

Industries  
Pharmaceutical & Life Sciences

# Investing in China's Pharmaceutical Industry – 2<sup>nd</sup> Edition





# Table of Contents

Introduction	2
<b>Chapter 1</b> Traditional Chinese Medicine, The Origin of Modern Medicine: Where Is It Now?	4
<b>Chapter 2</b> East Meets West in the OTC Market	5
<b>Chapter 3</b> Medical Devices – A Market of Opportunities	6
<b>Chapter 4</b> Contract Research Organisations Benefit from Pharma Moving Up the Value Chain	8
<b>Chapter 5</b> Contract Manufacturing Organisations Going Strong	11
<b>Chapter 6</b> Building An Innovation-Oriented Country Through Pharma R&D	12
<b>Chapter 7</b> Tax Incentives Support China In Becoming A World R&D Base	14
<b>Chapter 8</b> Navigating the Risks of Bribery and Corruption in Sales and Marketing	15
<b>Chapter 9</b> Cutting Drug Prices: Whom Does It Help?	17
<b>Chapter 10</b> Risks and Challenges of A Complex Distribution System	18
<b>Chapter 11</b> Intellectual Property Protection: Is It Getting Better?	20
<b>Chapter 12</b> The Pharma Sector: A Front-Runner in Consolidation	22
<b>Chapter 13</b> Capital Markets and Financial Reporting: What To Consider?	25
<b>Conclusion – Looking Forward</b>	27
<b>Appendix</b>	29
<ul style="list-style-type: none"><li>• List of Abbreviations</li><li>• References</li><li>• Acknowledgement</li><li>• Contacts</li></ul>	

# Introduction

*Investing in China's Pharmaceutical Industry* is the second edition of a paper published by PricewaterhouseCoopers looking into the current pharmaceutical market conditions in China. The report covers various subjects that are considered to be of concern to the pharmaceutical industry and/or investors in the pharmaceutical (pharma) industry in China. Building on the foundation set in the first report, published in 2006, this new edition includes six additional key areas, and reviews, updates and expands the different aspects discussed at that time.

By the time of this publication, three years will have elapsed since our previous report, and the pharmaceutical landscape globally and in China has evolved, the globalisation of the sector has continued, and regulations have changed.

After a waiting period of two years, on October 14<sup>th</sup>, 2008, the Chinese government released the draft of the healthcare reform plan under the official name, "Opinions on Deepening Pharmaceutical and Health System Reform (Draft)," for public comments. While this document offers limited details on the roadmap for the future of healthcare, it does provide clear statements on the high-level principles and objectives of China's new healthcare systems. In the coming years, multiple topics discussed in this paper will be significantly influenced by this healthcare reform plan.

[Chapter 1](#) focuses on the characteristics of the Traditional Chinese Medicine (TCM) market, while [Chapter 2](#) estimates the growth potential for the Chinese Over The Counter (OTC) market.

The medical devices sector is presenting a viable business opportunity for both domestic and multinational companies. [Chapter 3](#) provides an overview of the current market size and trends in this fast-growing industry.

Contract Research Organisations (CRO) are developing rapidly in China. Outsourcing to Asia and China is also moving up the value chain, from manufacturing to research and development (R&D). In [Chapter 4](#) we elaborate on the drivers and trends in the CRO sector in China.

Contract Manufacturing Organisations (CMO) have been established longer than CROs in China, and with an increased commitment to international standards, Chinese CMOs are securing more outsourcing orders from big pharmaceutical companies. In [Chapter 5](#), the challenges in this sector, which still shows double-digit growth, are discussed.

While China tries to build an innovation-oriented country, R&D activities of domestic pharma players are still in their early days. In [Chapter 6](#), we discuss how multinational pharma companies are actively setting up R&D centres in China and look into the motivation behind such an expansion. The new tax regulations established by the central government, which support the shift in China from the world's factory to an international R&D base, are reviewed in [Chapter 7](#).

Sales and marketing compliance is high on the agenda of CEOs of multinational pharma companies. [Chapter 8](#) explains how regulators in Western countries are keeping a close eye on sales and marketing activities overseas in an effort to eradicate illegal behaviour; and how China also has its own clear-cut version of anti-bribery and corruption legislation in the pharmaceutical and healthcare sector.

Over the last ten years, continual cuts to drug prices have pushed many Chinese domestic companies into the red. [Chapter 9](#) looks back on this trend and evaluates whether the price cuts have had their desired effect.

In contrast to the mature pharmaceutical markets in the US and Europe, drug distribution in China is substantially different and faces numerous challenges, which are discussed in [Chapter 10](#).

Intellectual Property Protection (IPP) has been a major concern for foreign companies operating in China. [Chapter 11](#) discusses how recent developments, such as the growth in R&D expenditures, the proposed changes in the calculation of monetary penalties for infringement, and improvements in Chinese patent law have influenced the level of confidence of foreign firms in the protection of intellectual property.

Consolidation in the Chinese pharmaceutical industry continues, as it is a growing sector for mergers and acquisition (M&A) activity in China. Although the impact of the worldwide financial crisis on M&A activity will most likely extend through out 2009 and perhaps beyond. [Chapter 12](#) provides an overview of transactions in the pharmaceutical, medical devices and healthcare services sector.

When investors plan to invest in a Chinese domestic pharmaceutical company, they often intend to expand their own product line or to take their target company public. Consequently, a comprehensive set of accounting standards is required. This is needed to meet the accounting standards of the investor for consolidation purposes abroad or for public listing in a foreign market. The implications that investors need to consider are reviewed in [Chapter 13](#).



# Chapter 1

## Traditional Chinese Medicine, The Origin of Modern Medicine: Where is it now?

TCM is a medical system developed in China about 3,000 years ago. It is based on the concept that one's health depends on a constant struggle between various opposing forces (e.g. yin and yang, or hot and cold). Excesses or imbalances in the body cause sickness or disease, with Chinese herbal medicines helping to restore balance and nurse the body back to health. Beyond their implicit meaning, Chinese herbal medicines actually comprise a combination of herbs, minerals and animal products. Other TCM-related therapies such as acupuncture, acupressure, massage and restorative physical exercises will not be discussed here.

In 2007, sales revenue for TCM products in China reached approximately US\$21 billion,<sup>1</sup> accounting for around 40% of the total pharmaceutical market in China.<sup>2</sup> In terms of sales volume, TCM currently represents around two-thirds of drug sales in China.<sup>3</sup> The widespread use of TCM poses substantial competition to the conventional drug industry and sales in TCM are forecast to reach US\$28 billion by 2010.<sup>4</sup> Currently, the sector remains fragmented (the top 10 formulated TCM companies combined account for 14% of total market share) and is largely dominated by local companies, including many state-owned enterprises.<sup>5</sup>

Conversely, Western medicine also has an opportunity to eat away at the TCM market. Although a study performed in October 2007 found that Chinese consumers overall tend to prefer TCM, Western medicine was sought when patients were certain of the cause of illness or sought quick alleviation for their symptoms.<sup>6</sup>

In recent years, the State Administration of Traditional Chinese Medicines has made TCM a strategic industrial priority, with a view to increasing export potential through modernisation of the sector. Examples of this new focus include the introduction of patent rights as well as the encouragement of modern applications for TCM-related products.

However, TCM still faces many challenges, one of which is to address the inconsistencies found in its manufacturing processes. Although the Chinese State Food and Drug Administration (SFDA) has regulated Chinese herbal medicine manufacturers based on Good Manufacturing Practice (GMP) since 1995, widespread corruption has severely undermined the effectiveness of this certification. In 2007, the SFDA reinforced its administrative oversight in an effort to reduce corruption by revising the practices of GMP regulation, implementation, enforcement and inspection.

Thus far, only one-third (300+ out of 1,100) of TCM manufacturers in China have been able to meet the January 2008 deadline to meet GMP under the revised guidelines.<sup>7</sup> Reasons for this difficulty include the initial capital investment necessary for additional manufacturing controls and updated production methods, as well as the increased stringency of the certification process.

Other challenges include potential exhaustion of herbal or animal resources, lack of product innovation, low IPP awareness and increasing international competition.



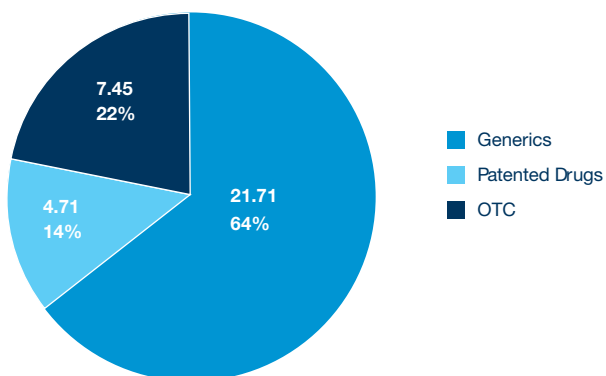
# Chapter 2

## East Meets West in the OTC Market



China's OTC market, valued at US\$7.45 billion in 2007, accounts for 22% of the overall pharmaceutical market (excl. TCM) in China (see Figure 1).<sup>8</sup>

Figure 1: China's Pharmaceutical Market (excl. TCM), 2007 (in US\$ billion)



Source: Business Monitor International

The market is forecast to grow to US\$21.49 billion by 2012 as consumers begin moving away from taking prescription drugs in hospitals to using self medication via pharmacies.<sup>9</sup>

The approval of the Internet as a proper sales channel in 2005 has also helped to drive growth, but thus far, traditional sales channels (mainly pharmacies) continue to dominate the market. Consumers still prefer to buy their OTC products in an environment in which products are clearly displayed and pharmacists are on hand to answer any questions. One drawback to on-line drug sales is that it has exacerbated the problem of counterfeit drug trafficking by providing an easy channel for fake medicine to enter the market.<sup>10</sup>

So far, growth in the market has not necessarily translated into profits for OTC manufacturers. As the cost in raw materials rise and competition stiffens, driving prices down, manufacturers are finding their profit margins being squeezed. This has hurt smaller manufacturers in particular, as they are left with fewer resources to re-invest. Major manufacturers, who can leverage their scale, are less affected, and continue the trend of expansion through mergers and acquisitions.

