidiary, obtained an Internet drug transaction service qualification certificate from the Henan Food and Drug Administration on 15 November 2007. We do not believe it would be difficult for us to renew this qualification certificate.

The *Measures regarding the Administration of Drug Information Service Over the Internet* (互聯網藥品信息服務管理辦法), which became effective on 8 July 2004 define the delivery of free publicly available drug information services over the Internet as a non-profit online drug information service. This service requires a qualification certificate from the provincial food and drug administration. The provincial food and drug administration must file its approval with the SFDA for records and make a public announcement. The qualification certificate is valid for five years and may be renewed by filing for an extension at least six months prior to its expiration date and undergoing a reexamination by the relevant authority.

As of the Latest Practicable Date, we had obtained Internet drug information service qualification certificates for three of our subsidiaries. We do not believe it would be difficult for us to renew these certificates.

Logistics Operation Permit

In accordance with the *Regulations on Road Transport* (道路運輸條例), which became effective on 1 July 2004, any enterprise engaged in the business of transporting goods must obtain a road transport business license from the road transport administration authority at the county level.

As of the Latest Practicable Date, we had obtained eight road transport business licenses for our subsidiaries mainly engaged in the business of transporting goods.

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), or 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, the *Administrative Measures for Archival Filing of Commercial Franchises* (商業特許經營備案管理辦法), or Archival Filing Measures, 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), or Disclosure Measures, collectively the Administrative Measures, which are also effective from 1 May 2007. The Franchise Regulations, Archival Filing Measures and Disclosure Measures form the basic legal framework for the regulation of PRC franchise operations, and addresses the requirements, fees, qualifications, administrative reporting and compliance procedures and other issues related to franchising.

MANUFACTURING OF PHARMACEUTICAL PRODUCTS

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

Pharmaceutical Manufacturing Permit and Business License

A manufacturer of pharmaceutical products must obtain a pharmaceutical manufacturing permit from the provincial food and drug administration of the PRC government. 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) effective on 15 September 2002, this permit is valid for five years and may be renewed at least six months prior to its expiration date upon a reexamination by the relevant authority.

In addition, before commencing business, a pharmaceutical manufacturer must also obtain a business license from the relevant administration for industry and commerce.

As of the Latest Practicable Date, we had obtained four pharmaceutical manufacturing permits for our subsidiaries that engage in manufacturing operations. We do not believe it would be difficult for us to renew the pharmaceutical manufacturing permits.

Good Manufacturing Practices

A manufacturer of pharmaceutical products and pharmaceutical materials must obtain GMP certification to produce pharmaceutical products and pharmaceutical materials in China. GMP comprises a set of detailed guidelines on practices governing the production of pharmaceutical products. GMP certification criteria 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. Under the *Administrative Measures for Certification of the Good Manufacturing Practices* (藥品生產質量管理規範認證管理辦法) a GMP certificate is valid for five years. The certificate may be renewed at least six months before its expiration date upon a reexamination by the relevant authority.

As of the Latest Practicable Date, our four subsidiaries engaged in pharmaceutical manufacturing had obtained 17 GMP certifications, each of which is valid.

Formulated by the World Health Organization, the guidelines 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, the Ministry of Health promulgated the first version of GMP standards, which was subsequently amended in 1992 and 1999. On 18 June 1999, SDA published the current version of GMP standards (1998 revised edition), which became effective on 1 August 1999.

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) effective on 1 October 2007, a new medicine must be registered 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. 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 the 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 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 process for the approval of certain new drugs.

If a medicine is approved by the SFDA as a new medicine, the SFDA will issue a new medicine 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 medicine, and will not accept new medicine certificate registrations for an identical medicine by another pharmaceutical company, change the ingredients of the registered medicine to be identical to the new medicine, 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 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 transfer to the relevant authority for criminal investigation.

Permits and Licenses for Chemical Reagents

Pursuant to the *Regulations on the Safety Administration of Dangerous Chemicals* (危險化學品安全管理條例), chemical reagents are divided into hazardous chemicals and non-hazardous chemicals. An enterprise manufacturing and marketing hazardous chemicals must obtain a special operating license for manufacturing hazardous chemicals from the relevant authority for work safety and apply for registration with the relevant administration for industry and commerce prior to manufacturing or marketing hazardous chemicals.

