
REGULATORY FRAMEWORK

INDUSTRY REGULATORY FRAMEWORK

Our operations within the PRC are subject to regulatory controls governing pharmaceutical products and medical devices. The following are the major PRC applicable laws and regulations that our operations are subject to:

| <u>Laws / Regulations</u> | <u>Issuing Authority</u> | <u>Date of Promulgation</u> | <u>Effective Date</u> |
|--|--------------------------|---|--|
| Law of the PRC on the Administration of Pharmaceuticals (中華人民共和國藥品管理法) | SCNPC | 20 September 1984 and amended on 28 February 2001 | 1 December 2001 |
| Regulations for the Implementation of the Law of the PRC on the Administration of Pharmaceuticals (中華人民共和國藥品管理法實施條例) | State Council | 4 August 2002 | 15 September 2002 |
| Regulations on the Supervision and Administration of Medical Devices (醫療器械監督管理條例) | State Council | 4 January 2000 | 1 April 2000 |
| Measures for the Administration of Pharmaceutical Products Registration (藥品註冊管理辦法) | SFDA | 10 July 2007 | 1 October 2007 |
| Measures for the Administration of Pharmaceutical Product Import (藥品進口管理辦法) | SFDA | 18 August 2003 and amended on 24 August 2012 | 1 January 2004 |
| Measures for the Administration of Pharmaceutical Supply Permits (藥品經營許可證管理辦法) | SFDA | 4 February 2004 | 1 April 2004 |
| Measures for the Administration of Licences to Engage in Medical Device Trading Business (醫療器械經營企業許可證管理辦法) | SFDA | 9 August 2004 | 9 August 2004 |
| Good Supply Practice for Pharmaceutical Products (藥品經營質量管理規範) | SDA | 30 April 2000, and amended on 22 January 2013 | 1 July 2000 and the amendments came into effect on 1 June 2013 |
| Measures for the Certification of Good Supply Practice (藥品經營質量管理規範認證管理辦法) | SFDA | 24 April 2003 | 24 April 2003 |
| Measures for the Administration of Pharmaceuticals Circulation (藥品流通監督管理辦法) | SFDA | 31 January 2007 | 1 May 2007 |

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We are subject to regulation and administration by different levels of governmental authorities in the PRC. CFDA and NHFPC are the two major bodies in the PRC that have national jurisdiction over the pharmaceutical and medical device industry. CFDA and NHFPC are established under the Proposals of the State Council Institutional Reform and Transformation of Government Functions (“**Reform Proposals**” 國務院機構改革和職能轉變方案) promulgated on 14 March 2013. Pursuant to the Reform Proposals, the MOH and the NPFPC have been removed. NHFPC has inherited (i) the powers and duties of the MOH, and (ii) NPFPC’s responsibilities of family planning administration and service. The main responsibilities of NHFPC include:

- overall planning for the allocation of resources for medical, health and family planning services;
- organising and formulating the national systems for essential drugs;
- formulating family planning policies, and supervising family planning administration and services;
- supervising and administering the public health and medical services; and
- assessing food safety risks and formulating food safety standards.

Under the Reform Proposals, the SFDA and the Office of Food Safety Commission of the State Council (國務院食品安全委員會辦公室) have also been removed and their powers and duties are transferred to the newly established CFDA. In addition, CFDA is also responsible for the supervision of food safety during the production process, and food safety that are in circulation. One of the responsibilities of CFDA is to implement uniform supervision and administration policy on food safety and on drug safety and efficacy.

Pharmaceutical Supply Permit

The establishment of a pharmaceutical wholesale supply enterprise in the PRC is subject to the approval of the local drug regulatory administration of the people’s government of the province, autonomous region or municipality directly under the central government. The enterprise is required to obtain a “pharmaceutical supply permit” (藥品經營許可證) for the wholesale supply of drugs. The grant of such permit is subject to the local drug regulatory administration’s assessment of the enterprise’s premises and facilities, warehouse, hygiene environment, quality control systems, personnel and equipment. No enterprises may distribute pharmaceutical products without a pharmaceutical supply permit.

Any changes to the terms of a pharmaceutical supply permit such as the business scope, registered address, warehouse address, legal representative or the person responsible for quality control will require the prior approval of the original permit-issuing authority. A pharmaceutical supply permit is valid for a term of five years. The permit holder may apply for its renewal within six months prior to the expiry date. A renewal application is subject to re-assessment by the original permit-issuing authority.

As of the Latest Practicable Date, two of our principal operating subsidiaries in the PRC, Xiantao Pioneer and Naqu Pioneer, had obtained the pharmaceutical supply permit for conducting business within the PRC and such permits remained in force and effect.

Licence to Engage in Medical Device Trading Business

Medical devices are classified into three categories in the PRC, namely Class I, Class II and Class III, depending on their risks posed to human upon application and the extent of the management required to ensure their safety and effectiveness. Class I refers to those medical devices which are considered to pose the lowest degree of risks and Class III are those carry the highest degree of risks. An enterprise that intends to engage in the supply of Class II and/or Class III medical devices is required to obtain a “licence to engage in medical device trading business” (醫療器械經營企業許可證) from the local drug regulatory administration of the people’s government of the province, autonomous region or municipality directly under the central government. An enterprise is exempted from obtaining a licence to engage in medical device trading business if it only distributes certain Class II medical devices, the safety and effectiveness of which can be maintained by ordinary management during the process of circulation. The CFDA has power to prescribe the catalogue of such Class II medical devices. Any changes to the terms of a licence to engage in medical device trading business such as a change in the person responsible for quality management, registered address, business scope, warehouse address will require the prior approval of the competent drug regulatory authority.

A licence to engage in medical device trading business is valid for five years. A person who wishes to apply for a licence renewal shall make an application within six months prior to the expiry date. A renewal application is subject to re-assessment by the drug regulatory authority of the province, autonomous region or municipality directly under the central government, or the entrusted drug administrative department of a city.

As of the Latest Practicable Date, four of our principal operating subsidiaries in the PRC, Xiantao Pioneer, Naqu Pioneer, Pioneer Ruici and Shanghai Saierling, had obtained the licence to engage in medical device trading business for the trading of Class II and Class III medical devices, and such licences remained in force and effect.

Good Supply Practice Certificate

A pharmaceutical supply enterprise in the PRC is required to obtain a “good supply practice certificate” (“**GSP Certificate**” 藥品經營質量管理規範認證證書). The good supply practice standard is a set of quality guidelines applicable to the distribution of pharmaceutical products. The certificate is only issued to an enterprise that has passed the assessment of its operation by the relevant administrative authorities. A GSP Certificate is valid for five years and, subject to re-assessment, may be renewed upon application. A person who wishes to apply for a permit renewal shall make an application within three months prior to the expiry date.

The Good Supply Practice Rules for Pharmaceutical Products (“**New GSP Rules**” 藥品經營質量管理規範) were amended on 22 January 2013 and came into effect on 1 June 2013. The New GSP Rules focus on improving the management of pharmaceutical trading companies and enhancing the risk and quality management of pharmaceutical products in circulation with the aim to strengthen and tighten the regulatory controls on pharmaceutical distribution activities.