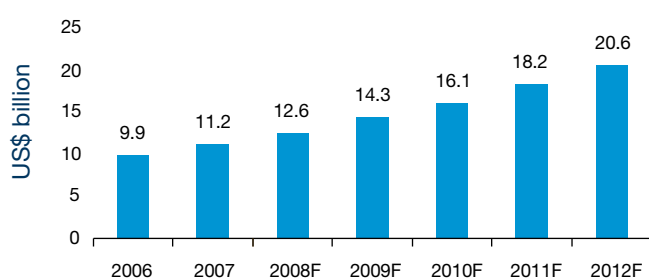
Competition is expected to increase as more and more global players try to break into the OTC market. Persistent and aggressive advertising as well as brand building may be two strategies that firms might use to distinguish their products. Other challenges for the OTC market include the need for more product quality and packaging design improvements as well as increased access to better distribution channels.

# Chapter 3

## Medical Devices – A Market of Opportunities

The medical device industry in China has seen double-digit growth over recent years, and has become a viable market opportunity for both multinational and domestic companies. In 2007, the market size for medical devices in China was estimated at US\$11.2 billion, and was forecast to reach US\$20.6 billion by 2012 (see Figure 2).<sup>11</sup>

Figure 2: China Medical Devices Market Size (in US\$ billion)



Source: Business Monitor International

The medical devices industry in China is regulated by the SFDA. Similar to Western standards, medical devices are categorised into three classes (Class I, Class II and Class III medical devices). While China's current regulatory regime for medical devices is not as comprehensive as that of the rest of the pharmaceutical industry, regulatory activity has increased lately in an attempt to tackle problems relating to quality standards and pricing.<sup>12</sup>

Over the last two years, the Chinese government has made strong efforts to strengthen regulations for medical devices across the value chain, including regulations related to pricing policies of medical devices, implementation of GMP rules, regulations on in vitro diagnostic products, strengthened supervision of medical device manufacturers and medical device testing, as well as the standardisation of technical reviews across different device classes.<sup>13 14</sup> Recent regulatory drafts on the pricing of medical devices in particular could have

a significant impact on multinational corporations (MNCs) who import or manufacture Class III medical devices in China. In October 2007, the NDRC issued a draft regulation introducing price ceilings for implantable medical devices, which has yet to be finalised, but would impact profit margins for companies operating in this segment.<sup>15</sup>

The market for medical devices is still highly fragmented and lacking major domestic industry players.<sup>16</sup> At the end of 2007, China had 12,601 registered manufacturers of medical devices.<sup>17</sup> In terms of market share, major multinational players that are well established in the Chinese market such as Siemens and General Electric still dominate the high-end segments, with local companies starting to catch up and move into high tech.<sup>18</sup>

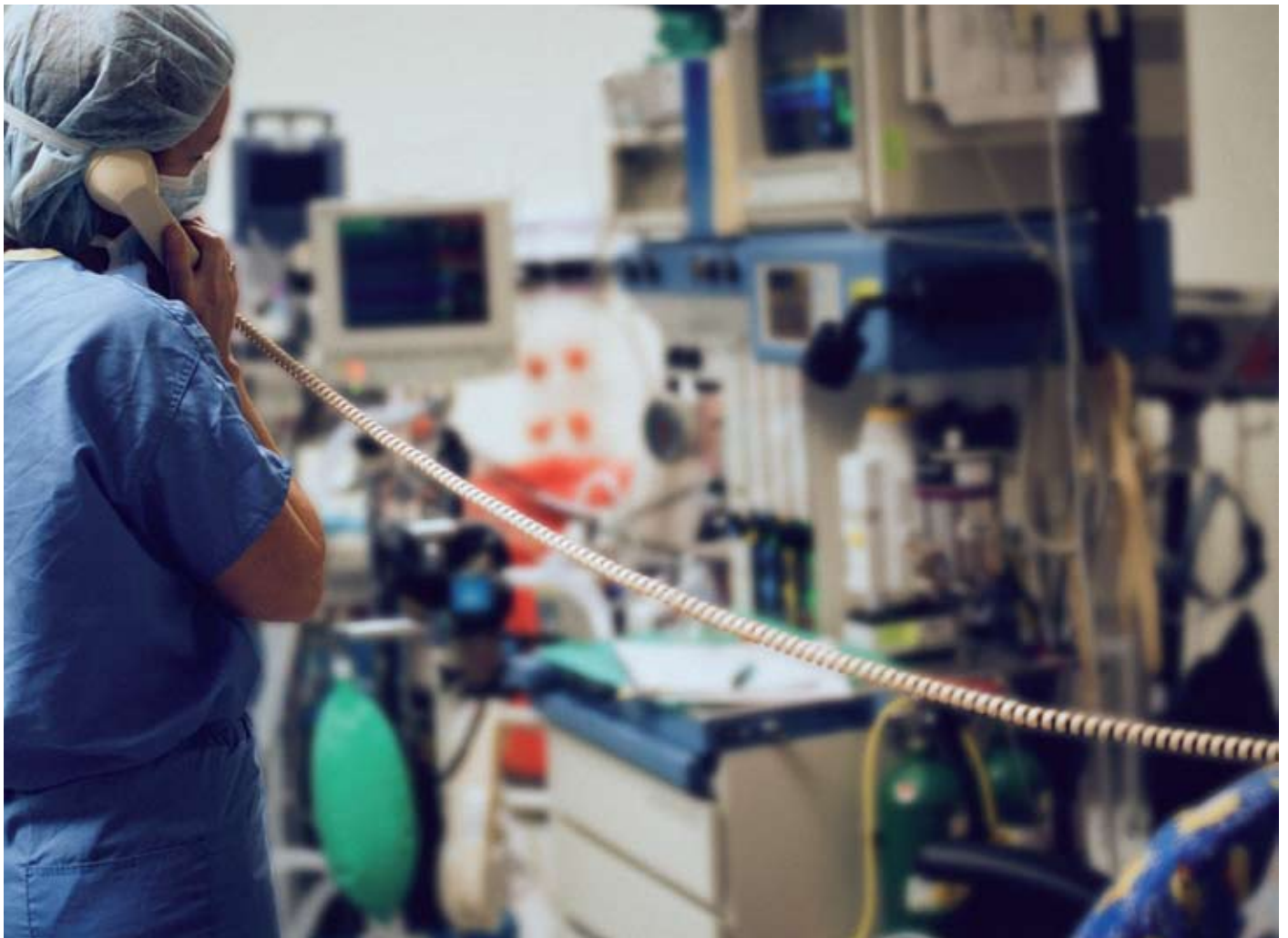
In the past, China has been highly reliant on imported medical devices. According to the General Administration of Customs of China, in 2007, China's total trade volume for medical devices reached US\$12.7 billion. Meanwhile, imports are still showing strong growth at a compound annual growth rate (CAGR) of 18.4% from 2000 to 2007, reaching US\$4.3 billion in 2007, with an increasing number of domestic companies (including MNCs' China-based subsidiaries) manufacturing for the export markets. Since 2000, Chinese exports of medical devices have more than quintupled, reaching US\$8.4 billion in 2007, leading to a significant trade surplus in the medical devices market.<sup>19</sup>

This trend of growing exports is reflected in Mindray Medical International Ltd.'s sales revenue. As a leading Chinese domestic manufacturer in patient monitoring devices, diagnostic laboratory instruments and ultrasound imaging systems, Mindray's revenues in the international markets surpassed revenues in the domestic market for the first time in 2007. The company's total sales revenue for that year reached US\$306 million.<sup>20</sup>



Like other segments of the Chinese pharmaceutical industry, the medical devices industry is facing challenges related to intellectual property (IP) infringement, quality and safety controls, and regulatory instability. Nevertheless, in light of strong economic growth, an aging population, and strong, government-supported growth in both the pharmaceutical and healthcare sectors, the medical device industry is expected to

continue its current growth pattern. Even today, about 75% of medical devices currently used in Chinese medical and healthcare institutions were produced before 1980. This further emphasises both the need and potential for future growth in the domestic market, as old devices are increasingly being replaced by new ones.<sup>21</sup>



# Chapter 4

## Contract Research Organisations Benefit From Pharma Moving Up the Value Chain



Beset by rising R&D costs, increasingly shorter cost-recovery times and a decreasing number of drug applications and approvals, Western pharmaceutical companies are facing a crisis that calls for effective solutions in order to secure long-term profitability. At the same time, fuelled by a strong and steadily growing economy, China has emerged as an increasingly attractive R&D outsourcing destination for foreign pharmaceutical companies trying to reduce their products' time and cost to market.

Today, leading Chinese CROs are able to offer contract research services at costs significantly lower than that of Western-based CROs. At the same time, Chinese CROs have shown an increasing ability to meet Western standards in drug quality and safety.<sup>22</sup>

While the majority of revenue from R&D outsourcing is still generated in the West, low-cost manufacturing countries such as China are expected to grow at a fast pace, albeit from a small base of around 1% of total global CRO revenues today.<sup>23 24</sup>

China's early R&D outsourcing skills lay mainly in chemistry-based research, due to more standardised procedures for that type of research, and the relative ease of quality control and assurance.<sup>25</sup> Today, China's biotech capabilities are developing rapidly, with domestic CROs moving into research areas such as genomics and gene therapy, while simultaneously expanding into service offerings such as Good Laboratory Practice (GLP) level preclinical outsourcing and full-scale clinical trials.<sup>26 27 28 29 30</sup>

While not an exhaustive data set, the World Health Organisation's (WHO) International Clinical Trials Registry Platform (ICTRP) provides an indication of the strong growth in China-based clinical trials in recent years. For 2007, the WHO database shows a total of 298 registered Chinese-based clinical trials, a year-on-year growth rate of 41% over 2006. During the same period, India registered only 244 trials in 2007, a growth rate of 12% over 2006.<sup>† 31</sup>

A number of factors contribute to China's increasing attractiveness as an outsourcing destination for the pharmaceutical industry:

- **Cost and time savings:** China's low-cost base offers significant savings in labour and laboratory set-up costs, as well as strong government incentive programmes such as tax holidays, tax cuts and value-added tax (VAT) exemptions (for a more detailed overview of China's current tax situation, please refer to Chapter 7). While most experts estimate that clinical trials costs in China are roughly 30% of costs in Western countries, conservative estimates will also include hidden costs such as geographic distance, communication, quality assurance and management, which suggest cost savings of around 50%.<sup>32 33</sup>
- **Talent pool:** China offers a large pool of talent in the field of science, including an increasing number of Western-educated graduates.<sup>34</sup> According to the Chinese Ministry of Education, the total number of Chinese graduates in the subjects of chemistry & pharmaceuticals and biotech in 2006 reached over 39,000 and 22,000 respectively.<sup>35</sup> The Development Research Centre of the State Council forecasts that the number of university graduates in China will increase at a CAGR of 11% from 2007 to 2010.

