
REGULATORY OVERVIEW

REGULATORY FRAMEWORK

Our business operations are subject to regulatory controls governing pharmaceutical products, medical devices and health food. Thus we are subject to regulation and oversight by different levels of the food and drug administration in the PRC, in particular, the China Food and Drug Administration (“CFDA”). The Law of the PRC 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 distributing, packaging, pricing and advertising of pharmaceutical products in the PRC.

We are also subject to other PRC laws and regulations that regulate the distribution of pharmaceutical products, medical devices and health food.

Principal Administrative Authorities

As the competent authority of the pharmaceutical and healthcare industries, the CFDA (which succeeded the State Food and Drug Administration (“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.

The National Health and Family Planning Commission (“NHFPC”, which succeeded the Ministry of Health (“MOH”)) is a ministerial department under the direct supervision of the State Council, which is the PRC central government and the highest administrative authority. NHFPC focuses primarily on public healthcare matters that are not directly related to the pharmaceutical industry. NHFPC 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 the National List of Essential Drugs, and supervising healthcare institutions.

The Ministry of Commerce of the PRC is the competent authority of the circulation industry, including but not limited to the pharmaceutical distribution industry 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, the supervision and management over the price of medicines and formulation of the national unified retail price for certain drugs falling under the National Medical Insurance Drugs Catalogues and for drugs that have a monopoly over their production and distribution.

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RETAIL AND 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. The establishment of a retail pharmaceutical company requires the approval of the local food and drug administration at or above the county level. Upon approval, the relevant authority will grant a pharmaceutical operation permit. The grant of such permit is subject to an inspection of the operator's facilities, warehouse, environment for hygiene standards, quality control systems, personnel (including of whether pharmacists and other professionals have the relevant qualifications) and equipment. Once the relevant permit is received, the wholesale or retail pharmaceutical company shall be registered with the relevant administration for industry and commerce prior to commencing its business.

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 pharmaceutical operation permit holder must apply for an extension of the permit within 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.

As at the Latest Practicable Date, we had 15 subsidiaries and 791 pharmacies engaged in the retail or wholesale operations of pharmaceutical products in the PRC. All pharmacies have obtained pharmaceutical operation permits and such permits are still valid.

Good Supply Practices

Each retail or wholesale operator of pharmaceutical products is required to operate its pharmaceutical business in accordance with the Good Supply Practice (GSP) and will obtain the GSP certificate after certified by competent pharmaceutical supervision authority. 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. Currently, applicable GSP standards include Good Supply Practice (《藥品經營質量管理規範》), Implementation Rules of Good Supply Practice (《藥品經營質量管理規範實施細則》) and Administrative Rules on Certification of Good Supply Practice (《藥品經營質量管理規範認證管理辦法》). 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 Rules on Certification of Good Supply Practice (《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 within three months prior to its expiration upon a re-examination by the relevant authority.

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As at the Latest Practicable Date, we had obtained 13 GSP certificates for our 15 subsidiaries engaged in the retail or wholesale pharmaceutical business in the PRC, of which 2 had expired, but the relevant local drug administrative authority had approved us in writing to postpone the time for applying re-verification of the expired 2 GSP certificates to January 2014 and June 2014 respectively. One subsidiary which has not obtained the GSP certificates had applied for GSP certificates and the relevant local drug administrative authorities had accepted the application. Another subsidiary and its pharmacies were newly established and we are preparing for the application of GSP certificate.

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.

Prescription Medicines and Over-the-Counter Medicines

In order to promote safety, efficacy and convenience in the use of pharmaceutical products, the State Drug Administration, the predecessor of the SFDA, published the Trial Administrative Measures regarding the Classification of Prescription Medicines and Over-the-Counter Medicines (《處方藥與非處方藥分類管理辦法(試行)》) in June 1999, which became effective on 1 January 2000. These administrative measures divide drugs according to their type, specification, the relevant disease or ailment which they are designed to treat, dosage and method of administration. Prescription medicines relate to those 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 Over-the-Counter Medicine Catalogue (《國家非處方藥目錄》). Depending on the safety of the relevant drug, over-the-counter medicines are further subdivided into type A and type B and administered separately. Wholesalers of prescription medicines and over-the-counter medicines and retailers selling prescription medicines and type A over-the-counter medicines are required to obtain a pharmaceutical operation permit. Retailers selling type B over-the-counter medicines require approval from the provincial food and drug administration or other designated authorities. In addition, retailers selling type B over-the-counter medicines are required to have professionally trained and suitably qualified staff before engaging in the sale of type B over-the-counter medicines.