Pursuant to the Circular on the Provisions Regarding the Main Functions, Internal Organs and Staffing of CFDA (國務院辦公廳關於印發國家食品藥品監督管理總局主要職責內設機構和人員編制規定的通知) issued by the General Office of the State Council on 26 March 2013, the administrative licences of a pharmaceutical supply permit and a GSP certificate will be gradually integrated into one administrative licence. Pursuant to the Circular on Implementation of the New GSP Rules (國家食品藥品監督管理總局關於貫徹實施新修訂《藥品經營品質管制規範》的通知) issued by CFDA on 24 June 2013, where a pharmaceutical supply permit or a GSP certificate will expire on and before

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31 December 2013 but the enterprise holding such permit or certificate cannot meet the new requirements stipulated by the New GSP Rules, the valid terms of such permit or certificate can be extended to 30 June 2014 provided that an application for extension was made by the enterprise.

As of the Latest Practicable Date, two of our principal operating subsidiaries in the PRC, Xiantao Pioneer and Naqu Pioneer, had obtained the GSP Certificate for conducting business within the PRC and such certificates remained in force and effect.

Measures for the Administration of Pharmaceuticals Circulation

Pursuant to the Measures for the Administration of Pharmaceuticals Circulation (藥品流通監督管理辦法), pharmaceutical manufacturers, pharmaceutical supply enterprises and medical institutions are responsible for the quality of the pharmaceutical products that they manufacture, distribute or use. Pharmaceutical supply enterprises are responsible for their purchase and sale activities, including activities carried out by their staff on their behalf. Pharmaceutical supply enterprises may not store or sell pharmaceutical products on premises not approved by the drug regulatory administration. Where a pharmaceutical supply enterprise knows or ought to know that any person who produces or distributes pharmaceutical products without permits or licences, but still provides such person with pharmaceutical products, the drug regulatory administration may give a disciplinary warning to the pharmaceutical supply enterprise, order the enterprise to rectify the non-compliance and impose a fine of not more than RMB10,000. In the case of a serious violation, the enterprise may be imposed a fine of not less than RMB10,000 but not more than RMB30,000. A pharmaceutical supply enterprise may not change its mode of operation without the prior approval of the drug regulatory department and may only conduct business within the approved business scope specified in its pharmaceutical supply permit.

Import of Pharmaceutical Products

Only pharmaceutical products which have been registered for import with an “imported drug registration certificate” (進口藥品註冊證), or in the case of pharmaceutical products manufactured in Hong Kong, Macau or Taiwan, with a “pharmaceutical product registration certificate” (醫藥產品註冊證) may be imported into the PRC. An imported drug registration certificate will only be granted in respect of a product if that product has already been approved for marketing and sale in the manufacturer’s home jurisdiction unless CFDA considers that the product is otherwise safe, effective and subject to high clinical demand. Imported drugs must also meet the good manufacturing practice standards adopted by the manufacturer’s home jurisdiction as well as those required in the PRC. A person who wishes to apply for an imported drug registration certificate for a particular product shall first apply to CFDA for an approval to conduct clinical trials on such product. Following completion of the clinical trials, an application may be made for the approval to import the product by submitting to CFDA, among other things, the clinical trial information and the product samples. The examination laboratory appointed by the NIFDC will examine the samples and NIFDC will report the examination results to CFDA. CFDA will then conduct a final assessment of the application to consider whether to approve the registration of the product for import. If CFDA is satisfied with its final assessment of the application, the applicant will be granted an imported drugs registration certificate or a pharmaceutical product registration certificate. The validity term of a registration certificate is five years, and a re-registration application shall be filed within six months prior to the expiry date. If no application for the re-registration of an imported drug is filed within the validity term of the registration certificate, or the application fails to pass the re-registration review, the imported drug registration certificate or the pharmaceutical product registration certificate will be cancelled or revoked.

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Pursuant to the Notice of Certain Issues Related to Re-registration of Imported Drugs (關於進口藥品再註冊有關事項的公告) and the Regulations on Temporary Import and Repackaging of Imported Drugs Pending Re-registration (進口藥品再註冊期間臨時進口和分包裝管理規定) issued by SFDA on 7 January 2009, an application, up to two times, may be made for an ad hoc approval (進口藥品批件) to import a consignment of the relevant drugs while the re-registration is being processed. Such ad hoc approvals may be granted for importing drugs to meet clinical consumption and production demand and is subject to stipulated regulatory requirements.

Under the Measures for the Administration of Pharmaceutical Product Import (藥品進口管理辦法), an enterprise that imports pharmaceutical products is required to report to the local food and drug administration which has jurisdiction over the import port before proceeding to custom clearance. In the case of certain biological products, medicines introduced to the PRC for the first time, and other medicines prescribed by the State Council, a port inspection is also compulsory prior to import into China.

Import of Medical Devices

Under the Regulations on the Supervision and Administration of Medical Devices and the Measures for the Administration of Medical Devices Registration (醫療器械註冊管理辦法), medical devices are classified according to a catalogue issued by the SFDA into three categories, Class I, Class II and Class III, depending on the risk associated with the device and the extent of management required to ensure its safety and effectiveness. All medical devices regardless of what class they fall under require registration before they can be used and sold in the PRC. Classification of medical devices determines the type of registration required and the level of regulatory authority involved in effecting the registration. For a medical device imported into the PRC for the first time, the importing enterprise shall provide the relevant materials such as the user manual, quality standards and testing methods, together with the medical device samples and production and sale approval certificates issued by the exporting country or region, for inspection and approval by the drug regulatory authority under the State Council, and shall obtain a registration certificate of medical devices. The validity term of a registration certificate of medical devices is four years and its holder may apply for a re-registration within six months before the expiry date. When the production of a medical device is ceased for more than two years, its registration certificate is automatically invalidated.

National List of Essential Drugs

The MOH and other eight ministries and commissions of the PRC issued the Provisional Measures for the Administration of National List of Essential Drugs (國家基本藥物目錄管理辦法(暫行)) and the Guidelines on the Implementation of the National List of Essential Drugs System (關於建立國家基本藥物制度的實施意見) on 18 August 2009, and the General Office of the State Council issued the Opinions Regarding Consolidation and Improvement of Essential Drugs System and Basic Operation Mechanism (國務院辦公廳關於鞏固完善基本藥物制度和基層運行新機制的意見), which aim to secure the supplies of essential drugs to the general public, ensure that essential drugs are available to the general public at fair prices, and ensure that the general public has equal access to those drugs listed in the national catalogue of essential drugs. In principle, the National List of Essential Drugs is subject to review every three years. The MOH promulgated the National List of Essential Drugs (Catalogue for the Basic Medical and Healthcare Institutions) (2009 Version) (國家基本藥物目錄(基層醫療衛生機構配備使用部分)(2009版)) on 18 August 2009, which applied only to basic medical and healthcare institutions including county-level hospitals, county-level Chinese medicine hospitals, rural clinics and community clinics. The National List of Essential Drugs (2012 Version) (國家基本藥物目錄(2012年版)) was released on 13 March 2013 and came into effect on 1 May 2013, which replaced the 2009 version.