- **Patient pool:** The country's large and relatively treatment-naïve patient population enables easy and cost-effective patient recruitment.<sup>36 37</sup>
- **Animal resources:** A significant amount of canines and primates used for animal testing in the US are already imported from China. By moving the trials to China, Western companies can save on transportation and quarantine expense costs.<sup>38</sup>
- **China's rapid economic development:** The rapid growth of the domestic pharmaceuticals industry makes China an increasingly attractive market. With the rising number of affluent Chinese, diseases such as diabetes, cancer and cardiovascular diseases are on the rise, offering a huge need for drug development that specifically targets the Chinese market.<sup>39 40 41</sup>

Notwithstanding China's enormous potential as an emerging outsourcing destination, initial advantages such as cost savings are offset somewhat by various factors. Despite efforts to comply with WTO commitments, China's domestic regulatory landscape remains complicated, with new regulations often lacking in clarity and transparency. Although regulatory bodies are increasingly addressing IP violations, the lack of enforcement of the IP laws currently in place leaves China with a challenging operating environment (please refer to Chapter 11<sup>42 43</sup> for more detailed overview of China's current IP issues).

While big domestic CROs such as Wuxi Pharmatech are increasingly complying with international standards, smaller companies still struggle to gain US Food and Drug Administration (FDA) approvals such as GLP or other US and European lab research certifications. Implementing standardised processes and procedures that adhere to Western working standards presents further challenges.<sup>44</sup> Similarly, recruitment of experienced project managers to

<sup>†</sup> The WHO's ICTRP provides access to a central database containing trial registration data sets and links to the full original records of (1) the Australian New Zealand Clinical Trials Registry, (2) ClinicalTrials.gov (a US clinical trials registry), and (3) the ISRCTN Register.

establish quality assurance systems comparable with Western standards still poses a challenge to many domestic CROs operating in China.<sup>45</sup> Despite good opportunities for graduate recruitment from China's abundant talent pool, recruitment of experienced talent can be another bottleneck for China's CRO industry. Chinese CROs experience difficulties both in hiring staff with good English language abilities as well as talent retention.<sup>46 47</sup>

With several hundred CROs currently operating in China, mainly in the booming coastal regions of Beijing, Shanghai and Guangzhou, the CRO market is highly fragmented. While many smaller CROs specialise in niche markets, an increasing number of domestic CROs emerge as one-stop service providers with the capability of providing all service offerings along the value chain, from drug discovery to registration and marketing.

As the Chinese market continues to develop and mature, local CROs are starting to expand beyond their original service offerings through mergers, acquisitions or strategic partnerships with other domestic and international market players. In January 2008, Wuxi Pharmatech acquired Apptec Laboratory Services, a US-based CRO, in order to expand Wuxi's current service offering and gain access to Apptec's established customer base abroad.<sup>48</sup> Other examples include

the founding of China's first Contract Research Organisation Service Alliance (CROSA) in May 2007;<sup>49</sup> Sundia MediTech's merger with Shanghai United PharmaTech in June 2007;<sup>50</sup> the forming of a preclinical CRO joint venture by MPI Research and Shanghai Medicilon in January 2008;<sup>51</sup> as well as a strategic alliance between Provid and Acesys, combining the drug discovery expertise of Acesys in China with the project management capabilities of Provid in the US.<sup>52</sup>

This coming of age for Chinese CROs is also reflected in the growing number of domestic companies going public, including firms such as Wuxi Pharmatech (listed on the New York Stock Exchange in 2007), Venturepharm Lab (listed on the Hong Kong Stock Exchange in 2003), and several other domestic CROs rumoured to be looking to go public once market conditions stabilise.<sup>53 54</sup>

Multinational firms are also increasing their presence in China. Today, most large multinational CROs have established a presence in China, either directly or indirectly through partnerships and JVs.

Going forward, the Chinese CRO industry is expected to continue on its path of growth and consolidation, resulting in an increasing number of domestic and cross-border M&A deals and other partnerships.

# Chapter 5

## Contract Manufacturing Organisations Going Strong

Rapid growth in the contract manufacturing industry continues as pharmaceutical companies seek to reduce costs, tap into flexible capacity and improve their time to market. Outsourcing has been identified by Big Pharma as key to protecting the bottom line – profit margin. Asian countries provide a significant cost advantage, footprint growth potential and market opportunity for pharmaceutical manufacturers, compelling reasons to outsource manufacturing to Asian CMOs.

China arguably ranks as the best pharmaceutical outsourcing destination among all Asian territories (China, India, Singapore, Japan, Australia, Korea, Taiwan, Malaysia, Thailand, Indonesia and the Philippines) when looking at the multiple factors of cost, risks and market opportunities.<sup>55</sup> In 2007, the export value of Chinese pharmaceutical contract manufacturers was US\$453 million, with an annual growth rate of 23%.<sup>56</sup>

Moreover, local Chinese GMP regulations have developed based on concepts similar to US Good Manufacturing Practices. China previously passed legislation requiring all pharmaceutical companies to meet GMP standards by 2005, resulting in the shutdown of thousands of unqualified companies. At the end of 2005, more than 5,000 Chinese drug manufacturers had been certified as compliant with Chinese GMP.<sup>57</sup> There is also an ongoing effort in China to increase inspections on already-certified manufacturing sites in response to evidence that some of the certified manufacturers have not consistently adhered to GMPs in the past.

With an increased commitment to international standards, Chinese CMOs are securing more outsourcing orders from large pharmaceutical companies. For example, AstraZeneca plans to increase its outsourcing activities significantly in China and India. AstraZeneca currently spends US\$9 billion per year on purchasing. Having set up a dedicated sourcing centre in Shanghai, AstraZeneca plans to use the centre to save 10% on purchasing costs over the next three years. So far, the centre has made US\$25 million in purchases. Plans are in place to further increase this to US\$100 million by 2010.<sup>58</sup>

Recent reports of deaths in the US linked to contaminated heparin sourced from China, highlight the importance of quality and safety control. The Chinese government is expected to further raise the standard of its GMP, the minimum quality standards that pharmaceutical manufacturers in China have to meet, to instil confidence in outsiders.

Chinese contract manufacturers also face challenges in intellectual property protection, which the Chinese government seeks to address through the implementation of tighter controls on IP laws (for further information regarding IP-related issues in China's pharmaceutical industry, please refer to Chapter 11).

With the appealing factors of cost, market opportunity, as well as improved IP and GMP standards, China is expected to attract more contract manufacturers in the near future.



## Chapter 6

# Building An Innovation-Oriented Country Through Pharma R&D



In January 2006, Chinese President Hu Jintao announced China's aim to build an innovation-oriented country by 2020. Pursuant to this goal, China's R&D expenditure ranked 3<sup>rd</sup> worldwide in 2006 (by purchasing power parity), trailing only the US and Japan.<sup>59</sup> Between 2000 and 2007, China's R&D expenditure grew at an average rate of 26.5% annually.<sup>60</sup> During the same period, China's R&D/GDP ratio increased to 1.49% in 2007, a 66% increase over the 2000 level. In comparison, the US's R&D/GDP ratio in 2007 was 2.66%.

A growing number of global pharmaceutical MNCs have set up R&D centres in China over the last few years, including AstraZeneca and Novo Nordisk in 2002; Eli Lilly and GSK in 2003; Roche in 2004; and Pfizer, sanofi-aventis and Johnson & Johnson the following years. In 2006, Wyeth set up an early clinical development centre (ECDC) with Peking Union Medical College Hospital, relocating its Asia-Pacific clinical trial administration offices at the same time from Australia to China.

A year later, Novartis's US\$100 million Shanghai R&D centre, the company's second R&D centre in China, began operations. Looking ahead, GSK is currently building a fully integrated, end-to-end R&D centre in China with plans to employ more than 1,000 staff by 2010.

China currently offers a number of key advantages for conducting domestic pharmaceutical research:

- **Lower costs:** Although Chinese average income levels increased at a CAGR of 16% from 2000 to 2006, the gap between local wages and that of developed countries is expected to remain substantial in the near term. In 2007, the average salary of a Chinese college graduate was US\$3,980 per year.<sup>61</sup> Organisations hiring locally to conduct R&D activities can therefore enjoy significant cost advantages.
- **Talent pool:** The local talent pool for R&D resources continues to expand: In 2007, China had 4.64 million university graduates. According to the Chinese Ministry of Education, the total number of Chinese graduates in subjects related to chemistry & pharmaceuticals and biotech in 2006 reached over 39,000 and 22,000, respectively, all of whom were potential candidates to become researchers in the pharmaceutical industry.<sup>62</sup> As of 2007, China had close to 20,000 hospitals with over 2 million physicians and 1.42 million nurses, making China an attractive destination for clinical trials ( please also refer to Chapter4 ).<sup>63</sup>
- **Patient pool:** China's large and relatively treatment naïve population offers cheap and easy access to potential patients, which has led to strong growth in China-based clinical trials over the last few years.
- **Pharmaceutical and biotech clusters:** A large number of companies, both MNCs and domestic players, choose to set up their research facilities in various biotech parks around the country. Shanghai Zhangjiang Hi-Tech Park for instance has attracted Roche, Novartis, AstraZeneca, GSK, Eli Lilly, Johnson & Johnson and Pfizer, as well as domestic and international CROs such as Shanghai ChemPartner, HD BioSciences, Medicilon, and Charles River Laboratories, to establish their R&D centres in the area.
- **Government support:** The Chinese government currently provides strong incentive programmes to support and foster the domestic pharmaceutical and biotechnology industry. These incentives include tax reliefs, direct funding opportunities, as well as the development of numerous technology parks. For example, in 2007, a US\$2.74 million (RMB20 million) national policy loan was granted by the National Development Bank to the North China Pharmaceutical Company's New Drug Research and Development Co. Ltd. for the industrialisation of a series of immunosuppressants.<sup>64</sup>

Although Chinese domestic pharmaceutical companies still lag behind in terms of R&D expenditure as a percentage of sales, averaging around 1.7% in 2007,<sup>65</sup> an increasing number of domestic companies have been placing more emphasis on R&D in an attempt to move up the value chain. For example, in July 2007, Zhejiang Huahai Pharmaceutical Co., Ltd. achieved a break-through in getting US FDA approval for its Abbreviated New Drug Application (ANDA) for nevirapine tablets. This marked the first time a Chinese pharmaceutical company has received US FDA certification for a finished (formulated) drug.