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 category II anti-psychotic drugs must obtain the prior approval of the provincial food and drug administration. National wholesale enterprises and regional wholesale enterprises may engage in the wholesale

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distribution of category II anti-psychotic drugs. An enterprise engaged in the retail distribution of category II anti-psychotic drugs must sell anti-psychotic drugs by the quantity provided by prescription from a licensed doctor, and must keep the prescription by two years for inspection. It is prohibited to sell category II anti-psychotic drugs to adolescents.

Jintian Ciji Pharma, Jintian Ciji Drug Store and Sui Hua are engaged in sale of category II anti-psychotic drugs and had obtained relevant pharmaceutical operation permits.

OPERATION OF MEDICAL DEVICES

Classification of Medical Devices

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, medical devices are classified into three classes:

- Class I medical devices refers to those whose safety and validity can be ensured by regular administration, for example, ultrasonic cleaner and ordinary operation scissors.
- Class II medical devices refers to those whose safety and validity shall be controlled, for example, glass syringe and blood pressure gauge.
- Class III medical devices refers to those implanted into human body, supporting or sustain life, or imposing potential threat to human body, and whose safety and validity shall be strictly controlled, for example, synthetic resin tooth and implantable cardiac pacemaker.

The category of medical devices classification is formulated, adjusted and published by the CFDA based on medical devices classification rules, after negotiating with the NHFPC.

Medical Device Operation Permit

Pursuant to 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 of class II and class III must obtain an operation permit from the provincial food and drug administration. 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 food and drug administration, along with all required information within six months before the expiration of the permit.

As at the Latest Practicable Date, we had 14 subsidiaries engaged in the retail or wholesale operations related to medical devices in the PRC, all of which have obtained and are holding valid operation permits of medical devices. Besides, we have 473 pharmacies engaged in the retail operations related to medical devices in the PRC, 470 of which have obtained operation permits of medical devices and such permits are still valid, and the other three of which have expired and we are in the process of renewing these permits. We do not believe it will be difficult for us to renew these operation permits.

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DISTRIBUTION OF HEALTH FOOD

Health Food Hygiene Permit

Pursuant to the Food Hygiene Law of the PRC (《中華人民共和國食品衛生法》) promulgated on 30 October 1995 (superceded by the Food Safety Law of the PRC (《中華人民共和國食品安全法》), which became effective on 1 June 2009), Measures for the Administration of Food Hygiene Permit (《食品衛生許可證管理辦法》), which became effective on 1 June 2006, and the Administrative Measures on Food Hygiene Permits (《保健食品管理辦法》) promulgated by MOH on 15 March 1996 and which became effective on 1 June 1996, a seller of health food products must obtain a hygiene permit or food hygiene permit which includes distribution of “health food” in the permitted business scope from the health administrative department.

Pursuant to the Food Safety Law of the PRC (《中華人民共和國食品安全法》) and the Measures for the Administration of Food Circulation Permits (《食品流通許可證管理辦法》) promulgated by the State Administration for Industry & Commerce on 30 July 2009, an enterprise engaged in food circulation shall legally acquire a food circulation permit from the local administration for industry & commerce at county level or above. The hygiene permits or food hygiene permits issued before the effectiveness of this law remain valid until expiration.

As at the Latest Practicable Date, we had 15 subsidiaries engaged in food or health food business in the PRC, all of which have obtained relevant operation permits. Besides, we have 485 pharmacies engaged in food or health food business in the PRC, 470 of which have obtained relevant operation permits, 15 pharmacies do not hold valid food or health food circulation permits after such permits expired, for in some areas where our pharmacies are located, it is still uncertain which authority is responsible for issuing new permits for health food business after the Food Safety Law became effective since 1 June 2009.

