

REGULATORY OVERVIEW

OVERVIEW

This section of this document contains a summary of certain laws and regulations currently relevant to the Group’s operations. Having made all reasonable enquiries and to their best knowledge, the Directors confirm that save as disclosed in this section and the section headed “Risk factors” in this document, we have complied with all material applicable laws and regulations in the PRC, where we operated during the Track Record Period and [as at the Latest Practicable Date], and we had obtained all necessary permits, licenses and certificates for our operations.

REGULATORY FRAMEWORK

As a distributor of pharmaceutical products, we are subject to regulations and supervision by different levels of the food and drug administration in the PRC. The Law of the PRC on the Administration of Pharmaceuticals (中華人民共和國藥品管理法) (the “**Pharmaceuticals Law**”) promulgated by the Standing Committee of the National People’s Congress of the PRC on 20 September 1984 and amended on 28 February 2001 (the amendments came into effect on 1 December 2001), together with the Implementation Regulation 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) (the “**Implementation Regulation**”) promulgated by the State Council on 4 August 2002 and effective on 15 September 2002, provides the legal framework for the administration of the production and sale of pharmaceutical products in the PRC which covers the manufacturing, distributing, packaging, pricing and advertising of pharmaceutical products in the PRC. We are also subject to other PRC laws and regulations governing the distribution of pharmaceutical products.

Principal Administrative Authorities

As the competent authority of the industry, CFDA, the successor of SFDA, is responsible for administrative supervision and technical supervision over the research, production, circulation and usage of drugs, including Chinese medicines in the PRC. 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.

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

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

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DISTRIBUTION

Pharmaceutical Operation Permit and Business License

In accordance with the Pharmaceuticals Law, the Implementation Regulation, and the Administrative Measures of Pharmaceutical Operation Permit (藥品經營許可證管理辦法) issued by SFDA on 4 February 2004 and effective from 1 April 2004, the establishment of a wholesale pharmaceutical distribution enterprise requires the approval from the provincial drug administrative authorities of the registered locality of such wholesale pharmaceutical distribution enterprise. Upon approval, the competent authority will grant a pharmaceutical operation permit to such wholesale pharmaceutical distribution enterprise. The establishment of a retail pharmaceutical enterprise requires the approval of the local drug administrative authorities at or above the county level. Upon approval, the competent authority will grant a pharmaceutical operation permit to such retail pharmaceutical enterprise. Once these permits are received, the wholesale or retail pharmaceutical enterprise (as the case may be) shall be registered with the relevant administration for industry and commerce. The grant of such permit is subject to an inspection of the operator's facilities, warehouse, hygiene environment, quality control systems, personnel (including whether pharmacists and other professionals have the relevant qualifications) and equipment. The pharmaceutical operation permit is valid for five years. Each operation permit holder must apply for an extension of its permit within six months prior to expiration, and extensions are granted only after a re-examination of the permit holder by the authority which issued the permit. In addition, a pharmaceutical operator must obtain a business license from the relevant administration for industry and commerce prior to commencing its business.

In this connection, we have obtained the pharmaceutical operation permit granted by Zhejiang Province Food and Drug Administration, which is the competent drug administrative authority of Zhejiang province, the province where we register. We have also obtained the business license granted by and registered with the relevant administration for industry and commerce in accordance with the applicable PRC laws and regulations. Our pharmaceutical operation permit is valid till 11 May 2016.

Good Supply Practices

Under the Pharmaceuticals Law, the Implementation Regulation, the Good Supply Practices (藥品經營質量管理規範) effective from 1 July 2000, and the Administrative Measures for Certification of Good Supply Practices (藥品經營質量管理規範認證管理辦法) promulgated on and effective from 24 April 2003, each wholesale or retail operator of pharmaceutical products is required to obtain a GSP certificate from the provincial drug administrative authorities of the registered locality of such wholesale or retail operator. The GSP standards, which comprise a set of quality guidelines for operations related to pharmaceutical products, regulate pharmaceutical wholesale and retail operators to ensure the quality of pharmaceutical products in the PRC. The current applicable GSP standards require pharmaceutical operators to implement strict controls on their operation of pharmaceutical products, including standards regarding staff qualifications, premises, warehouses, inspection, equipment and facilities, management and quality control. On 22 January 2013, the Ministry of Health issued the newly revised Good Supply Practices (the "2013 GSP") which will take effect on 1 June 2013. The 2013 GSP comprises 187 articles in four chapters, including the General Provisions, Quality Management for Wholesale of Pharmaceutical Products, Quality Management for Retail of Pharmaceutical Products and Supplementary Provisions. As compared with the current GSP, the 2013 GSP sets higher standards for

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engaging in pharmaceutical distribution, including but without limitation to improvements related to purchase channels, storage temperatures, keeping of receipts and other documents, cold-chain management and transportation. The pharmaceutical distribution enterprises will generally have a three-year transitional period to make necessary adjustments to comply with the 2013 GSP. The enterprises which fail to meet the requirements under the 2013 GSP after the three-year transitional period before 1 January 2016 will be prohibited from carrying out pharmaceutical operations. The GSP certificate is valid for five years and may be extended for another five years within three months prior to its expiration upon a re-examination by the relevant authority.