Reimbursement under National Basic Medical Insurance and Work-Related Injury Insurance

Pursuant to the Decision of the State Council on the Establishment of the Urban Worker Basic Medical Insurance System (國務院關於建立城鎮職工基本醫療保險制度的決定) issued by the State Council on 14 December 1998, all employers in urban cities are required to enroll their employees in a basic medical insurance programme whereby the insurance premium are jointly contributed by the employers and employees. Participants in the national medical insurance programme and their employees are required to contribute to the payment of insurance premiums on a monthly basis. These participants are eligible for reimbursement of all or a part of their expenses on drugs, medical services and diagnosis and treatments specified by the PRC governmental authorities. The Opinion on Management of Urban Worker Basic Medical Insurance Items (關於城鎮職工基本醫療保險診療項目管理的意見) issued on 30 June 1999 further clarifies the reimbursement items that are covered by the medical insurance programme. If medical treatment items are necessary and have certain effect for patients but are also easily abused or very expensive, the expenses of patients on such items will be partially reimbursed under the medical insurance programme.

The Notice Regarding the Tentative Measures for the Administration of the Scope of Medical Insurance Coverage for Drugs for Urban Workers (城鎮職工基本醫療保險用藥範圍管理暫行辦法) jointly issued by several authorities including the Ministry of Labour and Social Security and the MOF on 12 May 1999, further requires that a pharmaceutical product included in the national catalogue of medical insurance drugs must be clinically needed, safe, effective, reasonably priced, user-friendly, available in the market and must meet the following requirements (1) it is listed in the Pharmacopoeia of the PRC, (2) it meets standards promulgated by the SFDA, and (3) it is approved by the SFDA for import.

On 27 November 2009, the MHRSS issued the Notice on the National Catalogue of Medical Insurance Drugs, Work-Related Injury Insurance Drugs and Maternity Insurance Drugs (2009 Version) (“National Insurance Catalogue” 國家基本醫療保險、工傷保險和生育保險藥品目錄(2009年版)). According to the notice, authorities of the provinces, autonomous regions and municipalities throughout the PRC were required to issue the provincial catalogues before 31 March 2010. The Insurance Catalogue is modified from time to time, and consequently some drugs had been removed from and others had been included in the catalogue in the past few years.

The drugs listed in National Insurance Catalogue can be classified into three types: western medicine, traditional Chinese patent medicine and Chinese herbal pieces. When a patient who participates in the medical insurance programme purchases a western medicine or a traditional Chinese patent medicine which is listed in the catalogue or a Chinese herbal piece which is not listed in the catalogue, such purchase will be entitled to reimbursement according to the rules regarding national medical insurance drugs, work-related injury insurance drugs and maternity insurance drugs insurance funds.

The National Insurance Catalogue is divided into two parts, Part A and Part B. The drugs (including national essential drugs) listed in Part A are determined by the central government and local authorities may not alter the items of that part. The drugs listed in Part B of the National Insurance Catalogue are determined by the central government in the first instance, but the local authorities of the provincial level, based on local economic development, medical demand and medical treatment habit, may alter the items listed in Part B, provided that the total number of items altered may not exceed 243 kinds of drugs. Patients purchasing the drugs listed in Part A of the catalogue are entitled to full reimbursement of all expenses paid for the drugs purchased, while patients purchasing the drugs listed in Part B of the catalogue are required to pay a deductible and entitled to reimbursement of the

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remainder of the expenses. The amount of deductible expenses differs from region to region, and the drugs listed in Part B of the catalogue may differ from region to region due to alteration by local authorities.

Pricing Policy

Pharmaceutical Products

Certain pharmaceutical products sold in the PRC, primarily those pharmaceutical products included in the National List of Essential Drugs and Insurance Catalogue and those drugs the production or trading of which will constitute monopolies, are subject to price control by the PRC government.

Pursuant to the Opinions Regarding Reforms on Price Administration of Pharmaceutical Products (國家計委印發關於改革藥品價格管理的意見的通知) issued by the NDRC on 20 July 2000 and the Price-controlled Pharmaceutical Products Catalogue of NDRC (國家發展改革委定價藥品目錄) amended on 5 March 2010 and came into effect on 1 April 2010, prices of pharmaceutical products are either determined by the government or by market conditions. The prices of certain pharmaceutical products sold in the PRC are subject to price controls mainly in the form of price ceilings and in some other cases in the form of fixed prices. Manufacturers and distributors cannot set the actual price for any price-controlled product above the price ceiling or deviate from the fixed price set by the government. The prices of pharmaceutical products that are not subject to price controls are determined freely at the discretion of the pharmaceutical manufacturers, and pharmaceutical wholesale and retail enterprises may not set the actual price above the price ceiling set by the manufacturers. The prices of pharmaceutical products 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 pharmaceutical products that are subject to price controls. Fixed prices and price ceilings on pharmaceutical products are determined based on profit margins that the relevant government authorities deem reasonable, the type and quality of the medicine, its production costs, and the prices of substitute pharmaceutical products. The NDRC directly regulates the pricing of all prescription medicines on the Insurance Catalogue and all medicines on the National List of Essential Drugs, and delegates to provincial and regional price control authorities the authority to regulate the pricing of the non-prescription medicine on the Insurance Catalogue.

An enterprise which imports drugs may apply for a price increase and it must either apply to the provincial price control authorities in the province where it is incorporated, if the drug is in the list provincially regulated, or to the NDRC, if the drug is in the list centrally regulated. For a drug in the list provincially regulated, 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 drug is significantly superior to comparable products in terms of effectiveness, safety, treatment cycle and costs of treatment, its manufacturer or the relevant enterprise may apply for an approval for separate pricing, subject to NDRC's approval.

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 MOFCOM, the MOF and the Ministry of Labor and Social Security on 19 May 2006, the PRC government exercises price control over pharmaceutical products included in the Insurance Catalogues 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

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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 Chinese herbal pieces.

The NDRC issued the Notice on Adjusting the Price of Some Pharmaceutical Products (including drugs used for treatment of respiratory disease, antipyretic and analgesic drugs and drugs with special treatment effect) and Related Issues (國家發展改革委關於調整呼吸解熱鎮痛和專科特殊用藥等藥品價格及有關問題的通知) on 31 December 2012 and that came into effect on 1 February 2013. The lists attached to the notice prescribed the retail price ceilings of pharmaceutical products that are subject to separate pricing or centralised pricing. The medical institutions, retail drugstores, drug manufacturers and drug supply enterprises shall not sell the pharmaceutical products at a price higher than the retail price ceilings. The price administration at the provincial level is authorised to determine provisional retail price ceilings in its administrative region for the drugs that are not subject to price control by the NDRC, and the retail price ceilings for the pharmaceutical products, of which the dosage forms or specifications were not included in the lists.

With respect to drugs the prices of which 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.

Medical Devices

The PRC governmental authorities maintain a high level of involvement in and are expected to further strengthen regulations on the price control of medical devices, especially high-value, disposable or implantable medical devices. On 9 November 2009, the NDRC, the MOH and the MHRSS jointly issued the Notice of Opinions on Reform of Pricing System of Drugs and Medical Services (改革藥品和醫療服務價格形成機制的意見), pursuant to which the NDRC will strengthen price control on high-value medical devices (including implantable medical devices) by limiting the profit margins of the participants in the supply chain for such medical devices, periodically announcing market price information of such medical devices and other reasonable measures. From time to time, the administration authorities at provincial and municipal level may set pricing guidelines on certain medical devices, mainly including disposable or implantable medical devices.