LOGISTICS OPERATION

In accordance with the Regulations on Road Transport (《道路運輸條例》), which became effective on 1 July 2004 and was amended on 9 November 2012, any enterprise engaged in the business of transporting goods must obtain a road transport business licence from the road transport administration authority at the county level.

PRICE CONTROLS

Pursuant to 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, for pharmaceutical pricing, the State Council carries out a system under which the prices are fixed or guided by the government or regulated by the market. For pharmaceuticals listed in the National Medical Insurance Drugs Catalogues and pharmaceuticals not listed in such catalogue but monopolistically manufactured and distributed, their prices shall be fixed or guided by the government; the prices of all other pharmaceuticals shall be regulated by the market.

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Pursuant to the Opinion 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 the State Planning Commission, the predecessor of the NDRC, on 20 July 2000, and the Circular of the National Development and Reform Commission on Issue of Price-controlled Pharmaceutical Products Catalogue 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 Catalogue 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 adjusted the Price-controlled Pharmaceutical Products Catalogue issued in 2005. 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. The prices of certain pharmaceutical products sold in the PRC, primarily those included in the National Medical Insurance Drugs Catalogues and the Provincial Medical Insurance Drugs Catalogue are subject to price controls mainly in the form of fixed prices or price ceilings. 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.

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 National List of Essential Drugs.

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

REIMBURSEMENT UNDER THE NATIONAL MEDICAL INSURANCE PROGRAM

Basic Medical Insurance System for Urban Employees

Pharmaceutical products listed in the National Medical Insurance Drugs Catalogues are covered by the national medical insurance programme. The national medical insurance programme 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 enrol their employees in the basic medical insurance programme and the insurance premium is jointly contributed by the employers and employees.

Participants of the national medical insurance programme and their employers are required to contribute to the payment of the 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, on 12 May 1999, further requires that a pharmaceutical product included in the National Medical Insurance Drugs Catalogues must be clinically needed, safe, effective, reasonably priced, user-friendly and available in the market and must also meet one of the following requirements:

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

The National Medical Insurance Drugs, Industrial Injury Insurance Drugs and Maternity Insurance Drugs Catalogue

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

The National Medical Insurance Drugs Catalogues 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 National Medical Insurance Drugs Catalogues and Chinese herbal pieces which are not included in the National Medical Insurance Drugs Catalogues, they will get reimbursement according to the rules of national medical insurance drugs, industrial injury insurance drugs and maternity insurance drugs insurance funds.

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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 subsidising 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 per year from the PRC central government. In addition, local governments in the middle and western regions of the PRC are required to subsidise no less than RMB10.0 per person per year and those in the eastern regions of the PRC are encouraged to aim to subsidise up to RMB20.0 per person per year. The actual amount of subsidies contributed by local governments is dependent on the financial condition of the relevant local government.

The PRC central government further increased the amount of subsidies 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 subsidies 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 subsidies by an additional RMB10.0 per person per year.

Basic Medical Insurance for Urban Non-employed Residents

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 programmes of urban resident basic medical insurance, so as to cover the unemployed urban residents who are not covered by any arrangements under the medical security system. The opinion provides that the urban resident basic medical insurance premiums shall be mainly paid by households with appropriate subsidies from 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.

ADVERTISING RESTRICTIONS

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

- any unscientific assertions or assurances in terms of efficiency or uses;
- treatment efficiency or curative rate;
- comparisons with other medicines or medical apparatuses in efficacy or safety;

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- titles or images of medical research institutes, academic institutions, medical organisations or experts, doctors or patients; and
- other contents that are prohibited by laws and administrative decrees.