In this regard, we have obtained the GSP certificate granted by Zhejiang Province Food and Drug Administration which is the competent drug administrative authority of Zhejiang province where we register for our pharmaceutical distribution operation. Our GSP certificate is valid till 21 August 2016.

Medical Device Operation

In accordance with the Regulation on the Supervision and Administration of Medical Devices (醫療器械監督管理條例) promulgated by the State Council on 4 January 2000 and effective from 1 April 2000 and the Administrative Measures of Permits for Medical Devices Operation Enterprises (醫療器械經營企業許可證管理辦法) issued by SFDA on and effective from 9 August 2004, the state adopts classification and separate administration for medical devices. Class I medical devices are those for which safety and effectiveness may be adequately ensured through ordinary administration. Class II medical devices are those for which further control is required to ensure their safety and effectiveness. Class III medical devices are those which are implanted into human body or used for life support or sustenance, or pose potential danger to the human body and thus must be strictly controlled in respect of safety and effectiveness. No approval is required from any drug administrative authority for the establishment of an enterprise engaged in the wholesale or retail distribution of Class I medical devices. It is required to obtain an operation permit from the provincial drug administrative authorities of the registered locality of such enterprise before commencing the distribution of most Class II and all Class III medical devices. The list of classification for medical devices are set forth in the Medical Device Product Categories (醫療器械分類目錄), which is promulgated and updated by SFDA from time to time. An operation permit is valid for five years and a distributor needs to apply with the provincial drug administrative authority to renew the operation permit six months before the expiration date of the permit.

With a view to conducting the distribution of medical devices in the future, we have obtained the medical device operation enterprise permit granted by Zhejiang Province Food and Drug Administration which is the competent drug administrative authority of Zhejiang province where we register. Our medical device operation enterprise permit is valid till 28 May 2017. However, during the Track Record Period, we did not commence any business activities relating to the distribution of medical devices. Currently, we do not have any definite plan to commence such business.

Pursuant to the Pharmaceuticals Law, the Administrative Measures of Pharmaceutical Operation Permit, the Administrative Measures for Certification of Good Supply Practices, and the Administrative Measures of Permits for Medical Devices Operation Enterprises, to conduct pharmaceutical products and medical devices distribution in the PRC, our Group shall obtain approvals from the provincial drug administrative authority where it is registered, which is Zhejiang Province Food and Drug Administration. Therefore, we are not required to obtain approvals or permits from the provincial authorities other than in Zhejiang province.

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Supervision and Administration of Drug Distribution

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

Foreign Investment in Pharmaceutical Distribution

Under the Foreign Investment Industrial Guidance Catalog (外商投資產業指導目錄) (the "Guidance Catalog") jointly promulgated by MOFCOM and NDRC on 31 October 2007 and effective from 1 December 2007, the wholesale, retail and dispatch of pharmaceutical products fall within the category of industries in which foreign investment is restricted. MOFCOM and NDRC amended the Guidance Catalog on 24 December 2011, which provides that, effective from 30 January 2012, the wholesale, retail and dispatch of pharmaceutical products are removed from the category of industries in which foreign investment is subject to restrictions and become falling within the category of industries in which foreign investment is permitted.

Our pharmaceutical distribution business falls within the category of industries in which foreign investment is permitted.

OTHER RELATED REGULATIONS IN THE PHARMACEUTICAL INDUSTRY

Prescription Drugs and Over-the-Counter Drugs

In order to promote safety, efficacy and convenience in the use of pharmaceutical products, SFDA published the Trial Administrative Measures regarding the Classification of Prescription Drugs and Over-the-Counter Drugs (處方藥與非處方藥分類管理辦法(試行)) on 18 June 1999, which came into effect from 1 January 2000. The administrative measures divide drugs according to their type, specification, the relevant disease or ailment which they are designed to treat, dosage and method of administration. Prescription drugs are those whose prescription, purchase and intake require prescription by practising doctors or assistant doctors. Over-the-counter drugs are those whose prescription, purchase and intake do not require prescription by practising doctors or assistant doctors. SFDA is responsible for the selection, approval, publication, and revision of the State OTC Medicine Catalog (國家非處方藥目錄).

The National List of Essential Drugs

On 18 August 2009, the Ministry of Health and eight other ministries and commissions in the PRC issued the Provisional Measures on the Administration of the 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 Essential Drugs System (關於建立國家基本藥物制度的實施意見), which aim to promote essential medicines sold to consumers at fair prices in the PRC and ensure that the general public in the PRC has equal access to the drugs contained in the National List of Essential Drugs. On the same day, the Ministry of Health promulgated the National List of Essential Drugs (for Primary Healthcare Institutions) (國家基本藥物目錄(基層醫療衛生機構配備使用部分)). On 13 March 2013, the Ministry of Health issued the National List of Essential Drugs (2012 Edition) (國家基本藥物目錄(2012年版)) which will take effect as from 1 May 2013.