Centralised Procurement and Tender Process

Pharmaceutical Products

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, requires public hospitals and medical institutions to purchase pharmaceutical products through a centralised tender process. The MOH and other relevant government authorities have promulgated a series of regulations and releases in order to implement the tender requirements.

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

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Implementation) (“**Centralised Tender Sample Document**” 醫療機構藥品集中招標採購和集中議價採購文件範本(試行)) as the operational document of the Centralised Procurement Regulations. The Centralised Tender Regulations and the Centralised Tender Sample Document provide rules for the tender process and negotiations of the prices of drugs, operational procedures, a code of conduct and standards or measures of evaluating bids and negotiating prices.

On 15 July 2010, the MOH and five other ministries and commissions jointly promulgated the Working Regulations of Medical Institutions for Centralised Procurement of Drugs (醫療機構藥品集中採購工作規範) to further regulate the centralised procurement of drugs and clarify the code of conduct of the parties in centralised drug procurement.

According to the Notice on Issuing Certain Regulations on the Trial Implementation of Centralised Tender Procurement of Drugs by Medical Institutions (關於印發醫療機構藥品集中招標採購試點工作若干規定的通知) promulgated on 7 July 2000 and the Notice on Further Improvement on the Implementation of Centralised Tender Procurement of Drugs by Medical Institutions (關於進一步做好醫療機構藥品集中招標採購工作的通知) promulgated on 8 August 2001, medical institutions established by county or higher level government are required to implement centralised tender procurement of drugs.

The centralised tender process takes the form of public tender jointly organised by several medical institutions or through an intermediary jointly appointed by the medical institutions. Such intermediaries are legally established bidding agencies which are not permitted to engage in the distribution of drugs and have no conflict of interest with government authorities. The bids are assessed by a committee organised by pharmaceutical experts approved by the relevant authorities. The committee members assess the bids based on product quality, qualifications of the manufacturer, after-sale services and price. A medical institution is not permitted to bid for the same type of product more than twice a year.

On 17 January 2009, the MOH, the SFDA and other four national departments jointly promulgated the Opinions on Further Regulating Centralised Procurement of Drugs by Medical Institutions (關於進一步規範醫療機構藥品集中採購工作的意見). According to the notice, non-profit medical institutions owned by the government at the county level or higher or owned by state-owned enterprises (including state-controlled enterprises) shall purchase pharmaceutical products by centralised procurement. Each provincial government shall formulate its catalogue of drugs subject to centralised procurement. Except for drugs in the National List of Essential Drugs (the procurement of which shall comply with the relevant rules on National List of Essential Drugs), certain pharmaceutical products which are under the national government’s special control and traditional Chinese medicines, in principle, all drugs used by the medical institutions shall be covered by the catalogue of drugs subject to centralised procurement.

Medical Devices

On 21 June 2007, the MOH promulgated Notice on Further Strengthening the Centralised Procurement of Medical Devices (衛生部關於進一步加強醫療器械集中採購管理的通知), which requires non-profit medical institutions established by the people’s government at and above county level and state-owned enterprises shall purchase medical devices by centralised procurement. Centralised procurement shall be conducted mainly in the manner of public tender.

On 17 December 2012, the MOH and other five departments promulgated the Regulations on the Centralised Procurement of High-value Medical Consumables (for Trial Implementation) (高值醫用耗材集中採購工作規範(試行)). Pursuant to the regulations, all qualified non-profit medical

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institutions established by the people's government at and above county level and state-owned enterprises (including state-controlled enterprises) must purchase high-value medical consumables by centralised procurement. High-value medical consumables refer to vascular intervention, non-vascular interventional, orthopedic implants, neurosurgery, electrophysiology, pacemaker, extracorporeal circulation, blood purification and ophthalmology materials.

Restrictions on Advertising

Pursuant to the Provisions for Drug Advertisement Examination (藥品廣告審查辦法), which were promulgated on 13 March 2007 and became effective on 1 May 2007, and the Provisions for Medical Device Advertisement Examination (醫療器械廣告審查辦法) which were promulgated on 7 April 2009 and became effective on 20 May 2009, an enterprise seeking to advertise its drugs or medical devices must apply for an advertising approval code. The drug regulatory authorities of the provinces, autonomous regions or municipalities directly under the central government are the examination authorities responsible for examining drug advertisements or medical device advertisements within their administrative regions. The administrative bureau for industry and commerce at or above the county level are supervision authorities for such advertisements. Advertisements that merely contain the names of non-prescription drugs or medical devices, or advertisements published in professional medical or pharmaceutical journals that merely contain the names of the prescription drugs are exempt from advertisement examination. Advertisements that merely contain the names of medical devices shall incorporate the registration certificate number of the medical devices. Only the manufacturer or licenced distributors (with the consent of the manufacturer) for the relevant drugs or medical devices may apply for an advertisement approval number. An application for an advertisement approval number for imported drug or medical device shall be submitted to the drug advertisement examination authority in the place where the agent of the imported drug or medical device is located. The validity term of an advertisement approval number for a drug or medical device is one year. The content of an approved advertisement may not be altered without prior approval. Where any alteration to the advertisement is needed, a new advertisement approval number shall be obtained.

Regulations on Importing Goods

Under the Foreign Trade Law of the PRC (中華人民共和國對外貿易法), which was promulgated on 12 May 1994, amended on 6 April 2004 and came into effect on 1 July 2004, and the Measures for the Registration of Foreign Trade Business Operators (對外貿易經營者備案登記辦法) which were promulgated by the MOFCOM on 25 June 2004 and became effective on 1 July 2004, the PRC government adopted a filing and registration system for foreign trade operators engaged in imports and exports of goods or technology. Foreign trade operators that have not filed for registration will be declined by the customs to carry out the customs clearance and inspection procedures for import and export of goods. Pursuant to the Customs Law of the PRC (中華人民共和國海關法) promulgated by the SCNPC on 22 January 1987 and amended on 8 July 2000, the declaration of import and export goods may be made by consignees and consignors themselves, and such formalities may also be completed by their entrusted customs brokers that have registered with the customs. The consignees and consignors for import or export goods and the customs brokers engaged in customs declaration shall register with the customs in accordance with the law. Principal regulations on the inspection of import and export commodities are set out in the Import and Export Commodity Inspection Law of the PRC (中華人民共和國進出口商品檢驗法) promulgated by the SCNPC on 21 February 1989 and amended on 28 April 2002 and came into effect on 1 October 2002 and its implementation rules. According to the aforesaid relevant laws and regulations, the import and export commodities that are subject to compulsory inspection listed in the catalogue compiled by the state administration shall be inspected by the commodity inspection authorities, and the import and export commodities that are not subject to statutory inspection shall be subject to random inspection. Consignees and consignors themselves or its

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entrusted agent may apply for inspection to the commodity inspection authorities. Under the Provisions of the Customs of the PRC on the Administration of Registration of Declaration Entities (中華人民共和國海關對報關單位註冊登記管理規定) promulgated on 31 March 2005 and effective on 1 June 2005, enterprises engaged in direct import of goods and services which complete the customs formalities concerning declaration of inward and outward articles and payment of duties by themselves, shall also obtain the registration permit for dealers of imported and exported goods of the PRC (中華人民共和國海關進出口貨物收發貨人報關註冊登記證書) from the local customs office. The registration permit is valid for three years and its holder shall apply for renewal within thirty days prior to the expiry date.