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

Pursuant to the Law on the Administration of Pharmaceutical Products of the PRC (《中華人民共和國藥品管理法》), promulgated on 28 February 2001 and which became effective from 1 December 2001, pharmaceutical products advertisement shall be subject to approval by the drug regulatory department of the people's government of the province, autonomous region or municipality directly under the central government where the enterprise is located, and once approved a pharmaceutical products advertisement shall be issued an approval number. No one may launch pharmaceutical products advertisements without an approval number. Prescription medicine may be introduced in the medical or pharmaceutical professional publications jointly designated by the administrative department for health and the drug regulatory department under the State Council, but their advertisements may not be released by mass media or disseminated to the general public by other means. Any violation of the provision of this law related to the control over pharmaceutical products advertising shall be punished pursuant to the provisions of the Advertising Law of the PRC, and the relevant drug regulatory department that issued the advertisement approval number shall withdraw it and shall, within one year, reject any application for approval of advertising for the drug in question.

ANTI-BRIBERY

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

The Interim Provisions on Banning Commercial Bribery (《關於禁止商業賄賂行為的暫行規定》) (“Interim Provisions”), which became effective on 15 November 1996 provides a detailed scope of “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

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site visits in various forms. In addition, the Interim Provisions also made it clear that commercial bribery committed by any employee of a business operator for selling or purchasing commodities for the business operator shall be regarded as the business operator's act. According to the Criminal Law of the PRC, which became 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》), which became effective on 20 November 2008, business operators in the healthcare industry may be prosecuted with several charges due to commercial bribes, 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 business operator may be punished by a sentence of a fixed term of imprisonment, life sentence or even death sentence.

OCCUPATIONAL HEALTH AND SAFETY

Pursuant to the Labor Law of the PRC (《中華人民共和國勞動法》) which became 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 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 which became effective from 1 January 2008, employers are required, when employing labour, to truthfully inform prospective employees of the job description, working conditions, location, occupational hazards and status of safe production as well as remuneration and other conditions as required by the Labor Contract Law of the PRC.

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 PRC (《中華人民共和國民法通則》), which became effective on 1 January 1987, states that sellers of defective products causing property damage or injury shall bear civil liabilities.

The Product Quality Law of the PRC (《中華人民共和國產品質量法》), which was promulgated on 22 February 1993 and amended on 8 July 2000, aims to strengthen quality control of products and protect consumers' rights. Under this law, business operators who sell defective products may be subject to confiscation of earnings from such sales, the revocation of business licences and imposition of fines, and in severe circumstances, may be subject to criminal liability.

The Law of the PRC on the Protection of the Rights and Interests of Consumers (《中華人民共和國消費者權益保護法》), 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 sell goods and/or provide services to customers. In extreme situations, pharmaceutical business operators may be subject to criminal liability if their goods or services lead to the death or injuries of customers or other third parties.

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SAFE REGULATIONS ON OVERSEAS INVESTMENT OF PRC RESIDENTS

Circular 75

On 21 October, 2005, the SAFE issued the Notice on Relevant Issues Relating to the Administration of Foreign Exchange of Financing and Return Investment Activities by Domestic Residents Conducted via Offshore Special Purpose Vehicles (《國家外匯管理局關於境內居民通過境外特殊目的公司融資及返程投資外匯管理有關問題的通知》) (“Circular 75”), which became effective as at 1 November 2005. According to Circular 75, (a) a PRC resident (a “PRC Resident”) must register with the local SAFE branch before he or she establishes or controls a Special Purpose Vehicle (“SPV”) for the purpose of conducting overseas equity financing; (b) when a PRC Resident contributes assets or equity interests to an overseas SPV, or engages in overseas financing after contributing assets or equity interests in a domestic enterprise to an overseas SPV, such PRC Resident must register his or her interest in the overseas SPV or any change to his or her interest in the overseas SPV with the local SAFE branch; and (c) when the overseas SPV undergoes a material change in capital outside the PRC, such as a change in share capital or merger and acquisition, the PRC Resident must, within 30 days after the occurrence of such event, register such change with the local SAFE branch. Moreover, Circular 75 applies retroactively.

Under the relevant rules, failure to comply with the registration procedures set forth in Circular 75 may result in restrictions being imposed on the foreign exchange activities of the relevant onshore company, including the increase of its registered capital, the payment of dividends and other distributions to its offshore parent or affiliate and the capital inflow from the offshore entity, and may also subject relevant PRC residents to penalties under PRC foreign exchange administration regulations.