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The National Medical Insurance Drugs Catalog

Pursuant to the National Medical Insurance Drugs Catalog issued by the Ministry of Human Resources and Social Security on 27 November 2009 (as amended), there are three parts in such catalog, including western medicines part, TCM part, and TCM slices part. Drugs as listed in western medicines and TCM parts of the catalog can be refunded by the social security fund, and those drugs are divided into two grades, namely Grade A and Grade B, when they are refunded by the basic medical insurance. However when they are refunded by work injury insurance or maternity insurance, the division of two different grades will not apply. Drugs as listed in TCM slices part of the catalog cannot be refunded by the social security fund. The patients who consume Grade A drugs must be reimbursed in full by the national basic medical insurance. Patients consuming Grade B drugs will be partially reimbursed, in which the proportion would depend on the financial resources of the basic medical insurance. The amount of the deductible differs from region to region in the PRC.

As at the Latest Practicable Date, 42 out of our 55 products were included in the Medical Insurance Drugs Catalogs, and were therefore subject to price control in the PRC, which involved the imposition of retail price ceilings by the PRC government. During the Track Record Period, sales of these products accounted for approximately 85.0%, 93.7% and [93.0]% of our total revenue for each of the two years ended 31 December 2011 and 2012 and for the six months ended 30 June 2013, respectively.

Safety and Credibility Rating

In order to increase the awareness of pharmaceutical product manufacturers, operators and research institutions about the safety and credibility of pharmaceutical products and medical equipment, SFDA promulgated the Tentative Regulations Regarding the Safety and Credibility Rating of Pharmaceutical Products (藥品安全信用分類管理暫行規定) on 13 September 2004, pursuant to which drug administrative authorities at the county level or above regulate the safety and credibility rating of the pharmaceutical product and medical device manufacturers, operators and research institutions in their jurisdiction by establishment of an information system through which the relevant pharmaceutical product and medical device manufacturers, operators and research institutions may be rated and rewarded accordingly. On 13 August 2012, SFDA promulgated the Drug Safety Blacklist Administrative Measures (Trial) (藥品安全“黑名單”管理規定(試行)) effective from 1 October 2012, according to which, relevant information of producers, operators and responsible persons, who have received administrative punishments due to severe violations of laws, regulations and rules regarding drug and medical device administration, will be publicised on government websites for social supervision.

Our Distributor Customers, being pharmaceutical operators in the PRC, are also subject to the safety and credibility rating administration by their respective drug administrative authorities. For example, according to the notice issued by Zhejiang Province Food and Drug Administration in June 2012, among our Distributor Customers, Huadong Medicine, Zhejiang Intec, Ningbo Pharma, Sinopharm Group Wenzhou Co., Ltd. (國藥控股溫州有限公司, formerly known as 溫州市生物藥械供應有限公司), Zhejiang Zheda Yuanzheng Medicine Co., Ltd. (浙江浙大圓正醫藥有限公司), Zhejiang Pharmaceutical Industry Co., Ltd. (浙江省醫藥工業有限公司), Wenzhou Time Pharmaceuticals Co., Ltd. (溫州時代醫藥有限公司), Wenzhou Intec Pharmaceuticals Co., Ltd. (溫州市英特藥業有限公司), Zhejiang Dade Medicine Group Zhejiang Pharmaceuticals Co., Ltd. (浙江大德藥業集團浙江醫藥有限公司), Zhejiang Xinxin Pharmaceuticals Co., Ltd. (浙江新欣醫藥有限公司), and Zhejiang Zhenyuan Co., Ltd. (浙江震元股份有限公司) are rated as "faith" for the year of 2011, and our Group are not rated as "bad faith".

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Advertising Restriction

Pursuant to the Pharmaceuticals Law, the Implementation Regulation, and the Measures on the Examination of Pharmaceuticals Products Advertisement (藥品廣告審查辦法) jointly issued by SFDA and SAIC on 13 March 2007 and effective from 1 May 2007, a pharmaceutical operation enterprise seeking to advertise its pharmaceutical products must apply for an advertising approval code with the provincial drug administrative authority, subject to the prior consent from the pharmaceutical manufacturer.

Price Controls

Pursuant to the Pharmaceuticals Law, the Implementation Regulation, and the Circular on Issue of Price-controlled Pharmaceutical Products Catalog of the NDRC (國家發展和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) issued by NDRC on 27 June 2005 and effective from 1 August 2005, prices of pharmaceutical products are either determined by the PRC government or by market conditions. The prices of certain pharmaceutical products sold in the PRC, primarily those included in the Medical Insurance Drugs Catalogs, are subject to price controls mainly in the form of fixed prices or price ceilings. Manufacturers and operators are not allowed to set the actual price for any price-controlled product above the price ceiling or deviate from the fixed price imposed by the government. The prices of medicines that are not subject to price controls are determined freely at the discretion of the respective pharmaceutical product enterprises. The prices of medicines that are subject to price controls are administered by NDRC and provincial price control authorities. From time to time, NDRC publishes and updates a list of medicines that are subject to price controls.