As of the Latest Practicable Date, two of our principal operating subsidiaries in the PRC, Xiantao Pioneer and Naqu Pioneer have obtained the registration permit for dealers of imported and exported goods of the PRC and such permits remain in full force and effect.

Product Liability and Customer Protection

Under the General Principles of the Civil Law of the PRC (中華人民共和國民法通則), which were promulgated on 12 April 1986 and became effective on 1 January 1987, distributors shall assume civil liabilities if the defective products sold by them caused property damage or personal injury.

Under the Product Quality Law of the PRC (中華人民共和國產品品質法) implemented on 1 September 1993 and amended on 8 July 2000, sellers shall be liable for compensation if the damages caused to the property of others are due to defects resulting from the fault on the part of sellers. Sellers shall be liable for compensation if they cannot identify the producers or suppliers of the defective products. If damages are caused by defective products, the infringed party may claim compensation from the producers or the sellers of the products. If the liability lies on the producers and the compensation has been paid by the sellers, the sellers have the right to recover their losses from the producers. If the liability lies on the sellers and the compensation has been paid by the producers, the producers have the right to recover their losses from the sellers.

Under 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) promulgated on 31 October 1993 and implemented from 1 January 1994, all business operators have to comply with this law when they produce or sell goods and/or provide services to customers. In extreme situations, pharmaceutical manufacturers and distributors may be subject to criminal liability if their goods or services lead to the death or injuries of customers or third parties.

Under the Tort Law of the PRC (中華人民共和國侵權責任法) promulgated on 26 December 2009 and implemented from 1 July 2010, if damages to other persons are caused by defective products that are resulted from the fault of a third party such as the parties providing transportation or warehousing, the producers and the sellers of the products have the right to recover their respective losses from such third parties. If defective products are identified after they have been put into circulation, the producers or the sellers shall take remedial measures such as issuance of warning, recall of products, etc. in a timely manner. The producers or the sellers shall be liable under tort if they fail to take remedial measures in a timely manner or have not made efforts to take remedial measures, thus causing damages. If the products are produced and sold with known defects, causing deaths or severe damage to the health of others, the infringed party shall have the right to claim respective punitive damages in addition to compensatory damages.

REGULATIONS RELATING TO LABOUR PROTECTION

Under the Labour Law of the PRC (中華人民共和國勞動法), which was promulgated by the SCNPC on 5 July 1994 and became effective on 1 January 1995 and subsequently amended on 27 August 2009, the PRC Employment Contract Law (中華人民共和國勞動合同法), which was promulgated by the SCNPC on 29 June 2007 and became effective on 1 January 2008 and subsequently amended on 28 December 2012 and became effective on 1 July 2013 and the Implementing Regulations of the Employment Contract Law (中華人民共和國勞動合同法實施條例), which were promulgated by the State Council and became effective on 18 September 2008, a written employment contract shall be executed within one month from the commencement of the employment. Under some circumstances prescribed by law and the employees request or agree to renew or conclude an employment contract, an unfixed-term employment contract shall be concluded, unless the employee requests the conclusion of a fixed-term employment contract. Wage of the employee cannot be lower than local minimum wage. An employer must establish a system for labour safety and sanitation, strictly abide by state standards, and provide relevant education to its employees. Employers may adopt labour dispatching arrangements and it is generally implemented on job positions which are temporary, ancillary or replaceable in nature. A labour dispatching entity shall conclude a labour dispatching agreement with the entity that accepts labour services in the form of labour dispatching. If an employer violates the regulations on labour dispatching, the labour administrative authorities and other competent departments shall order it to make correction. Prior to 1 July 2013, where the circumstances are serious, the relevant authority may impose a fine of up to RMB5,000 per dispatched worker. If harm is done to the dispatched worker, the labour dispatching entity and the entity that accepts labour services shall assume joint and several liabilities. In the event of a violation of the Employment Contract Law, the labour administrative department may order rectification and issue a warning. If harm is caused to the employees, the employer shall assume compensation liability.

Pursuant to applicable PRC laws, rules and regulations, including the Social Insurance Law (社會保險法) which was promulgated by the SCNPC on 28 October 2010 and became effective on 1 July 2011, the Interim Regulations on the Collection and Payment of Social Security Funds (社會保險費征繳暫行條例) which was promulgated by the State Council and became effective on 22 January 1999, Interim Measures concerning the Maternity Insurance (企業職工生育保險試行辦法) which was promulgated by the Ministry of Labour on 14 December 1994 and became effective on 1 January 1995, the Regulations on Work-related Injury Insurance (工傷保險條例) which was promulgated by the State Council on 27 April 2003 and became effective on 1 January 2004 and subsequently amended on 20 December 2010, employers are required to contribute, on behalf of their employees, to a number of social security funds, including funds for basic pension insurance, unemployment insurance, basic medical insurance, work-related injury insurance, and maternity insurance. An employer who fails to register with the social insurance administrative authority may be ordered to rectify within a specific time period. If it fails to do so, the social insurance administrative authority shall impose a fine on the employer equivalent to one to three times the amount of the overdue social insurance contributions, and those management personnel and other personnel who are directly responsible for shall be imposed with a fine of between RMB500 to RMB3,000. If the employer fails to make social insurance contributions timely and in full amount, the social insurance collecting authority will order the employer to make up outstanding contributions within the prescribed time period and impose a late payment fee at the rate of 0.05% per day from the date on which the contribution becomes due. If such employer fails to make the overdue contributions within such time limit, the relevant administrative department may impose a fine equivalent to one to three times the overdue amount.

Pursuant to the Regulations on the Administration of Housing Fund (住房公積金管理條例) which was promulgated by the State Council and became effective on 3 April 1999 and amended on

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24 March 2002, employers shall register with the local housing fund management center and establish a special housing fund account with an entrusted bank. Employers are also required to make adequate contributions of no less than 5% of each employee's average monthly salary in the preceding year to the housing fund on a timely basis. If an employer does not undertake payment and deposit registration of housing fund or fails to go through the formalities of establishing housing fund account for its employees, the housing fund management center shall order it to go through the formalities within a prescribed period. If the employer fails to do so at the expiration of the prescribed period, a fine of not less than RMB10,000 nor more than RMB50,000 shall be imposed. If an employer is overdue in the payment and deposit of, or underpays, the housing fund, the housing fund management center shall order it to make the payment and deposit within a prescribed time limit, where the payment and deposit has not been made after the expiration of the time limit, an application may be made to a people's court for compulsory enforcement.

Pursuant to the Regulations on Paid Annual Leave for Employees (職工帶薪年休假條例) which became effective on 1 January 2008, employees who have continuously worked for more than one year are entitled to paid holidays ranging from five to 15 days, depending on their length of service. Employees who agree to waive their holiday at the request of their employers must be compensated with three times their normal daily salary for each holiday day waived.