REGULATION

PRESCRIPTION DRUGS AND OVER-THE-COUNTER DRUGS

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 Drugs and Over-the-Counter Drugs* (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 drugs relate to those whose prescription, purchase and intake require prescription by practicing doctors or assistant doctors. Over-the-counter drugs 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 drugs are further subdivided into type A and type B and administered separately. Manufacturers of both prescription and over-the-counter drugs are required to obtain a Pharmaceutical Manufacturing Permit and to obtain production approvals for the relevant drugs. Retailers and wholesalers of prescription drugs and over-the-counter drugs and retail outlets selling prescription medicines and type A over-the-counter drugs are required to obtain a Pharmaceutical Operation Permit. Retail outlets selling type B over-the-counter drugs require approval from the provincial food and drug administration or with the designated bureau. In addition, retail outlets selling type B over-the-counter drugs are required to have professionally trained and suitably qualified staff before engaging in the sale of type B over-the-counter drugs. Retail outlets are required to source their drugs from qualified manufacturers and operators holding the prerequisite permits and approvals.

NATIONAL LIST OF ESSENTIAL DRUGS

On 18 August 2009, the Ministry of Health and other eight ministries and commissions in China 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 aims to promote essential medicines sold to consumers at fair prices in China and ensure that the general public in China has equal access to the drugs contained in the National List of Essential Drugs. On the same day, the Ministry of Health promulgated the *National List of Essential Drugs (Catalog for the Basic Healthcare Institutions)* (國家基本藥物目錄（基層醫療衛生機構配備使用部分）),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 comprise a small part of the pharmaceutical market in China. For this reason, we do not believe the Measures and Essential Drugs Guidelines will have a material impact on our pharmaceutical distribution, retail pharmacy or other business operations. In particular, distribution sales to hospitals, direct or indirect through distributor customers, constitute the major part of our pharmaceutical distribution operations. Distribution sales to clinics, retail pharmacies and other healthcare institutions represented approximately 7.2% and 8.8% of our total sales in 2008 and the five months ended 31 May 2009. In general, we believe the National List of Essential Drugs will benefit leading pharmaceutical distributors because the Measures and Essential Drugs Guidelines provide for pharmaceutical distributors with "modern logistics capabilities" to play a major role in pharmaceutical distribution in China and encourage further industry consolidation, both of which should benefit our operations. However, as of the Latest Practicable Date, the PRC Government has not yet released further detailed implementation rules in relation to the National List of Essential Drugs and the full

National List of Essential Drugs has not yet been released. As a result, the full impact of these and future regulatory actions by the PRC Government with respect to its essential drug policies on our business and results of operations is uncertain.

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) effective on 1 August 2005, prices of pharmaceutical products are either determined by the PRC Government or by market conditions. The prices of certain pharmaceutical products sold in China, primarily those included in the national and provincial Medical Insurance Catalog 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 respective pharmaceutical companies. Sales of pharmaceutical products by pharmaceutical manufacturers in China to overseas markets are not subject to any price control by the PRC Government.

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. 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, its average production costs, and the prices of substitute medicines. The NDRC directly regulates the price of a portion of the medicines on the list, and delegates to provincial and regional price control authorities the authority to regulate the pricing of the rest of the medicines on the list. According to information published by the PRC Central Government in 2006, approximately 2,400 types of pharmaceutical products, were subject to price controls. As of the Latest Practicable Date, we were not aware of any material changes to the number of products since the publication of the such information. Of the total pharmaceutical products we manufactured as of 31 May 2009, 100 products were subject to price controls. During the Track Record Period, over 80% of our revenue from the pharmaceutical manufacturing operations, before the eliminations of inter-segment sales, was derived from the sales of pharmaceutical products that were subject to price controls.

Since May 1998, the PRC Government has ordered reductions in the retail prices of various pharmaceutical products 24 times. The latest price reductions occurred in January and March 2007 and affected 354 and 278 different pharmaceutical products, respectively. During the Track Record Period, the PRC Government implemented seven rounds of reductions in the retail prices of various pharmaceutical products, which affected substantially all the products in our pharmaceutical distribution and retail pharmacy segments and the products we manufacture in our other business operations segment.