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的通知) jointly issued by NDRC, the Office of Redressing Malpractices of the State Council, the Ministry of Health, SFDA, MOFCOM, the Ministry of Finance and the Ministry of Human Resources and Social Security on 19 May 2006, the PRC government exercises price control over pharmaceutical products included in the Medical Insurance Drugs Catalogs, 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 such products have not been produced in large quantities by manufacturers due to their low retail price levels. In particular, the retail price charged by hospitals at the county level or above may not exceed 115% of the procurement cost of the relevant pharmaceutical products or 125% for certain TCM slices.

On 3 September 2012, NDRC, the Ministry of Health and the Ministry of Human Resources and Social Security jointly issued the Circular on Strengthening the Reform of Pricing for Medicines and Medical Services in County Level Public Hospitals (關於推進縣級公立醫院醫藥價格改革工作的通知). The circular sets out the general objective to further reduce patients' economic burden for medicines by way of eliminating the difference between the purchase costs and sale prices of medicines of the county level public hospitals. The circular further requires that, at the current stage of reform, certain selected pilot hospitals shall eliminate the difference between the purchase costs and sale prices of medicines and announce their medicine sales prices to the public which aims to ensure the prices of medicines sold by the selected pilot hospitals to be reduced by approximately 15%. Under the current PRC laws and regulations, no deadline for the 15% price reduction as stipulated in such circular has been set, and it is not stipulated that the aforesaid price reduction should be made one-off. As we do not own public hospitals in the PRC and our business does not render

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healthcare services in the PRC, such circular does not apply to our Group. However, given that a majority of our products are distributed through our Distributor Customers to the ultimate customers which are mainly hospitals and medical institutions in the PRC, if the public hospitals have to reduce sale prices of medicines as required by the circular, there is no assurance that the public hospitals will not reduce their purchase prices of the medicines distributed by our Distributor Customers, which may in turn make us experience downward pressure on our wholesale prices and may therefore have a material adverse effect on our results of operations.

On 9 November 2009, NDRC, the Ministry of Health 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 Medical Insurance Drugs Catalogs and certain drugs whose production or trading tend to create monopolies, drugs listed in the National List of Essential Drugs are subject to PRC government price control. The prices of other drugs are determined by the market conditions. Moreover, on 5 March 2010, NDRC promulgated the Notice on Relevant Issues Regarding the Revising of the Price-controlled Pharmaceutical Products Catalog (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 issued the new version of the Price-controlled Pharmaceutical Products Catalog of NDRC (國家發展改革委定價藥品目錄). The latest price adjustments by NDRC occurred in December 2012 and effective as from 1 February 2013 when NDRC promulgated the Notice for Adjustment of the Prices of Medicines for Respiratory, Antipyretic Analgesics and Specialty Special Medications (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) setting out the ceiling prices for certain medicines within these therapeutic areas.

Fixed prices and price ceilings on medicines are determined based on the profit margins that the relevant government authorities deem reasonable, the type and quality of the medicine, the average production costs, and the prices of substitute medicines. If a particular pharmaceutical product is significantly superior to comparable products in terms of effectiveness, safety, treatment cycle and costs of treatment, its manufacturer or operator may apply to the provincial price authority for preliminary examination for separate pricing. In the event that the applicant is satisfied with the requirements of separate pricing, the provincial price authority will come up with its preliminary opinion on the application and submit such opinion to NDRC. Upon receiving the preliminary examination opinion from the provincial price authority by NDRC, the separate pricing plan for the pharmaceutical product in question will be determined by NDRC after expounded through peer review or public hearing. For the separately priced pharmaceutical products, NDRC will conduct market tracking survey and make adjustments from time to time.

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To properly determine and adjust drug prices, NDRC has conducted investigations several times on the ex-factory drug prices since 2005. For example, NDRC has issued the Notice on the Investigation of Actual Ex-Factory Prices of Drugs (國家發展和改革委員會辦公廳關於調查藥品實際出廠價格的通知) on 17 May 2005 and the Notice on the Investigation of Ex-Factory Prices of Certain Drugs (國家發展和改革委員會辦公廳關於對部分藥品進行出廠價格調查的通知) in July 2010 to conduct investigations of ex-factory prices of selected drugs. To comprehensively regulate how investigation of ex-factory prices of drugs should be conducted, NDRC issued the Measures on the Investigation of Ex-Factory Prices of Drugs (Trial Implementation) (藥品出廠價格調查辦法(試行)) (the “Measures”) on 9 November 2011 and effective as from 1 December 2011, which apply to the investigation of ex-factory prices of domestic or repackaged import drugs organised by NDRC, acting through the drug pricing evaluation center of NDRC or the provincial price control authorities. The Measures have stipulated the scope of investigation which will generally cover information relating to the ex-factory prices and the sales of the selected drugs during certain period, the obligation of the pharmaceutical manufacturers under investigation to provide relevant information and to submit supporting materials, as well as the approaches and procedures of investigation conducted by NDRC or provincial price control authorities. Furthermore, to strengthen the implementation of the Measures, NDRC issued the Notice on Enforcement of Investigation and Survey of Ex-Factory Prices of Drugs (國家發展和改革委員會辦公廳關於加強藥品出廠價格調查和監測工作的通知) on 26 March 2012. Due to the implementation of the Measures and other relevant regulations, the government will be able to use the results of the investigation to set the fixed prices or price ceilings of the price-controlled drugs, which may lead to further downward adjustments in the prices of drugs.