REGULATIONS ON FOREIGN INVESTMENT

Pursuant to the Provisions on Guiding the Foreign Investment Direction (指導外商投資方向規定) promulgated by the State Council on 11 February 2002 and effective on 1 April 2002, foreign investments in industries in China are classified into encouraged, permitted, restricted and prohibited categories. Foreign investment in the encouraged category is entitled to certain preferential treatment and incentives, while foreign investment in the restricted category is permitted but subject to certain restrictions under the PRC law. Foreign investment in the prohibited category is not allowed. Additional details as to each of the encouraged, restricted and prohibited categories are provided in the updated Industrial Guidance Catalogue for Foreign Investment (as amended in 2011) (外商投資產業指導目錄(2011年修訂)), which was jointly issued by the NDRC and the MOFCOM on 24 December 2011 and became effective on 30 January 2012. The industries engaged by our PRC subsidiaries are generally not included in any of these three categories and therefore fall into the permitted category.

Under the Company Law of the PRC (中華人民共和國公司法) promulgated by the SCNPC on 29 December 1993, became effective on 1 July 1994 and last amended on 27 October 2005, there are two types of companies in the PRC, namely limited liability companies and joint stock limited companies. All our subsidiaries established in the PRC are limited liability companies.

The Wholly Foreign Owned Enterprises Law of the PRC (“WFOE Law” 中華人民共和國外資企業法), which was promulgated by the SCNPC on 12 April 1986, became effective on 12 April 1986, and subsequently amended on 31 October 2000, and the Implementation Regulations for the Wholly Foreign Owned Enterprises Law of the PRC (中華人民共和國外資企業法實施細則), which were promulgated on 12 December 1990 and subsequently amended on 12 April 2001, are the fundamental laws and regulations to govern the establishment and operation of a wholly foreign-owned enterprise. According to the WFOE Law and its implementation regulations, in order to establish a WFOE, the foreign investor(s) shall apply for approval from the Ministry of Foreign Trade and Economic Cooperation under the State Council, currently, the MOFCOM, or its local counterparts, and a WFOE must obtain a business licence from the relevant administration for industry and commerce before commencing business. In the event of a split, merger or change of other approved items, the

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enterprise concerned shall apply for approval from the original approval authority and complete the registration procedure with the relevant administration for industry and commerce.

A WFOE is required to have a registered capital contributed by the foreign investor(s). The liability of the foreign investor(s) is limited to the amount of registered capital it subscribed to contribute. A foreign investor is permitted to make its contributions by instalments and the registered capital shall be contributed within the required period as approved by the MOFCOM or its local counterparts in accordance with the relevant PRC laws and regulations.

A WFOE shall withdraw reserve fund from the after-tax profit, and at least 10% of the after-tax profits must be allocated to the reserve fund. If the cumulative total of allocated reserve funds reaches 50% of its registered capital, a WFOE will not be required to make any additional contribution. After the effectiveness of the new Company Law since 1 January 2006, the employee bonus and benefit fund is no longer required to be withdrawn, however, the boards of a WFOE can make a resolution to withdraw the employee bonus and benefit fund from the after-tax profit. A WFOE is prohibited from distributing dividends unless the losses (if any) of previous years have been made up.

Pursuant to the Interim Provisions on Domestic Investment by Foreign-invested Enterprises (關於外商投資企業境內投資的暫行規定) promulgated on 25 July 2000 and amended on 26 May 2006, a foreign-invested enterprise (“FIE”, including a WFOE) may establish or purchase equity interests of a company engaging in the industries into which foreign investment is encouraged or permitted, the FIE shall file with the original approval authority for record within 30 days from the date when the relevant registration procedures is completed by the invested company. FIEs may establish or purchase equity interests of a company engaging in the industries into which foreign investment is restricted after obtaining the approval by the competent authority for commerce. FIEs are not permitted to establish or purchase equity interests of a company engaging in the industries into which foreign investment is prohibited.

FOREIGN CURRENCY EXCHANGE

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

The Notice on the Relevant Operating Issues Concerning the Improvement of the Administration of Payment and Settlement of Foreign Currency Capital of Foreign-invested

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Enterprises (“**Circular No. 142**” 關於完善外商投資企業外匯資本金支付結匯管理有關業務操作問題的通知) was promulgated and became effective on 29 August 2008. It regulates the conversion by a FIE of foreign currency into Renminbi by restricting how the converted Renminbi may be used. It requires that Renminbi converted from the foreign currency-denominated capital of a FIE may only be used for purposes within the business scope approved by the relevant governmental authorities and may not be used for equity investments within the PRC unless otherwise specifically provided. Further, it cannot be used to repay Renminbi loans if the proceeds of such loans have not yet been used.

Pursuant to the Circular on Further Improving and Adjusting the Direct Investment Foreign Exchange Administration Policies (“**Circular No. 59**” 國家外匯管理局關於進一步改進和調整直接投資外匯管理政策的通知) promulgated by SAFE on 19 November 2012 and became effective on 17 December 2012, approval is not required for the opening of and account entry in foreign exchange accounts under direct investment, for re-investment with the domestic lawful incomes by the foreign investors, for the foreign exchange purchasing and offshore payments under the direct investment, for domestic transfer of the foreign exchange under direct investment. Circular No. 59 also simplifies the capital verification and confirmation formalities for the FIEs and the foreign capital and foreign exchange registration formalities required for the foreign investors to acquire the equities of Chinese party, and further improve the administration on exchange settlement of foreign exchange capital of FIEs.

Regulations on Foreign Exchange in Onshore and Offshore Transactions

Pursuant to the Notice on Relevant Issues Concerning Foreign Exchange Administration for PRC Residents to Engage in Financing and Inbound Investment via Overseas Special Purpose Vehicles (“**Circular No. 75**” 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), which was issued by the SAFE on 21 October 2005 and became effective on 1 November 2005, and Circular No. 59, (1) a PRC resident is required to register with the local branch of SAFE before he or she establishes or controls an overseas special purpose vehicle, or overseas SPV, for the purpose of overseas equity financing (including convertible debt financing), (2) when a PRC resident transfers assets of or equity interests in a domestic enterprise to an overseas SPV, or engages in overseas financing after contributing assets or equity interests into an overseas SPV, such a PRC resident shall register his or her interest in the overseas SPV and the change thereof with the local branch of SAFE, and (3) when the overseas SPV undergoes a material capital change event outside of China, such as a change in share capital or merger and acquisition, the PRC resident shall, within 30 days from the occurrence of such event, register such change with the local branch of SAFE. If a SPV has other changes, the PRC resident concerned may go through the registration formalities in a centralised manner with the local branch of the SAFE where the SPV is registered during the annual examination periods of foreign-invested enterprises.

For the purpose of Circular No. 75, a PRC resident refers to a resident who holds a PRC passport or a PRC identity card or an individual who does not have a legal status in the PRC but chronically resides in the PRC due to economy interest in the PRC. Circular No. 59 further clarify that a non-PRC individual who chronically resides in the PRC due to economy interest mainly fall into the following three categories: (1) an individual who has a permanent residence in the PRC, but temporarily leaves the PRC for reasons such as travel, study, medical treatment or work outside the PRC or satisfying a residence requirement in a foreign country, and who returns to his or her permanent domicile in the PRC after the aforementioned reasons no longer exists, (2) an individual who holds equity interests in a domestic-funded enterprise, or (3) an individual who originally held equity interests in a domestic-funded enterprise and has remained the beneficial owner after legal ownership of such interests are converted to equity interests in a foreign-invested enterprise.