# Chapter 7

## Tax Incentives Support China In Becoming A World R&D Base

With the expansion of China's economy, one of the key objectives on the central government's agenda is to shape the country from the world's factory to a world R&D base. Towards that end, the new Corporate Income Tax (CIT) Law, effective from 1st January 2008, and other new regulations have been issued to provide for tax incentives/schemes to encourage R&D activities in China. Biological and medical technology is one of the domains that stand to benefit from some of these incentives. The key income tax incentives available to pharmaceutical companies carrying out or thinking of carrying out R&D in China are set out below. Pharmaceutical companies may wish to explore these incentives to see if there is opportunity to help improve the overall tax efficiency of their Chinese operations.

- **High/New Technology Enterprise (HNTE) incentive:** Enterprises that are qualified as HNTEs upon assessment by the relevant authorities will be entitled to a reduced CIT rate of 15% as compared with the standard CIT rate of 25%. In addition to the reduced tax rate, newly established HNTEs in the Five Special Economic Zones<sup>†</sup> and the Pudong New Area within Shanghai may enjoy a tax holiday of 2 years' full exemption followed by 3 years of 50% reduction in CIT.

The key criteria to qualify as HNTE include, amongst others, ownership of core proprietary IP rights, products/ services falling under the scope of "encouraged" domains and R&D expenditure, and both income from relevant activities and headcount of R&D/technical personnel meeting certain minimum thresholds. While some of these conditions may prove challenging to meet, careful planning/restructuring and management of the IP strategy have allowed some companies to successfully obtain HNTE status in various local jurisdictions.

- **CIT super-deduction:** To encourage R&D activities, companies, including pharmaceuticals, are allowed an extra 50% expense deduction for eligible R&D costs. Such eligible R&D costs include expenses incurred through the development of new technology and products. They also cover salary expenses for R&D personnel, and the depreciation of instruments and equipment used for R&D purposes.
- **Income tax exemption for the transfer of technology:** The portion of income derived from the transfer of technology during a tax year not exceeding RMB5 million can be exempt from CIT. The portion exceeding RMB5 million is eligible for a 50% reduction in CIT.



<sup>†</sup> Five Special Economic Zones: Shenzhen, Hainan, Zhuhai, Xiamen, Shantou



# Chapter 8

## Navigating the Risks of Bribery and Corruption in Sales and Marketing

Bribery and corruption have fallen squarely in the sights of global regulators. Enforcement and investigation activity has been on the rise in recent years and companies are taking notice. Regulators are keeping a close eye on overseas activities, and are increasingly focused on particular industry segments in an effort to stamp out illegal behaviour. No industry is safe from scrutiny; however, some industries are receiving more attention than others at the moment. Industries that have previously undergone government scrutiny include energy, defence contracting, automotive, and the United Nations Oil for Food Programme.

The pharmaceutical industry is particularly prone to bribery and corruption, given the extensive use of distributors, sales representatives, and the classification of many physicians as government officials. In 2007, the United States Securities and Exchange Commission and the United States Department of Justice sent letters to five healthcare companies in an effort to gather more information on payments to government-employed physicians in foreign countries which may have violated the US Foreign Corrupt Practices Act (FCPA).

In mid-2008, the US Department of Justice levied a US\$2 million criminal penalty against, and entered a deferred prosecution agreement with AGA Medical Corporation (AGA) in relation to allegations of illegal payments made to government officials in China. A high-ranking company officer and other employees at AGA were alleged to have used distributors in China to make illegal advances to government-owned hospitals and physicians to influence the sales of AGA products. Additionally, there were allegations that payments were made to the China State Intellectual Property Office to influence the approval of AGA patents.

The US is not alone in its efforts to stamp out illegal behaviour in the pharmaceutical sales and marketing sector. In 2007, China investigated over 1,000 bribery cases related to the purchase and distribution of drugs, medical equipment and services in the health sector.<sup>66</sup>

China has its own clearly defined anti-bribery and corruption legislation, and the standards are not dissimilar to those of its better-known Western counterparts. The Chinese government has clearly outlined its intent to fight bribery and corruption in the medical and pharmaceutical sector,<sup>67 68</sup> emphasising the need to expand the use of an on-line drug procurement system in hospitals designed to curtail bribery practices. Though the on-line system is used in 20 provincial-level regions and handles over 85% of hospital drug purchases, it cannot single-handedly stamp out bribery in the sales process. While useful in monitoring, controlling costs and improving transparency, the system only addresses part of the problem. Drug companies still give incentives to doctors who increase sales by writing an excess number of prescriptions after drugs are procured. Only through continued monitoring and enforcement of the bribery legislation can such practices be eliminated.

Similarly, in regards to drug prescription and sales, the hospital environment poses further risks to the consumer. Hospitals enjoy healthy mark-ups on the drugs that they sell, giving them an incentive to increase the number of prescriptions that are filled at the hospital. In response to this practice and to protect consumer needs, the government is attempting to more clearly segregate the entities responsible for the writing and filling of prescriptions. This effort is aided by the growth in retail pharmacies outside of the hospitals. However, short of eliminating out-patient hospital drug dispensaries altogether, thereby cutting off an essential revenue source for hospitals, resolving this problem in the near term will be difficult. By shifting drug profits away from doctors, the profit incentive for prescribing drugs will decrease in favour of effectiveness and affordability considerations. This will not eliminate the possibility of pharmaceutical representatives influencing the prescription decision through direct bribery and corruption, but it does change the doctor/hospital prescription dynamic in favour of the patient.

Historically, the government's investigations have been internally driven, focusing on punishing government officials who take bribes; but there are indications that the focus is shifting towards the influence peddler. Some estimate that over 60% of corrupt money handed out in China in the past decade came from foreign companies.<sup>69</sup> As China increases its investigations and enforcement efforts, companies should be increasingly aware of their obligations under domestic and international regulations.

Additionally, there has been a significant amount of merger and acquisition activity in China as companies try to keep pace with the tremendous growth in the local market. When considering acquisition or investment opportunities, potential suitors must keep in mind the associated risk of assuming liability for their target company's activities. Illegal practices, before or after acquisition, constitute regulation violations for which the new owners can be held accountable. Similarly, sales via improper means tend to inflate the value of legitimate sales. It is important to take into account how sales may be affected post-acquisition after weeding out improper sales methods so that a proper valuation can be conducted. It is with this in mind

that many companies looking to expand through M&A in China are embedding more anti-bribery and corruption procedures into their standard due diligence (for further details on M&A activities in the Chinese pharmaceutical market, please refer to Chapter 12).

In addition to addressing these regulatory risks in M&A activities, many international companies – not only in the pharmaceutical industry – are revisiting their internal anti-bribery and corruption control framework to ensure adequate design and function. Well-designed and well-maintained anti-bribery and corruption policies and procedures are essential for organizations that operate globally. Local and international regulations have clear documentation and record-keeping standards that must be met to avoid and/or refute accusations of bribery and corruption. Ensuring that necessary transaction and cash approvals are in place, which will involve staff training and the vetting and oversight of distributors, sales representatives and investment targets, is critical for maintaining compliance and the development of sustainable sales and marketing initiatives.



# Chapter 9

## Cutting Drug Prices: Whom Does It Help?

As the main payer of healthcare costs in China, the Chinese government has a strong interest in keeping drug prices down. The National Development and Reform Commission (NDRC), the drug-pricing policy maker in China, has set up pricing policies to control the price of drugs on the market. The maximum retail prices for about 2,400 types of drugs, which account for 20% of all available products and 60% of the overall drug sales revenue in China, are set.<sup>70</sup>

However, drug prices are still not under control due to several flaws in China's healthcare system:<sup>71</sup>

- The drug distribution system is congested with middlemen who operate between the drug makers and the hospitals and inflate the cost of the drugs several times over (for further details regarding the domestic drug distribution system please refer to Chapter 10).
- Revenues for hospitals in China are heavily dependent on drug sales due to inadequate government funding. On average, government subsidies only cover 6% of hospital expenses.<sup>72</sup>
- Since the government allows them to mark up the price of their drugs by 15%, hospitals tend to buy more expensive drugs. This could potentially change when the healthcare reform is implemented.

Since 1996, the Chinese government has imposed 24 mandatory drug price cuts covering about 2,000 pharmaceutical compounds and 300 TCM products.<sup>73</sup> Each time, the average price reduction across therapeutic categories came to about 20%. These cuts have made a significant impact on the Chinese pharmaceutical industry. From 2003 to 2006, the average profit percentage in the pharmaceutical industry decreased from 9.7% to 6.3%.<sup>74</sup>

Although the mandated price cuts have affected the industry significantly, its impact on actual pricing has been limited. The

pricing policy has so far failed to make a significant impact. When the price of a drug is cut, hospitals and retailers switch to alternative brands. This, as a result, usually causes sales declines, or even a withdrawal from the market of the drug subjected to such a mandated cut. When the profit margin of the drug erodes substantially, many manufacturers will stop producing that product. Furthermore, many manufacturers may opt to change the packaging, form or specification of the drug, registering it as a new one to avoid the former's price restrictions. According to Chinese National Bureau of Statistics, China's drug price index<sup>†</sup> declined only 2.8% between 1996 and 2007.<sup>75</sup>

In April 2007, around 100 Chinese pharmaceutical companies filed a complaint concerning the price-cut policy with the State Council, pointing out that the domestic hospitals which are financed through profits from drug sales are the root cause of high drug costs in China.<sup>76</sup> The NDRC set 2011 as the deadline to solve this problem. It is expected to introduce price ceiling regulations for all prescription drugs at different stages in the supply chain, including ex-factory, wholesale and retail, in an attempt to keep healthcare costs down and prevent irregularities and price manipulation through distribution channels. A pilot of this model is currently under way in Guangdong province. Recently, there is also news that the NDRC is thinking of implementing a "fixed-price increase" policy. Under this policy, hospitals will earn a fixed and independent service fee for each prescription they dispense thus "equalising" the incentives for prescribing more expensive medications.<sup>77</sup>

Recent healthcare reforms talk of preferential pricing policies for innovative drug products; however, it is still unclear how this will fit in with other pricing measures the government will adopt. Drug pricing regulations will continue to have a major impact on the industry, so corporate strategies will need to take them into account.