As at the Latest Practicable Date, 42 out of our 55 products were included in the Medical Insurance Drugs Catalogs, and were therefore subject to price control by NDRC or provincial price control authorities under applicable PRC laws and regulations principally including the regulations mentioned above. As patients in the PRC purchasing pharmaceutical products that are listed in the Medical Insurance Drugs Catalogs are eligible for full or partial reimbursement under national and provincial medical insurance, work injury insurance and maternity insurance programs, pharmaceutical products that are listed in the Medical Insurance Drugs Catalogs are generally more attractive to hospitals and end customers than other products that are not listed. During the Track Record Period and as at the Latest Practicable Date, none of our products is sold above the price ceilings prescribed by the PRC government. For the products affected by the price adjustments, we will renegotiate with the relevant suppliers to adjust the purchase prices and/or renegotiate with the relevant Distributor Customers to adjust the selling prices. We may consider ceasing to distribute our certain products or selecting other suppliers to mitigate the impact of the price adjustments. Although our results of operation during the Track Record Period were not materially and adversely affected by any price adjustments imposed by the PRC government in relation to our products included in the Medical Insurance Drugs Catalogs, there is no assurance that the PRC government will not implement stricter price control or impose additional restrictions. Any such measures may cause our sales to decline and adversely affect our revenue. Please refer to the section headed “Risk Factors – Risks Relating to the Industry – Our products are subject to price controls and we do not have full discretion over the pricing of such products”.

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Collective Tendering System for Procurement of Pharmaceutical Products by Medical Organisations

On 7 July 2010, the Ministry of Health and six other authorities jointly promulgated the Rules on Collective Procurement of Pharmaceutical Products by Medical Organisations (醫療機構藥品集中採購工作規範). Pursuant to these Rules, non-profit-making medical organisations established by the governments of county or above level and State-owned enterprises must participate in the collective tendering system for procurement of pharmaceutical products. The medical organisations are required to purchase substantially all pharmaceutical products (except certain anesthetics and anti-psychotic drugs, bulk drugs, Chinese traditional medicines and other drugs as specified in relevant regulations) through the centralised platforms organised by the provincial governments. The collective tendering system include open tendering, invited tendering and direct procurement organised by the provincial governments. In principle, open tendering shall apply to all pharmaceutical products that can be purchased by this means. Invited bidding may be adopted in the circumstances where there is a relatively lower demand for procurement of the relevant pharmaceutical product or where there are less or no potential bidders. Direct procurement applies only in respect of certain low-price pharmaceutical products whose prices have been stabilised after being purchased through the collective tendering system for a number of times. The manufacturers of pharmaceutical products are directly responsible for the tendering process and after winning the tenders may entrust distributors of the relevant pharmaceutical products to deliver the products to the medical organisations.

As a majority of our products are distributed through our Distributor Customers to the ultimate customers which are mainly hospitals nationwide in the PRC, if our suppliers are unsuccessful in the tender processes, our sales to hospitals through the Distributor Customers would inevitably decrease, which could result in a material adverse effect on our business, financial condition and results of operations. Please refer to the section headed "Risk Factors – Risks Relating to the Business – Our suppliers may not be always successful in winning the tender process which may hence affect our product penetration to the hospitals in the PRC".

According to the Rules on Collective Tender Procurement of Pharmaceutical Products by Medical Organisations (Trial) (醫療機構藥品集中招標採購工作規範(試行)) jointly issued by six authorities including without limitation the Ministry of Health and SFDA in November 2001 which have been abolished in July 2010, the Document Template for Collective Tender and Collective Centralised Bargaining Procurement of Pharmaceutical Products by Medical Organisations (Trial) (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)) issued by the Ministry of Health in November 2001, and the Rules on

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Collective Procurement of Pharmaceutical Products by Medical Organisations, the main differences between open tendering and centralised bargaining are set forth in the following table:

Open tendering	Centralised bargaining
Collective procurement of pharmaceutical products by public medical organisations shall principally take the form of tendering, including open bidding and invited bidding.	Collective procurement of pharmaceutical products by public medical organisations shall not be conducted by way of centralised bargaining, unless pharmaceutical products cannot be purchased through tendering process.
No price negotiation is allowed between bidders and bid inviters.	Price negotiation is allowed between bidders and bid inviters.
The bid offer during tendering process is confidential.	The offer during centralised bargaining process is open.

Regulations relating to the Manufacturing of Pharmaceutical Products Distributed by Us

We, being only a pharmaceutical distributor, source and procure our products from the pharmaceutical manufacturers and pharmaceutical companies throughout different provinces in the PRC. Therefore, the regulations relating to the manufacturing of pharmaceutical products may also affect our pharmaceutical distribution operation.