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Under Circular No. 75, failure to comply with the registration procedures may result in the imposition of restrictions on an SPV's PRC subsidiary's foreign exchange activities and its ability to distribute dividends to the SPV and penalties, including orders of remittance of foreign exchange illegally paid out of China back into China and the imposition of fines.

REGULATIONS ON M&A AND OVERSEAS LISTING

On 8 August 2006, six PRC regulatory agencies, including the MOFCOM, the State Assets Supervision and Administration Commission, the SAT, the SAIC, the CSRC and the SAFE, jointly issued the Regulations on Mergers and Acquisitions of Domestic Enterprises by Foreign Investors (“M&A Rules” 關於外國投資者併購境內企業的規定), which was amended on 22 June 2009. An SPV is defined under the M&A Rules as an offshore entity directly or indirectly controlled by PRC individuals or enterprises with the objective of an overseas listing, and the main assets of which are the rights and interests in affiliated domestic enterprises. Under the M&A Rules, if an SPV intends to merge with or acquire any domestic enterprise affiliated with such PRC individuals or enterprises that control the SPV, the proposed merger or acquisition shall be submitted to the MOFCOM for approval. The M&A Rules also require an SPV to obtain an approval from the CSRC prior to the listing and trading of its securities on an overseas stock exchange.

Pursuant to the M&A Rules, a “PRC individual” means an individual who is a PRC national or resident, holding a PRC *hukou* (戶口) or a PRC passport. Prior to the Reorganisation, Mr. Li and Mrs. Li, being our Controlling Shareholders, obtained permanent residence status in Saint Christopher (St. Kitts) and Nevis and passports thereof, deregistered their *hukou* and entered into PRC with their Saint Christopher (St. Kitts) and Nevis passports. Therefore, prior to the Reorganisation, they became foreign nationals and were no longer PRC individuals as defined under the M&A Rules. Accordingly, none of the overseas companies in our Group, namely our Company, Pioneer Pharma (BVI) and Pioneer HK, is controlled directly or indirectly by PRC individuals or PRC enterprises for the purpose of the M&A Rules. In addition, Xiantao Medical is a wholly foreign owned enterprise established under PRC laws, and its acquisition of Xiantao Pioneer is regulated by the Interim Provisions on Domestic Investment by Foreign-invested Enterprises (關於外商投資企業境內投資的暫行規定), rather than the M&A Rules. Therefore our Company is not required to obtain approvals from the MOFCOM for the Reorganisation and approvals from the CSRC for the Listing.

REGULATIONS RELATING TO TAXATION

Enterprise Income Tax

On 1 January 2008, the Foreign-invested Enterprise and Foreign Enterprise Income Tax Law of the PRC (中華人民共和國外商投資企業和外國企業所得稅法) was abolished and replaced by the EIT Law. Under the EIT Law and its implementation rules promulgated by the State Council on 6 December 2007, the tax rate for both domestic-funded enterprises and foreign-invested enterprises is 25%, and the high-technology enterprises receiving key support from the State enjoy a reduced EIT rate of 15%.

Under the EIT Law and its implementation rules, enterprises are classified as either “resident enterprises” or “non-resident enterprises”. Enterprises established outside the PRC whose “de facto management bodies” are located in the PRC are considered “resident enterprises” and subject to the uniform 25% EIT rate for their global income. According to the implementation rules of the EIT Law, “de facto management body” refers to a managing body that exercises, in substance, overall management and control over the manufacture and business, personnel, accounting and assets of an enterprise. Dividends from resident enterprises to their investors, which are treated as resident enterprises, are exempted from withholding tax.

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The EIT Law provides that a non-resident enterprise refers to an entity established under foreign law whose “de facto management bodies” are not within the PRC but which have an establishment or place of business in the PRC, or which do not have an establishment or place of business in the PRC but have income sourced within the PRC. The implementation rules of the EIT Law provide that after 1 January 2008, an income tax rate of 10% will normally be applicable to dividends declared to non-resident enterprise investors which do not have an establishment or place of business in the PRC, or which have such establishment or place of business but the relevant income is not effectively connected with the establishment or place of business, to the extent such dividends are derived from sources within the PRC. The income tax on the dividends may be reduced pursuant to a tax treaty between the PRC and the jurisdictions in which the non-resident enterprise investors located. In addition, any gain realised on the transfer of shares by non-resident enterprise investors is also subject to 10% PRC income tax if such gain is regarded as income derived from sources within the PRC.

Pursuant to the Circular on Issues Concerning Tax Policies for In-depth Implementation of Western Region Development Strategies (關於深入實施西部大開發戰略有關稅收政策問題的通知) promulgated on 27 July 2011 and Notice on Issues Concerning Enterprise Income Tax Policies for In-depth Implementation of Western Region Development Strategies (國家稅務總局關於深入實施西部大開發戰略有關企業所得稅問題的公告) promulgated on 6 April 2012, from 1 January 2011 to 31 December 2020, enterprise income tax may be levied at a reduced tax rate of 15% on enterprises engaging in encouraged industries that are established in the western regions. The above-mentioned enterprises in encouraged industries shall refer to enterprises whose principal business are the industries prescribed in the catalogue of encouraged industries in the western regions, the income of which accounts for more than 70% of the total income of such enterprises.

Pursuant to the Notice Issued by the Government of the Tibet Autonomous Region Regarding Adjusting the Enterprise Income Tax Rate (西藏自治區人民政府關於調整企業所得稅稅率的通知) which became effective on 31 October 2008 and the Notice of the Government of the Tibet Autonomous Region on the Enterprise Income Tax Rate in the Region (西藏自治區人民政府關於我區企業所得稅稅率問題的通知) which was issued on 12 January 2011, an enterprise incorporated in the Tibet Autonomous Region may enjoy a 15% enterprise income tax rate from 2008 to 2020.

In accordance with an Approval Notice of Tax Reduction and Exemption (Jian Zi No. 000035 [2012]) (那國稅那曲地區國稅局直屬稅務分局一所減字[2012]000035號《減免稅批准通知書》) issued by the sub-taxation bureau of Naqu region office, SAT (西藏自治區那曲地區國家稅務局直屬稅務分局) on 20 April 2012, the 15% tax rate applicable to Naqu Pioneer was further reduced by 40%, the applicable period for such reduction is 10 years from 1 January 2010 to 31 December 2019. As a result of the above approvals, the effective enterprise income tax rate for Naqu Pioneer was 15% and 9% for 2011 and 2012, respectively, and Naqu Pioneer is entitled to a preferential tax rate of 9% until 31 December 2019, and 15% for 2020. Based on the laws and regulations and the fact that Naqu Pioneer has made tax registration with the sub-taxation bureau of Naqu region office, the SAT, we are advised by our legal adviser as to PRC laws, Jingtian & Gongcheng, that the sub-taxation bureau of Naqu region office, the SAT is the competent authority to issue such approval notice of tax reduction and exemption.