<sup>†</sup> China's Drug Price Index ("Traditional Chinese and Western Medicines and Health Index") is one sub-category of China's Commodity Retail Price Index, an economic index measuring price change trends in both urban and rural China. We have used 1996 (1996=100) as the base for our calculations.

# Chapter 10

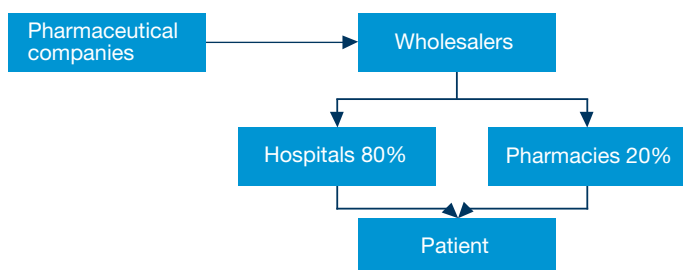
## Risks and Challenges of A Complex Distribution System

The US\$44 billion pharmaceutical distribution market in China continues to face several key challenges. In a country with a huge rural population (700-800 million) lacking in key infrastructure and logistical expertise, it is difficult to ensure that drugs are delivered to patients in a timely, safe and cost-effective manner.

While the government is taking steps to meet these challenges, a distribution network composed largely of thousands of small, local distributors has made it difficult for regulators to monitor products and manufacturers to track their goods and ensure reliable delivery to retailers. However, a combination of government guidance, market forces and foreign involvement are helping China to slowly improve its pharmaceutical distribution system.

China's distribution chain is three tiered. Most multinationals distribute pharmaceuticals through national and provincial wholesalers, which then sell the drugs through hospitals, clinics and pharmacies, which then sell to patients. Up to 80% of all Western-style drugs are thought to be distributed through hospitals and clinics, whilst the remaining 20% are distributed through pharmacies (see Figure 3).<sup>78</sup>

Figure 3: China Distribution Channels Overview



Source: Business Monitor International

Historically, the wholesaler network was a state-owned distribution system that focused on provincial and local networks, with few links to other regional markets. However, as China began its transformation toward a market economy in the 1980s, the demand for pharmaceutical products increased dramatically, and the distribution system began to decentralise. A surge in the number of distributors created a competitive environment of local operators competing for smaller shares of the market. Of the over 7,000 distributors in China, 80% are considered small and the top 3 distributors account for only 20% of the market.<sup>79</sup>

Thus far, many of these small, local distributors have lacked both the scale to automate and the logistical expertise of distributors in developed countries. In addition, this lack of scale has meant that manufacturers seeking to distribute their products on a national basis need to bring in multiple distributors to help their products reach the retailer. One current challenge is the lack of a comprehensive product tracking system set up between the various distributors. Consequently, product traceability is hard to guarantee, and when problems arise, product recalls can be extremely difficult to manage. The complexity of the supply chain has also left it vulnerable to the entry of counterfeit products, a substantial threat to the pharmaceutical industry. The need to use multiple distributors can also risk interruption of the cold chain and negatively affect product quality.

In the meantime, regulatory changes and the need for scale have led to consolidation in the distribution sector, while international pressure has led to more government oversight. On the regulatory front, China's 2001 accession to the World Trade Organisation (WTO) prompted some improvements, and the Chinese government has issued compliance mandates to meet Good Supply Practices (GSP) standards in an attempt to rid the industry of players who engage in questionable practices. The need for firms to reach critical mass in order to survive deteriorating profit margins (which are nonetheless

higher than US profit margins) is also driving the recent wave of consolidation. The average gross profit of China's drug distribution companies is around 8%, while net profits<sup>†</sup> have declined to about 0.5%.<sup>80</sup> Some pharmaceutical distributors that started to operate at a loss have chosen to change their business models and become product agents instead, generating revenue through commissions and discounts from manufacturers. According to the NDRC, this drive for scale coupled with increased government regulation have more than halved the number of drug distributors from 16,000 to around 7,000.<sup>81</sup>

Foreign firms are also beginning to have their effect on China's pharmaceutical distribution system. Since 2003, in compliance with WTO agreements, China has slowly opened its borders to foreign drug distributors. A year later, the government further unleashed the limit on the proportion of capital contribution of the foreign investors, unless the same investor opens more

than 30 retail outlets accumulatively within China, whereby the proportion of such is capped at 49%.<sup>82</sup> Thus far, several have entered the market.

In 2004, the first modern pharmaceutical logistics center was built by the Beijing Pharmaceutical Group Co., Ltd., using foreign-bought advanced logistics equipment and technologies. Following this trend, similar logistics centers are now being established in several major cities across China. However, there are areas in which foreign firms dominate. For example, in 2007, global giant World Courier launched a cold chain logistics network in China to provide pharmaceuticals to 36 major cities with access to temperature-controlled and clinical trial shipments.<sup>83</sup> In building the nascent logistics industry, the Chinese government has been actively encouraging local development through financial support to major distributors.



<sup>†</sup> Net Profits = Gross Profits – Expenses

# Chapter 11

## Intellectual Property Protection: Is It Getting Better?

Intellectual property protection has long been a hot topic among foreign companies in China, both in the pharmaceutical industry and many others. Companies are conscious of the need to protect their valuable IP in whatever form it takes along the supply and distribution channel, from R&D to end-user sales. Limiting revenue loss, public health incidents and brand damage from copyright, trademark and patent infringement will remain a priority.

As R&D expenditures expected to reach US\$10 billion or 2% of global spending by 2010,<sup>84</sup> continue to grow in China, more and more companies will seek protection under Chinese law. Historically, much of the IP litigation in China could be attributed to foreign companies suing domestic companies for infringement. In recent years, however, domestic companies have stepped up their efforts to protect their own IP assets in court by successfully suing both foreign and domestic infringers. In 2007, Aida Pharmaceuticals, Inc., a Chinese company, successfully sued four counterfeit drug suppliers in the Intermediate Court of Hainan. The infringing companies were ordered to stop producing the counterfeit products and pay damages to Aida.

China is working hard to keep pace with domestic and international demands for patent protection, while IP disputes in China have outnumbered those filed in the US since 2005.<sup>85</sup> On December 27<sup>th</sup>, 2008, an amendment to the Chinese Patent Law was passed by the National People's Congress Standing Committee, which will be put into force on October 1<sup>st</sup>, 2009.<sup>86</sup> The amendment is the third revision of the Patent Law, which was first enacted in 1983. The latest revision replaces the historical "first-to-file" approach with a requirement known as "absolute novelty". This concept can be found in corresponding European and US laws, and requires that officials consider evidence of public use of the relevant technology before issuing a patent. If a technology or invention has been made available to the public prior to the filing date,

then it can no longer be considered novel, and only novel ideas are eligible for patent issuance. The revised regulations also increase the ceiling on monetary penalties for IP infringement.

Calculating monetary penalties on infringement is an important aspect of Chinese law, both in its current and new revisions. At the moment, damages are calculated as a multiple of either three times the lost profits of the patent holder or three times the benefits gained by the infringer. Under the newly passed amendment, this ceiling multiple has been increased to four. Companies pursuing damages should carefully prepare clear and reliable calculations. In the absence of a clear method of determining lost profits or gained benefits, Chinese regulation defaults to a current maximum threshold of RMB500,000, which increased to RMB1 million under the new amendment. It remains unclear how a court would determine the appropriate penalty under these ceilings when no clear calculation methodology can be identified. Clearly in some cases, the default maximum penalty cannot cover the full market value of losses sustained by ongoing infringement in a high-value industry such as pharmaceuticals, which means loss calculation and its methodology take on a critical role in damage recovery.

Pharmaceutical industry players are keeping a close eye on developments in other sectors, and they have reason to be pleased. In 2007, a Beijing court upheld a ruling that Yahoo China violated Chinese law by facilitating mass copyright infringement by providing links to unlicensed music downloads. Emboldened by the legal victory, three large music companies are now suing China's top Internet search engines, Baidu.com and Sohu.com, for US\$9 million and US\$7.5 million, respectively, for similar copyright infringements. Advancements such as this, along with the Aida case mentioned above, in which infringers were forced to pay US\$77,180, are encouraging signs of the strengthening legal framework across all IP industries in China.

However, despite improvements in Intellectual Property Rights (IPR) law and an increase in the amount of recoverable damages, there are still practical challenges to the enforcing of legal rulings. As of April 2008, Yahoo China still has not paid the US\$28,750 (RMB 210,000) awarded to the music companies as part of their suit, and the company continues to provide links to music downloading sites despite the court injunction against it. The music industry returned to court in February 2008 to ask for execution proceedings in an attempt to force Yahoo China into compliance. Given the fragmented legal system and local government protectionism, collecting court-ordered monetary awards or successfully enforcing manufacturing/sales injunctions may be difficult. It may be these challenges that have caused 80% of the US companies surveyed by the American Chamber of Commerce in China to say they believe China's IPR protection is "less than effective".<sup>87</sup>

The Chinese State Intellectual Property Office and high-ranking government officials continue to declare that the protection and rights of intellectual property are their key objectives. The pharmaceutical community appears to have faith in these efforts. This faith was clearly evident in the responses given by multinational companies to PwC's 2007 pharmaceutical-focused survey, "Gearing up for a global gravity shift." Of the respondents, 52% indicated that they were "quite optimistic" that IP protection in Asia would improve in the next five years, while 11% indicated they were "very optimistic". Much has been achieved over the past 25 years, and as the IP landscape continues to mature and develop, and an increasing number of domestic firms seek IP protection through Chinese regulation, we should see a reduction in these challenges.