According to the Implementation Regulation and the Administrative Measures on the Supervision of the Manufacture of Pharmaceuticals (藥品生產監督管理辦法) issued by SFDA on 5 August 2004, the manufacturer of pharmaceuticals must obtain a pharmaceutical production permit from the provincial drug administrative authority of its registered locality and a GMP certificate, both of which will be valid for five years and may be renewed upon a re-examination by the relevant authority at least six months prior to its expiration date. On 17 January 2011, the Ministry of Health promulgated the current version of GMP standards (2010 revised version), which became effective on 1 March 2011. The current GMP standards place greater emphasis on the use of effective quality control system by pharmaceutical manufacturers, through the strengthening of drug manufacturing quality management systems, and also include new processes and measures for supplier audits, change control, more secure approaches for procurement of excipients and other raw materials, and other measures to help prevent and correct quality failures.

The major new requirements under the revised GMP standards are as follows:

- The revised GMP standards have 14 chapters and 313 articles, as compared with the previous GMP standards which had only 14 chapters and 88 articles, and contain much more detailed requirements on key aspects of the manufacturing process of the pharmaceuticals.
- The revised GMP standards shift the focus of GMP requirements from the technical standards of the manufacturing facilities to the maintenance and operation of a comprehensive, effective pharmaceutical quality control system by the manufacturer.

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- The revised GMP standards have raised the clean room requirements, added online surveillance requirements and refined standards for sterile drugs.
- The revised GMP standards set forth in details the responsibilities of key personnel in the manufacturing process and quality control of pharmaceuticals.
- The revised GMP standards have added more specific requirements on such aspects as documentation, concept of quality risk management, new requirements on supplier audit, change control, corrective and preventive actions, product quality review, deviation management, continuous product stability inspection, and product quality retrospective analysis.

The existing pharmaceutical manufacturers will generally have a transitional period up to five years (before 31 December 2015, but for sterile manufacturers such as blood/vaccine/injection product before 31 December 2013) to make necessary adjustments to comply with the 2010 revised version GMP. The enterprises which fail to meet the requirements under the 2010 revised version GMP after the transitional period will be prohibited from carrying out pharmaceutical manufacturing operations. In addition, according to the Administrative Measures on Drug Registration (藥品註冊管理辦法) issued by SFDA on 10 July 2007 and effective from 1 October 2007, a medicine must be registered with and approved by SFDA before it can be manufactured.

Regulations relating to Antibiotics

NHFPC issued the Campaign Schemes to Regulate the Use of Antibiotics for the Years of 2011, 2012 and 2013 (2011年全國抗菌藥物臨床應用專項整治活動方案, 2012年全國抗菌藥物臨床應用專項整治活動方案 and 2013年全國抗菌藥物臨床應用專項整治活動方案), respectively, on 18 April 2011, 5 March 2012 and 6 May 2013, and the Administrative Measures on the Clinical Use of Antibiotics (抗菌藥物臨床應用管理辦法) on 24 April 2012, which (i) classify antibiotics into three categories, including non-limited use, limited use and special use, (ii) require the hospitals to sort the antibiotics they use and assign different prescription rights to doctors on different levels, (iii) limit the numbers of antibiotics used by hospitals on different levels, and (iv) require the provincial health authorities to formulate their catalogues of the antibiotics on their own. On 19 July 2012, Zhejiang Provincial Health Bureau issued the Administrative Catalogue of the Clinical Use of Antibiotics of Zhejiang Province (2012 version) (浙江省抗菌藥物臨床應用分級管理目錄(2012版)), according to which certain of the major products distributed by us, including Cefoxitin Sodium for Injection (注射用頭孢西丁鈉), Cefodizime Sodium for Injection (注射用頭孢地嗪鈉), Isepamicin Sulfate Injection (硫酸異帕米星注射液), Cefixime Dispersible Tablet (頭孢克肟分散片) and Ceftizoxime Sodium for Injection (注射用頭孢唑肟鈉), fall within the category of limited use.

Regulations on Commercial Bribery in the Pharmaceutical Industry

According to the Anti Unfair Competition Law of the PRC (中華人民共和國反不正當競爭法) promulgated by the Standing Committee of the National People's Congress of the PRC on 2 September 1993 and effective on 1 December 1993, business operators who practise bribery by giving properties or using any other method in order to sell or purchase the commodities shall be imposed fine in an amount from more than RMB10,000 to less than RMB200,000 and shall have their illegal income confiscated, and in severe circumstances, may be subject to criminal liability.