Pursuant to Article 26 of the Qinghai-Tibet Railway Naqu Logistics Centre (Zang Zheng Fa [2008] No. 62) (青藏鐵路那曲物流中心招商引資優惠政策若干規定(藏政發[2008]62號) and Article 4 of the Implementation Rules of the Provisions of Investment Preferential Policy on the Qinghai-Tibet Railway Naqu Logistics Centre (青藏鐵路那曲物流中心招商引資優惠政策若干規定實施細則(藏政辦發[2011]52號)), the PRC central government may allocate or return the portion of enterprise income tax paid by enterprises to the PRC central government in accordance with the applicable laws and

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regulations to the government of the Tibet Autonomous Region under budget management system; further, the Finance Bureau of Naqu Region shall, within three months from receiving the fund allocation or return from the Finance Bureau of the Tibet Autonomous Region, reimburse an enterprise, which (i) is established in Naqu logistics centre, (ii) has completed tax registration with the local taxation bureau of Naqu, and (iii) paid enterprise income tax in accordance with above-mentioned regulations, in the form of government grant in an amount equal to the enterprise income tax paid by such enterprise in the prior year to support its development. Since Naqu Pioneer satisfies the requirements set out above, Naqu Pioneer is entitled to the reimbursement in the form of government grant from the Finance Bureau of Naqu Region for a period of ten years since its incorporation in Naqu logistic centre in 2010.

Business Tax

Pursuant to the Provisional Regulations of the PRC on Business Tax (中華人民共和國營業稅暫行條例), which was promulgated by the Stated Council on 13 December 1993 and subsequently amended on 10 November 2008 and its Implementation Rules(中華人民共和國營業稅暫行條例實施細則) which was promulgated by the MOF and the SAT in 18 December 2008 and subsequently amended on 28 October 2011, all of which became effective on 1 January 2009, unless stated otherwise, the taxpayers providing taxable services the PRC are required to pay a business tax at a normal tax rate of 5% of their revenues.

Value-Added Tax

Pursuant to the Provisional Regulations of the PRC on Value-Added Tax (中華人民共和國增值稅暫行條例), which was promulgated by the State Council on 13 December 1993 and subsequently amended on 10 November 2008 and its implementation rules (中華人民共和國增值稅暫行條例實施細則) promulgated on 18 December 2008 and subsequently amended by the MOF on 28 October 2011, all of which became effective on 1 January 2009, unless stated otherwise, the tax rate for value-added tax payers who are selling or importing goods, and providing processing repairs and replacement services in the PRC shall be 17%.

Additionally, pursuant to the Provisions of Investment Preferential Policy on the Qinghai-Tibet Railway Naqu Logistics Center (Zang Zheng Fa [2008] No.62) (青藏鐵路那曲物流中心招商引資優惠政策若干規定(藏政發[2008]62號)) issued on 30 June 2008 and its implementation rules (青藏鐵路那曲物流中心優惠政策若干規定實施細則(藏政辦發[2011]52號)) issued on 30 May 2011, when an enterprise incorporated in the Naqu logistics centre has paid value added tax and business tax exceeding RMB200,000 for the year, the enterprise is eligible to obtain support fund from the Finance Bureau of Naqu Region for 10 years from the year when the first payment of such support fund was granted or realised. The amount of the support fund is determined by the authority based on the annual amount of value added tax and business tax paid in excess of RMB200,000, and multiplied by a prescribed rate ranging from 15% to 50%. Naqu Pioneer obtained such support fund for the first time in 2012.

Dividend Withholding Tax

Under the Arrangement between Mainland and Hong Kong Special Administrative Region for Avoiding Dual Taxation on Income and Preventing Escape of Taxation (內地和香港特別行政區關於對所得避免雙重徵稅和防止偷漏稅的安排), a PRC resident enterprise which distributes dividends to its Hong Kong shareholders should pay income tax, however, if the beneficiary of the dividends is a Hong Kong resident enterprise, which directly holds not less than 25% equity of the aforesaid enterprise or the dividend distributor, the tax levied shall be 5% of the distributed dividends. If the beneficiary is a Hong Kong resident enterprise, which directly holds less than 25% equity of the aforesaid enterprise, the tax levied shall be 10% of the distributed dividends.

REGULATORY FRAMEWORK

In addition, pursuant to the Circular of the SAT on Relevant Issues Relating to the Implementation of Dividend Clauses in Tax Treaty (國家稅務總局關於執行稅收協定股息條款有關問題的通知) issued by the SAT on 20 February 2009, all of the following requirements should be satisfied where a tax resident of the counterparty to the tax treaty needs to be entitled to such tax treatment specified in the tax treaty for the dividends paid to it by a PRC resident company: (1) such a tax resident who obtains dividends should be a company as provided in the tax treaty, (2) the equity interests and voting shares of the PRC resident company directly owned by such a tax resident reach a specified percentage, and (3) the capital ratio of the PRC resident company directly owned by such a tax resident reaches the percentage specified in the tax treaty at any time within 12 months prior to acquiring the dividends.

Pursuant to the Administrative Measures for Non-residents to Enjoy Treatment under Tax Treaties (for Trial Implementation) (非居民享受稅收協定待遇管理辦法(試行)) which came into effect on 1 October 2009, where a non-resident enterprise as defined under the PRC tax laws wishes to enjoy the tax treatment under the tax treaty, it shall apply for approval to or file with the competent tax authority for record because the preferential tax treatment is not automatically applicable. Without approval or record filing, the non-resident enterprise is not entitled to the tax treatment in the tax treaty.

Tax Collection for Share Transfer by Non-PRC Resident Enterprises

Pursuant to the Notice on Strengthening Administration of Enterprise Income Tax for Share Transfers by Non-PRC Resident Enterprises (“Circular No. 698” 國家稅務總局關於加強非居民企業股權轉讓所得企業所得稅管理的通知) issued by the SAT on 10 December 2009 with retroactive effect from 1 January 2008, except for the purchase and sale of equity through a public securities market, where a foreign investor transfers its indirect equity interest in a PRC resident enterprise by disposing of its equity interests in an overseas holding company, and such overseas holding company is located in a tax jurisdiction that: (1) has an effective tax rate less than 12.5% or (2) does not tax foreign income of its residents, the foreign investor shall report to the competent tax authority of the PRC resident enterprise this indirect transfer. If the tax authority, upon examining the nature of the indirect transfer, deems that the indirect transfer has no reasonable commercial purpose other than to avoid PRC tax, the tax authority may disregard the existence of the overseas holding company that is used for tax planning purposes and re-characterise the indirect transfer.

Circular No. 698 also provides that, where a non-PRC resident enterprise transfers its equity interests in a PRC resident enterprise to its related parties at a price lower than the fair market value, the relevant tax authority has the power to make a reasonable adjustment to the taxable income of the transaction.

OTHER REGULATIONS IN THE PRC

We are subject to evolving regulations under many other laws and regulations issued by the authorities of national, provincial and city levels, some of which are, or may be, applicable to our business. Our customers are also subject to a wide variety of laws and regulations that could affect the nature and scope of their relationships with us. Laws regulating marketing, promoting or sale of pharmaceutical products and medical devices cover a broad array of subjects. We must comply with numerous additional regulations relating to matters such as land use, recall of pharmaceutical products, anti-unfair competition, intellectual property protection, continuing CFDA regulation, labelling and packaging of pharmaceutical products and classification of prescription medicines and over-the-counter medicine. We may be required to incur significant costs to comply with these laws and regulations in the future. Unanticipated changes in existing regulatory requirements or adoption of new requirements could have a material adverse effect on our business, financial condition and results of operations.