# Chapter 12

## The Pharma Sector: A Front Runner in Consolidation

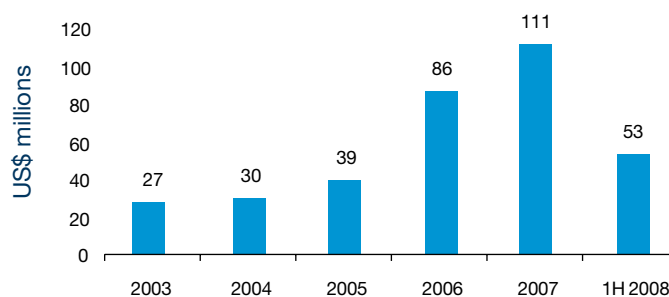
China's reform policies and the introduction of the 11th Five-Year Plan in 2006 were catalysts for significant M&A activity in the pharmaceutical and healthcare industry. New medical reforms introduced in September 2006, intended to create nationwide healthcare coverage initiatives for over 600 million people in rural areas, created an increased demand for medicine and healthcare services. This tremendous growth potential has attracted more and more investors to this sector. To increase competition, as the 11<sup>th</sup> Five-Year Plan encourages, the state-dominated industry is welcoming investment from both foreign and private investors. Stricter enforcement of certifications and intellectual property rights, including those of GMP, GSP, and Good Agricultural Practice of Medicinal Plants and Animals (GAP), has made many companies which are unable to fulfil such requirements easy targets for mergers and acquisitions.

In addition, the NDRC has required pharmaceutical companies to make the cost of medicine more competitive and affordable, despite rising raw material costs. Measures adapted from this policy have weakened some small or medium companies financially, making them easy prey for mergers and acquisitions.

A record number of deals were closed in 2007, as shown in Figures 4 and 5, representing an unprecedented transaction value of US\$2.1 billion in the sector. Although 2007 may prove to be a high point, the upward trend shown in recent years has continued into the first half of 2008, when 53 deals, valued at US\$1.1 billion, were announced. However, the global economic downturn will most certainly reduce the number of deals in the last quarter of 2008 and into 2009.

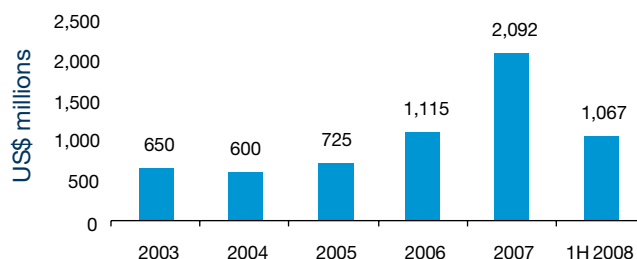
Among the three segments of pharmaceuticals, devices and healthcare, pharmaceuticals remains the largest sector for M&A activities. This sector had a record disclosed deal value of US\$1.5 billion in 2007 due to an increase in both transaction volume and average transaction size. An increasing number of deals took place in medical devices and healthcare services, reflecting the growing importance of these two sectors (see Figure 6).

Figure 4: China M&A Deal Volume



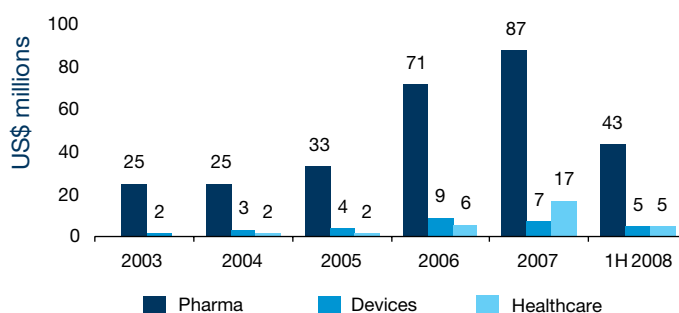
Source: Asian Venture Capital

Figure 5: China Disclosed M&A Deals



Source: Asian Venture Capital

Figure 6: China M&A Deal Volume by Segment



Source: Asian Venture Capital



Amongst the 2008 top ten deals in the pharmaceuticals industry, three were in healthcare services and three were in medical devices. The largest transaction in 2008 was US listed company, Pantheron China Acquisition Corporation's

US\$329 million, acquisition of a 93.94% stake in China Cord Blood Services Corporation. The company provides umbilical cord blood collection, laboratory testing, hematopoietic stem cell processing and stem cell storage services (see Figure 7).

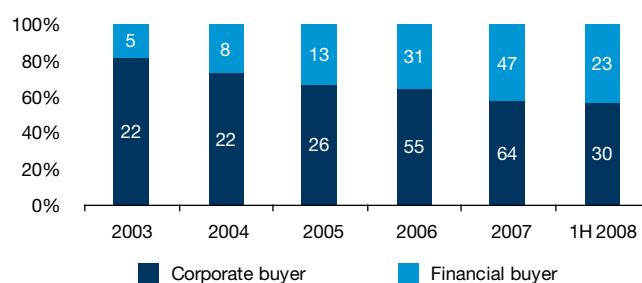
Figure 7: Top Ten Deals in 2008

Rank	Value (\$ m)	Target / Merger Partner	Bidder / Merger Partner	Industry Sector	Country	Deal Geography
1	329	China Cord Blood Services Corporation	Pantheon China Acquisition Corp	Services	China (PRC)	Inbound
2	258	Asiapharm Group Ltd.	MBK Partners	Pharma	China (PRC)	Inbound
3	209	Datascope Corp-Patient Monitor	Mindray Medical International	Devices	China (PRC)	Outbound
4	185	Topsun Science & Tech Qidong	Bayer Healthcare AG	Pharma	China (PRC)	Inbound
5	163	APPTec Laboratory Services	Wuxi Phama Tech	Services	China (PRC)	Outbound
6	106	Daopei Hospitals Group	Golden Meditech	Services	China (PRC)	Inbound
7	90	JW Medical Systems Limited	Biosensors International Group (Formerly Sun Biomedial Limited)	Devices	China (PRC)	Inbound
8	54	China Medical Technologies	Chengxuan International Ltd.	Devices	China (PRC)	Domestic
9	51	Northeast Pharmaceutical Group Co Ltd	Northeast Pharmaceutical Group Corp (NPGC)	Pharma	China (PRC)	Domestic
10	50	Hubei Ready Medicine Co Ltd	Greater Pacific Capital LLP	Pharma	China (PRC)	Inbound

Source: Thomson Financial Mergers & Acquisitions and other public available sources

Private equity and venture capital houses have played a more active role in this sector, evidenced by the continuous growth in M&A activity from these buyers (see Figure 8). This is due partly to stringent monetary policies that have made investments difficult to finance through banks, thereby requiring alternative funding sources to make up for it. In addition, favourable P/E ratios and new listings in overseas capital markets, including reverse takeovers, have also provided robust exit opportunities for private equity and venture capitalist investments.

Figure 8: China M&A Deal Volume by Investor



Source: Asian Venture Capital



# Chapter 13

## Capital Markets and Financial Reporting: What To Consider?



When investing in China's pharmaceutical industry, there may be capital markets and financial reporting considerations which will impact either the ultimate exit strategy for financial buyers or the assessment of a business's operating results for strategic buyers.

Investors should understand that, when investing initially in a Chinese pharmaceutical company, the target will most likely not be using a comprehensive set of accounting rules such as International Financial Reporting Standards (IFRS) or Accounting Principles Generally Accepted in the United States (US GAAP). Such a comprehensive basis of accounting would be required if the company were to ultimately list on a foreign market or to converge with the investor's basis of accounting for consolidation purposes. Although public Chinese companies were required to adopt Chinese Accounting Standards (CAS), which converges significantly with IFRS, with certain differences, from January 1<sup>st</sup>, 2007, adoption was not required for private companies. As a result, most private companies in China prepare their accounting records on a cash basis for tax purposes, and more significantly, many transactions are unrecorded and undisclosed.

There are several implications the investor needs to consider:

- **Ongoing monitoring of the performance and prospects of the investment:** Whether the investor plans to continue operating the Chinese pharmaceutical company as part of their ongoing business or to exit the investment at some time in the future, they must be able to monitor the performance and prospects of their investment in order to make informed operating and financing decisions. The investor will therefore need access to financial information prepared with guidelines they are familiar with and which ensure that all significant transactions and events are disclosed and accounted for consistently and transparently. It is likely that the target company's historical books and records will not provide this level of information and that the investor will require some form of conversion or reconciliation to a comprehensive basis of accounting. Such conversion or reconciliation would require qualified people either at the target company or through external advisors familiar with the target's operations, the Chinese regulatory, tax and legal environment, and the appropriate basis of accounting, be it IFRS, US GAAP, CAS or some

other standard. For example, recognizing revenue is a significant challenge for pharmaceutical companies, due to the level of risk involved in the underlying products and processes, with complex arrangements made to mitigate these risks. In addition, most of these arrangements tend to be non-standard and verbal, making their accounting even more challenging. Qualified personnel can assist the investor in reviewing these contracts and assessing the financial reporting implications of these arrangements to help the investor better monitor the true performance of the company and their investment.

- **Accounting for the investment:** A strategic buyer planning to operate a Chinese pharmaceutical company as part of their business will need to properly account for their investment in that company. If the target's financial statements, books and records are based on a different set of accounting standards, there will be significant implications for ongoing internal management and external financial reporting requirements. Further, the target company may continue to have home country filing or other regulatory requirements under their domestic GAAP, for which the investor would then be responsible.

In order to properly account for the acquired subsidiary or investment, the target company's accounting policies and records will need to be converted to and aligned with the investor's group policies and guidelines. Without first converting the target's financial information, the investor will not be able to appropriately consolidate or equity account for the acquired interests. Depending on the target's accounting guidelines, significant adjustments might be needed to align the records to reflect consistent accounting policies. The investor will also need to implement internal reporting processes and procedures in order to perform this conversion on a periodic basis and in a timely manner so that ongoing reporting requirements are met. Even if the target does appropriately apply

CAS, which reflects most of IFRS's principles, there are still areas where both guidelines differ and areas where CAS is silent, which may be relevant to accounting for the target. The investor will need to understand the target's accounting policies so that they are aware of the business and accounting implications of the target's business arrangements under their own operating and financial reporting framework. Further, accounting for business combinations and consolidated financial statements is increasing in complexity and evolving constantly. This will affect the extent and nature of the valuations required during acquisition due diligence and for purposes of any ongoing financial reporting. This will impact the planning around the acquisitions/investments and require increased involvement of valuation and accounting specialists before, during and after the transaction.