REGULATORY OVERVIEW

Under the Pharmaceuticals Law, if pharmaceutical manufacturers, operation enterprises or medical institutions give or receive commissions or other interests in secret during the purchase or sale of pharmaceuticals, or if pharmaceutical manufacturers, operation enterprises or their agents give any property or other interests to the responsible persons, purchasing staff, physicians or other relevant persons in the medical institutions where their medicines are used, fines shall be imposed and the unlawful income shall be confiscated by the relevant administration for industry and commerce who, if the circumstances are severe, shall revoke the business licenses of the pharmaceutical manufacturers or operation enterprises, and shall notify the drug administrative authorities which shall revoke the pharmaceutical manufacturing permits or pharmaceutical operation permits. If a crime is constituted, an investigation shall be made for criminal liabilities. If the responsible persons or purchasing staff of pharmaceutical manufacturers or operation enterprises receive any property or other interests from other manufacturers or operation enterprises or their agents during the purchase or sale of medicines, they shall be punished according to relevant regulations and shall have their unlawful income confiscated, and in severe circumstances, may be subject to criminal liability.

To prevent the occurrence of any incident concerning corruption, bribery, abuse or other improper conducts engaged by our Group or our employees or affiliates, we have established an internal control system. For details of the internal control system of our Group, please refer to the section headed “Business – Internal Control” of this document.

OCCUPATIONAL HEALTH AND SAFETY

Pursuant to the Labour Law of the PRC (中華人民共和國勞動法) promulgated by the Standing Committee of the National People’s Congress of the PRC on 5 July 1994 and effective from 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.

Pursuant to the Law of Manufacturing Safety of the PRC (中華人民共和國安全生產法) effective from 1 November 2002 and amended on 27 August 2009, manufacturers and operators must establish a comprehensive management system to ensure manufacturing safety in accordance with applicable laws and regulations. Manufacturers or operators who do not meet relevant legal requirements are not permitted to conduct business activities.

According to the Labour Contract Law of the PRC (中華人民共和國勞動合同法) promulgated by the Standing Committee of the National People’s Congress on 29 June 2007 and effective from 1 January 2008 and as amended on 28 December 2012 (the amendments will take effect on 1 July 2013), employers are required to truthfully inform prospective employees of the job description, working conditions, location, occupational hazards and status of safe production as well as remuneration and other conditions as requested by the Labour Contract Law of the PRC.

Our Group had complied with the aforesaid occupational health and safety regulations during the Track Record Period.

REGULATORY OVERVIEW

PRODUCT LIABILITY

In accordance with the Product Quality Law of the PRC (中華人民共和國產品質量法) (as amended on 8 July 2000 and 27 August 2009, respectively) and the PRC Tort Liability Law (中華人民共和國侵權責任法) (effective as at 1 July 2010) issued by the Standing Committee of the National People’s Congress of the PRC on 22 February 1993 and 26 December 2009, respectively, where a product with any defect caused by the fault of the seller causes any harm to another person, the seller shall assume the tort liability. If a seller can neither specify the manufacturer nor specify the suppliers of a defective product, the seller shall assume the tort liability caused by such defective product. Where any harm is caused by a defective product, the victim may require compensation to be made by the manufacturer or the seller of such defective product, and if the defect of the product is caused by the manufacturer and the seller has made the compensation for the defect, the seller shall be entitled to be reimbursed by the manufacturer. If any product defect is found after such product has been put into circulation, the manufacturer or seller shall take such remedial measures as warning and recall in a timely manner. The manufacturer or seller, who fails to take remedial measures in a timely manner or take sufficient and effective measures and has caused any harm, shall assume the tort liability. In the case that a manufacturer or seller knowing any defect of a product continues to manufacture or sell the product and the defect causes a death or any serious damage to the health of another person, the victim shall be entitled to require the corresponding punitive compensation. In addition, operators who sell defective products may be subject to the confiscation of earnings from such sales, the revocation of business licenses and imposition of fines, and in severe circumstances, may be subject to criminal liability.

During the Track Record Period, there was no product liability claim against our Group. Please refer to the section headed “Risk Factors – Risks Relating to the Business – We may incur losses resulting from product liability claims as the quality of the products distributed by us is not under our control”.

Drug Recalls

On 10 December 2007, SFDA issued the Administrative Measures on Drug Recalls (藥品召回管理辦法) for the purpose of strengthening supervision over drug safety and safeguarding consumers’ drug use safety. Pursuant to the measures, pharmaceutical manufacturers are responsible for recalling their products that have “hidden safety problems” from the market. The “hidden safety problem” is defined as an unreasonable risk to endanger human health and life that may be caused by the drugs due to reasons in research and development or production. The recalls may be conducted on a pharmaceutical manufacturer’s own initiative or at the request by SFDA or its local branches at the provincial level. Under the measures, pharmaceutical distributors mainly have the following obligations in respect of drug recalls: (i) to assist pharmaceutical manufacturers to carry out the recalls, make communications and provide feedbacks in respect of the recalls in a timely manner in accordance with the recall plans, and control and take over the returned products; (ii) when discovering any “hidden safety problems” in the drugs distributed by them, to immediately cease the distribution of the relevant drugs, and report to the manufacturers or suppliers as well as SFDA or its local branches; and (iii) to cooperate with pharmaceutical manufacturers or SFDA or its local branches in their investigations on the “hidden safety problems” of the relevant drugs and provide relevant documents.