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 centrally regulated. 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-users, 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.

REIMBURSEMENT UNDER THE NATIONAL MEDICAL INSURANCE PROGRAM

Pharmaceutical products listed in the *State Basic Medical Insurance Medicine Catalog* (國家基本醫療保險藥品目錄), or the Medical Insurance 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.

According to the PRC National Bureau of Statistics, as of 31 December 2007, 180.2 million people in China were enrolled in the national medical insurance program. Most program participants are urban residents who are currently employed or retired. Participants of the national medical insurance program and their employers are required to contribute to the payment of insurance premium on a monthly basis. Program participants are eligible for full or partial reimbursement of the cost of medicines included in the national Medical Insurance Catalog, which is divided into two tiers. Purchases of Tier A medicines are fully reimbursable, but certain Tier A medicines are only reimbursable if the medicine is used for a particular stated purpose in the Medical Insurance Catalog. Purchasers of Tier B medicines are required to pay a deductible, with the remaining amount being reimbursable. The amount of deductibles and the percentage reimbursement for Tier B medicines varies in different regions in the PRC.

Factors that affect the inclusion of medicines in the Medical Insurance Catalog include whether the medicine is consumed in large volumes and commonly prescribed for clinical use in China and whether it is considered to be important in meeting the basic healthcare needs of the general public. The PRC Ministry of Human Resources and Social Security, together with other government authorities, has the power to determine which medicines are included in the national Medicine Insurance Catalog, under which of the two tiers the included medicine falls, and whether an included medicine should be removed from the catalog. Provincial governments are required to include all Tier A medicines listed on the National Medical Insurance Catalog in their provincial Medical Insurance Catalog. For Tier B medicines listed in the national Medical Insurance Catalog, provincial governments have the discretion to adjust upwards or downwards by no more than 15% from the number of Tier B medicines listed in the national Medical Insurance Catalog that is to be included in the provincial Medical Insurance Catalog.

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 Program in a calendar year is capped to the amounts in that participant's individual account under the program. The amount in a participant's account varies, depending on the amount of contributions from the participant and his or her employer.

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), 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. The Ministry of Health and other relevant government authorities have promulgated a series of regulations and releases in order to implement the tendering requirements. On 12 November 2001, the Ministry of Health 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, the Ministry of Health 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, the Ministry of Health 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 perfect the tendering process system.

In accordance with these laws and regulations, public hospitals and healthcare institutions belonging to the people's government 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 once every year in the relevant province or city in China. 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 hospitals' formularies and are in demand by these hospitals are invited to bid and participate in the centralized tendering process, which they must do directly. 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.

ENVIRONMENTAL PROTECTION

The Ministry of Environmental Protection of the People's Republic of China is responsible for uniform supervision and control of environmental protection in China. 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, promulgated and 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, providing 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) promulgated on 28 October 2002 and 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 includes adoption of effective measures to control and properly dispose of waste gases, waste water, waste residue, dust or other waste materials. Any entity that discharges pollution must register with the relevant environmental protection authority.

Remedial measures for breaches of the Environmental Protection Law include a warning, payment of damages or imposition of a fine. 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.

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) 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 *Administrative Measures Governing the Production Quality of Pharmaceutical Products* (藥品生產質量管理規範) effective on 1 August 1999, 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 incur 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) was enacted in 1993 and amended in 2000 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) was promulgated on 31 October 1993 and enacted from 1 January 1994 to protect consumers' rights when they purchase or use goods and accept services. All business operators must comply with this law when they manufacture or sell goods and/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.

PRC PATENT LAW

The PRC first allowed patents for the protection of proprietary rights, 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 later 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 China, 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 China, a patent must possess novelty, innovation and practical application. Under the Patent Law as amended, novelty means that before a patent application is filed, no identical invention or utility model has been publicly disclosed in any publication in China 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 China. 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 State or local administration for industry and commerce, which can, at its discretion, launch an investigation. The Administration for Industry and Commerce may take such actions as: order the infringer to immediately cease the infringing behavior, seize and destroy any infringing products and representations of the trademark in question, close the facilities used to manufacture the infringing products or impose 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 transferred to the judicial departments for handling according to law.