- **Planning for the ultimate exit strategy:** If the investor plans to exit the investment in the future through, for example, an initial public offering, then a significant amount of advance preparation would be required to prepare the company for listing. This includes preparing the company's financial statements using accounting guidelines permitted by the relevant exchange and regulatory bodies. There are several Chinese pharmaceutical companies currently listed in the United States, such as Mindray Medical International Ltd, Simcere Pharmaceutical Group, Wuxi Pharmatech and American Oriental Bioengineering, which include both foreign private issuers as well as domestic registrants, and which all report under US GAAP. While foreign private issuers have the option of reporting under IFRS, most of them continue to report under US GAAP for various reasons, including comparability of financial information with peer companies, compliance with financing arrangements, etc. Conversion from IFRS to US GAAP (or vice-versa) is a complicated process, which must be managed carefully by qualified personnel.

## Conclusion – Looking Forward



The healthcare reform policies issued in October 2008 and mentioned in the introduction to this paper will have a major impact on multiple aspects of China's pharmaceutical industry; as a result, the industry and its investors will need to adequately prepare themselves.

The implementation plan that was expected from the Ministry of Health (MOH) before the end of 2008, was issued on January 21<sup>st</sup>, 2009. This document – although still high level-includes already more specifics on a roadmap for healthcare reform over the next three years.

Five separate policy documents are expected in addition to this implementation plan. The five immediate areas of reform are:<sup>88</sup>

1. Expansion of basic medical insurance programs to enrol more than 90% of urban and rural residents.
2. Establishing a national drug system for essential drug selection, production and supply, clinical applications, and medical insurance reimbursement.
3. Building a competent primary medical care service infrastructure (in rural township centres, village clinics and urban community healthcare centres).
4. Enhancing equal access to basic public health services by urban and rural residents.
5. Moving public hospital reform forward: This includes reform for the funding of hospitals, which is now predominantly based on sales of drugs and diagnostic examination fees.

The draft of the healthcare reform plan, “Opinions on Deepening Pharmaceutical and Health System Reform (Draft),” refers to increased investment from the Chinese government in healthcare and continued expansion of basic medical insurance coverage. This will boost domestic demand for drug products and support growth in the pharmaceutical market. The funding will be directed primarily to rural healthcare, which would significantly expand the Chinese pharmaceutical market. However, in order to access this new market, an efficient distribution network will become more important than ever. The lack of such a network is a source of major concern for multinational players.

Tighter control on drug distribution profit margins will accelerate the consolidation of the pharmaceutical distribution sector and offer significant opportunities for leading pharmaceutical distributors or foreign investors. A move to separate drug prescription and dispensation will trigger a rise in the number of retail pharmacies, which will impact the drug distribution landscape as well. This segregation in prescription and dispensation will also support a reduction and hopefully the eradication of the practice of giving kickbacks to healthcare practitioners in the near future.

The preferential drug pricing policies for innovative drugs, another healthcare reform topic, will stimulate investment in R&D activities and the success of these drugs. With the expansion of China’s economy, one of the key objectives on the central government’s agenda is to shape the country from a world factory into a world R&D base. The new tax regulations providing tax incentives are set out to encourage research and development activities in China.

Under healthcare reform, there is substantial support for traditional Chinese medicine. This will stimulate growth in the TCM sector. Combined with an increased interest from multinational pharmaceutical players in TCM, the investor interest in this sector has risen. While the TCM sector is not as well known in the West, it might be a source for new molecules

that could help fill the drug pipeline. In another interesting development, Western governments are gradually starting to regulate botanical products, opening up export channels for Chinese TCM products and routes to premium prices.

The business model of the pharmaceutical industry is changing globally. In the future, it is of strategic and tactical importance that the industry moves toward a more collaborative model that encompasses a network of other healthcare stakeholders such as regulators, research institutes, academia, technology providers and outsourcing. Against this backdrop, contract research organisations and manufacturing organisations are sectors that are growing fast in China, and double-digit growth is expected to continue in the coming years.

Even though intellectual property protection remains a concern for those outsourcing in China, continuous improvements are being made that will stimulate foreign investment in R&D activities in China.

The Chinese pharmaceutical market is consolidating, with a high number of deals both by foreign and domestic players, due to an appetite (albeit reduced by the current worldwide economic downturn) for domestic IPOs. The amount of investment from foreign (pharmaceutical) players continues to grow and is starting to venture into areas outside of manufacturing, such as R&D, distribution and retail pharmacies.

Despite market challenges, China is now among the top five in worldwide drug markets in terms of overall size. Although current market conditions are uncertain, pharmaceutical sales in China are forecasted to grow at double-digit, and reach US\$28.3 billion by 2010.<sup>89</sup> Rising per-capita drug expenditures, supported by strong economic growth, will further feed market gains.

Although there are challenges to overcome, the rewards of cost benefits and a growing market are continuous and consistent drivers for investment in the Chinese pharmaceutical industry.

# Appendix

# List of Abbreviations

ANDA	Abbreviated New Drug Application
CAGR	Compound Annual Growth Rate
CAS	Chinese Accounting Standards
CIT	Corporate Income Tax
CMO	Contract Manufacturing Organisation
CRO	Contract Research Organisation
CROSA	Contract Research Organisation Service Alliance
ECDC	Early Clinical Development Centre
FCPA	Foreign Corrupt Practices Act
FDA	Food and Drug Administration
GAP	Good Agricultural Practice of Medicinal Plants and Animals
GDP	Gross Domestic Product
GLP	Good Laboratory Practice
GMP	Good Manufacturing Practice
GSP	Good Supply Practices
HNTE	High/New Technology Enterprise
ICTRP	International Clinical Trials Registry Platform
IFRS	International Financial Reporting Standards
IP	Intellectual Property
IPP	Intellectual Property Protection
IPR	Intellectual Property Rights
M&A	Mergers & Acquisitions
MNC	Multinational Corporation
MOH	Ministry of Health
NDRC	National Development and Reform Commission
OTC	Over The Counter
PPP	Purchasing Power Parity
R&D	Research & Development
SFDA	State Food and Drug Administration
TCM	Traditional Chinese Medicine
US GAAP	Accounting Principles Generally Accepted in the United States
VAT	Value Added Tax
WHO	World Health Organisation
WTO	World Trade Organisation



# References

- <sup>1</sup> Business Monitor International, China Pharmaceuticals & Healthcare Report 4Q 2008
- <sup>2</sup> Business Monitor International, China Pharmaceuticals & Healthcare Report 4Q 2008
- <sup>3</sup> Business Monitor International, China Pharmaceuticals & Healthcare Report 4Q 2008
- <sup>4</sup> Business Monitor International, China Pharmaceuticals & Healthcare Report 4Q 2008
- <sup>5</sup> China Commercial Intelligence Website, The development and trend of pharmaceutical industry in China, March 2008
- <sup>6</sup> Wharton, Traditional vs. Western Medicine: Which One Is Easier for Chinese Consumers to Swallow?, October 2007
- <sup>7</sup> The Ministry of Commerce of the People's Republic of China, Supplementary Provisions to the Measures for the Administration of Foreign Investment in the Commercial Sector (III), November 2007
- <sup>8</sup> Business Monitor International, China Pharmaceuticals & Healthcare Report Q4 2008
- <sup>9</sup> Business Monitor International, China Pharmaceuticals & Healthcare Report Q4 2008
- <sup>10</sup> ScienceDaily, Combating Counterfeit Pharmaceuticals From China, July 2007
- <sup>11</sup> Business Monitor International, China Pharmaceuticals & Healthcare Report Q4, 2008
- <sup>12</sup> The China Business Review, A dose of reform: Healthcare, drugs and medical devices, May/June 2008
- <sup>13</sup> Medical Device Link Online, Medical Device Regulatory Update: China and Japan, October 2006
- <sup>14</sup> The China Business Review, A dose of reform: Healthcare, drugs and medical devices, May/June 2008
- <sup>15</sup> FDC, The Gray Sheet, October 2007
- <sup>16</sup> Goldman Sachs, China: Healthcare, December 2007
- <sup>17</sup> SFDA, Official release of 2007 statistics, September 2008
- <sup>18</sup> GB Information, China Pharmaceutical & Biotechnology Monthly, April 2008
- <sup>19</sup> ResearchinChina, China Medical Device Industry & Listed Company Report, April 2008; PwC Analysis
- <sup>20</sup> Mindray Medical International Limited, 2007 Annual Report
- <sup>21</sup> Medical Devices Today, Chinese Healthcare Reform: Market Opportunities and Challenges, October 2008
- <sup>22</sup> Burrill and Company, Burrill Quarterly China Life Sciences, January 2007
- <sup>23</sup> Goldman Sachs, China: Healthcare, December 2007
- <sup>24</sup> Business Insights, Drug Development Opportunities in China, September 2007
- <sup>25</sup> PharmaAsia News, Insider Analysis From BioForesight: Navigating the Life Sciences Silk Road Frontier, June 2008
- <sup>26</sup> Chemical and Engineering News, China's Pharma Leaps into Discovery, February 2008
- <sup>27</sup> CROChina, China's Preclinical Services Scene Evolving Outwards, May 2008
- <sup>28</sup> PharmaAsia News, Insider Analysis from BioForesight: Navigating the Life Sciences Silk Road Frontier, June 2008
- <sup>29</sup> Datamonitor, Pharmaceutical Outsourcing Part 2: An introduction to drug discovery strategies, August 2006
- <sup>30</sup> Express Pharma Online, India or China?, January 2008
- <sup>31</sup> WHO, International Clinical Trials Registry Platform, accessed October 2008
- <sup>32</sup> Burrill and Company, Burrill Quarterly China Life Sciences, January 2007