REGULATORY OVERVIEW

We, as a pharmaceutical distributor, have established policies and procedures for quality control in accordance with the GSP requirements, which ensure that we would be able to fulfill the obligations under the above-mentioned measures when a recall situation occurred in respect of the products distributed by us. During the Track Record Period and up to the Latest Practicable Date, we have not experienced a recall of any products distributed by us and have not received any notification from SFDA or its local branches or any pharmaceutical manufacturer for recall of any product distributed by us.

OTHER REGULATIONS

PRC Taxation

As we are not incorporated in the PRC, your investment in our Shares is largely exempt from PRC tax laws. However, as substantially all of our business operations are conducted in the PRC and we carry out these business operations through our subsidiaries and joint venture organized under PRC law, our PRC operations and subsidiaries and joint venture in the PRC are subject to certain PRC tax laws and regulations, including those summarized below.

Enterprise Income Tax

On 1 January 2008, the EIT Law and the Implementation Rules to the EIT Law became effective, under which, both foreign invested enterprises and domestic enterprises are subject to a uniform income tax rate of 25%, unless they qualify for certain reductions or exemptions, and dividends payable by foreign invested enterprises, such as Hong Rui Bio-medical, to foreign investors are subject to PRC withholding tax at the rate of 10% unless the foreign investor's jurisdiction of incorporation has a tax treaty with the PRC that provides for a different withholding tax arrangement. Pursuant to the Arrangement between the Mainland China and Hong Kong Special Administrative Region for the Avoidance of Double Taxation and the Prevention of Fiscal Evasion with respect to Taxes on Income (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) effective from 8 December 2006, such withholding tax rate is lowered to 5% if a Hong Kong resident enterprise owns more than 25% of the capital of the PRC enterprise distributing the dividends. Furthermore, according to the Administrative Measures for Favorable Treatment of Non-residents under Taxation Treaties (Trial) (非居民享受稅收協定待遇管理辦法(試行)) issued by the State Administration of Taxation on 24 August 2009 and effective from 1 October 2009, approvals from competent tax authorities are required before an enterprise can enjoy the aforesaid 5% preferential tax rate. An enterprise established outside of the PRC with "de facto management bodies" within the PRC is considered a "resident enterprise" and is subject to PRC enterprise income tax at the rate of 25% on its global income. Dividends received by such enterprise from its PRC subsidiaries may be exempt from paying enterprise income tax to the extent such dividends are deemed as dividends among qualified PRC resident enterprises. Under the Implementation Rules to the EIT Law, "de facto management bodies" are defined as those bodies that have material and overall management control over the business, personnel, accounts and properties of an enterprise.

Value Added Tax

According to the Interim Regulations of the People's Republic of China on Value Added Tax (中華人民共和國增值稅暫行條例) promulgated by the State Council on 13 December 1993 and as amended on 10 November 2008 (the amendments took effect from 1 January 2009), all entities and individuals engaged in the sale of goods, the provision of processing, repairs and replacement services, and the importation of goods into the PRC are generally required to pay value added tax, or VAT, at a rate of 17% of the gross sales proceeds received, less any deductible VAT already paid or borne by the taxpayer. We are subject to a 17% VAT with respect to our pharmaceutical distribution operations in the PRC.

REGULATORY OVERVIEW

Municipal Maintenance Tax

Under the Interim Regulations of the People's Republic of China on Municipal Maintenance Tax (中華人民共和國城市維護建設稅暫行條例) promulgated by the State Council on 8 February 1985 and as amended on 8 January 2011, a taxpayer, whether an individual or otherwise, of product tax, value added tax or business tax shall be required to pay municipal maintenance tax. The tax rate shall be 7% for a taxpayer whose domicile is in an urban area, 5% for a taxpayer whose domicile is in a county or a town, and 1% for a taxpayer whose domicile is not in any urban area or county or town. From 1 December 2010, municipal maintenance tax became applicable to foreign invested enterprises, foreign enterprises and individuals, as well as domestic enterprises and individuals.

Education Surcharge

Under the Interim Provisions on Imposition of Education Surcharge (徵收教育費附加的暫行規定) promulgated by the State Council on 28 April 1986 and as amended on 7 June 1990, 20 August 2005 and 8 January 2011 respectively, a taxpayer, whether an individual or otherwise, of product tax, value added tax or business tax shall pay an education surcharge at a rate of 3%, unless such obliged taxpayer is instead required to pay a rural area education surcharge as provided by the Notice of the State Council on Raising Funds for Schools in Rural Areas (國務院關於籌措農村學校辦學經費的通知). From 1 December 2010, education surcharge became applicable to foreign invested enterprises, foreign enterprises and individuals, as well as domestic enterprises and individuals.

Stamp Duty

Under the Interim Regulations of the People's Republic of China on Stamp Duty (中華人民共和國印花稅暫行條例) promulgated by the State Council in on 6 August 1988 and as amended on 8 January 2011, for purchase and sale contracts, the duty rate shall be 0.03% of the amount stated therein, and for account books, the stamp duty shall be levied at the rate of 0.05% of the total amount of the original value of fixed assets and working capital.