# References

- <sup>33</sup> CROChina, Why China?, March 2008
- <sup>34</sup> CROChina, Why China?, March 2008
- <sup>35</sup> Ministry of Education of China (various sources incl. domestic universities), PwC Analysis, 2008
- <sup>36</sup> Pharmaceutical Technology Europe, China captivates the clinical trial sector, May 2008
- <sup>37</sup> China Economic Review, Special Report: Pharmaceuticals, September 2007
- <sup>38</sup> CROChina, Why China?, March 2008
- <sup>39</sup> Pharmaceutical Technology Europe, China captivates the clinical trial sector, May 2008
- <sup>40</sup> CROChina, Global Drug Industry Restructure Fuels R&D Outsourcing Growth in China, August 2008
- <sup>41</sup> Datamonitor, Emerging Markets Series: Benchmarking Key Countries, December 2007
- <sup>42</sup> CROChina, Global Drug Industry Restructure Fuels R&D Outsourcing Growth in China, August 2008
- <sup>43</sup> Datamonitor, Emerging Markets Series: Benchmarking Key Countries, December 2007
- <sup>44</sup> Datamonitor, Pharmaceutical Outsourcing Part 2: An introduction to drug discovery strategies, August 2006
- <sup>45</sup> Burrill and Company, Burrill Quarterly China Life Sciences, January 2007
- <sup>46</sup> Burrill and Company, Burrill Quarterly China Life Sciences, January 2007
- <sup>47</sup> Datamonitor, Pharmaceutical Outsourcing Part 2: An introduction to drug discovery strategies, August 2006
- <sup>48</sup> Reuters, Wuxi Pharmatec to Acquire Apptec Laboratory Services Inc., January 2008
- <sup>49</sup> ChinaBio Today, CRO Service Alliance Expands Again, Adding Tigermed, April 2008
- <sup>50</sup> OutsourcingPharma.com, First Chinese CRO Merger Announced, June 2007
- <sup>51</sup> CROChina, China's Preclinical Services Scene Evolving Outwards, May 2008
- <sup>52</sup> CROChina, Provid and Acesys Form US-China Medicinal Chemistry CRO Alliance, September 2008
- <sup>53</sup> CROChina, CROs Bring Innovation into Chinese Pharmaceutical Industry, March 2008
- <sup>54</sup> ChinaBio Today, Four Shanghai CROs To Go Public, September 2007
- <sup>55</sup> PricewaterhouseCoopers, The changing dynamics of pharma outsourcing in Asia: Are you readjusting your sights?, September 2008
- <sup>56</sup> National Bureau of Statistics of China, China Trade and External Economic Statistical Yearbook, 2007 and 2008
- <sup>57</sup> BioPlan Associates, Biopharma CMOs in China: Will 45% excess capacity drive the industry?, June 2006
- <sup>58</sup> Pharma Technologist, China to play starring role in AstraZeneca API outsourcing, July 2007
- <sup>59</sup> New Science Foundation, Info Brief, August 2008
- <sup>60</sup> Ministry of Science and Technology of China, Report on China's Science & Technology Statistics, 2008
- <sup>61</sup> MyCOS, 2008 Survey on employment of Chinese university graduates, 2008
- <sup>62</sup> Ministry of Education of China (various sources incl. domestic universities), PwC Analysis, 2008
- <sup>63</sup> China Ministry of Health, 2008 Statistics Report on China's Healthcare, 2008
- <sup>64</sup> XinhuaNet, China Development Bank had a financing contract for Biopharma Industry, June 2007
- <sup>65</sup> Pharma News Website, Drug Innovation in China: huge gap between R&D investment and market expectation, September 2008

# References

- <sup>66</sup> People's Daily Online, China uncovers 1,001 commercial bribery cases in health sector, March 2008
- <sup>67</sup> State Food and Drug Administration, Drug Administration Law of the People's Republic of China, February 2001; Articles 59, 90 and 91 relating to criminal liabilities and revoking of licenses for drug manufacturers, drug distributors and medical institutions and their employees (such as physicians) offering or accepting bribes
- <sup>68</sup> Supreme People's Court, Opinions on Certain Issues Involving Applicable Laws for Commercial Bribery Criminal Cases, November 2008; Article 4, 7, 8, 9 and 10 relating to bribery of government personnel, non-government personnel and medical personnel in medical institutions
- <sup>69</sup> China Law & Practice, Commercial bribery: What are the boundaries, March 2007
- <sup>70</sup> National and Development and Reform Commission, News Release, July 2005
- <sup>71</sup> Shanghai Stock Newsletter, News Releases, April 2007
- <sup>72</sup> National Bureau of Statistics of China, China Health Statistics Yearbook, 2008
- <sup>73</sup> PharmaChinaOnline, Government Drug Pricing Reform in China, August 2008
- <sup>74</sup> Wang Ziyang, China's Pharmaceutical Price Policies and Practices, Dissertation, August 2007
- <sup>75</sup> National Bureau of Statistics of China, 2008; PwC Analysis
- <sup>76</sup> Beijing Business Today, Analysis of pharmaceutical companies' activity – a document criticising the drug cuts policy handed to the State Council for the second time, April 2007
- <sup>77</sup> Economic Observation, NDRC plans a new medical reform on the "markup limited" policy, 2008
- <sup>78</sup> Business Monitor International, China Pharmaceuticals & Healthcare Report Q1, 2008
- <sup>79</sup> Goldman Sachs, China: Healthcare Report, December 2007
- <sup>80</sup> Research and Markets, China Medical Sales Channel Report 2006-2007
- <sup>81</sup> National Development and Reform Commission, 11th 5-Year Development Guidance for the Pharmaceutica Industry, September 2006
- <sup>82</sup> The Ministry of Commerce of the People's Republic of China, Measures for Administration on Foreign Investment in Commercial Fields, June 2004
- <sup>83</sup> Business Monitor International, China Pharmaceuticals & Healthcare Report Q1 2008
- <sup>84</sup> EuroBiz (Journal of the European Union Chamber of Commerce in China), Growing R&D in China, September 2008
- <sup>85</sup> Federation of Indian Chambers of Commerce and Industry, Non-tariff barriers stump pharma exports to China, January 2007
- <sup>86</sup> State Intellectual Property Office, the National People's Congress Standing Committee's decision to the amendment of Chinese Patent Law, December 2008
- <sup>87</sup> American Chamber of Commerce, American corporate experience in a changing China – insights from AmCham business climate surveys, January 2006
- <sup>88</sup> PharmaChinaOnline, Public comment seeking for healthcare reform concludes with continued uncertainties, November 2008
- <sup>89</sup> PricewaterhouseCoopers, The Gearing up for a global gravity shift, May 2007

# Acknowledgement

This report was developed by PricewaterhouseCoopers's China Pharmaceutical Team based in Beijing and Shanghai, with contributions from a number of PwC subject matter experts in China. We gratefully acknowledge the following team members who contributed their knowledge, experience and administrative support for this report - Darren Buck, Susie Chen, Ruth Dobson, Nicki Fung, Annie Han, Diane Howell, Betty Ko, Sarah Li, Benjamin Qiu, Zhilin Qiu, Anke Schrader, Aya Su, Beatrijs Van Liedekerke, Xulu Wang, Jia Xu, Franklin Zhai, Allan Zhang and Hong Zhu.

# Contacts

## Global Pharmaceutical Team

### Simon Friend

Partner, Global Pharmaceutical and Life Sciences,  
Industry Leader  
PricewaterhouseCoopers (UK)  
Tel: +44 (20) 7213 4875  
Email: [simon.d.friend@uk.pwc.com](mailto:simon.d.friend@uk.pwc.com)

### Steve Arlington

Partner, Global Pharmaceutical and Life Sciences  
Advisory Services Leader  
PricewaterhouseCoopers (UK)  
Tel: +44 (20) 7804 3997  
Email: [steve.arlington@uk.pwc.com](mailto:steve.arlington@uk.pwc.com)

### Mike Swanick

Partner, Global Pharmaceutical and Life Sciences  
Tax Leader  
PricewaterhouseCoopers (US)  
Tel: +1 (267) 330 6060  
Email: [michael.f.swanick@us.pwc.com](mailto:michael.f.swanick@us.pwc.com)

### Attila Karacsony

Director, Global Pharmaceutical and Life Sciences  
Marketing  
PricewaterhouseCoopers (US)  
Tel: +1 (973) 236 5640  
Email: [attila.karacsony@us.pwc.com](mailto:attila.karacsony@us.pwc.com)

### Marina Bello Valcarce

Global Pharmaceutical and Life Sciences Marketing &  
Knowledge Management  
PricewaterhouseCoopers (UK)  
Tel: +44 (20) 7212 8642  
Email: [marina.bello.valcarce@uk.pwc.com](mailto:marina.bello.valcarce@uk.pwc.com)

## China Pharmaceutical Team

### Ruth Dobson

Partner, Advisory Services (Beijing)  
Tel: +86 (10) 6533 2011  
Email: [ruth.dobson@cn.pwc.com](mailto:ruth.dobson@cn.pwc.com)

### Mark Gilbraith

Partner, Advisory Services (Shanghai)  
Tel: +86 (21) 2323 2898  
Email: [mark.gilbraith@cn.pwc.com](mailto:mark.gilbraith@cn.pwc.com)

### Diane Howell

Partner, Assurance Capital Markets (Beijing)  
Tel: +86 (10) 6533 2356  
Email: [diane.howell@cn.pwc.com](mailto:diane.howell@cn.pwc.com)

### Betty Ko

Partner, Tax Services (Shanghai)  
Tel: +86 (21) 2323 3380  
Email: [betty.ko@cn.pwc.com](mailto:betty.ko@cn.pwc.com)

### Brian McGinley

Associate Director, Forensics Services (Beijing)  
Tel: +86 (10) 6533 7363  
Email: [brian.mcginley@cn.pwc.com](mailto:brian.mcginley@cn.pwc.com)

### Beatrijs Van Liedekerke

Associate Director, Advisory Services (Beijing)  
Tel: +86 (10) 6533 7223  
Email: [beatrijs.vanliedekerke@cn.pwc.com](mailto:beatrijs.vanliedekerke@cn.pwc.com)

### Annie Han

Marketing & Business Development (Beijing)  
Tel: +86 (10) 6533 7012  
Email: [a.han@cn.pwc.com](mailto:a.han@cn.pwc.com)

