



cutting through complexity™

# China's pharmaceutical industry – Poised for the giant leap

[kpmg.com/cn](http://kpmg.com/cn)

# China's pharmaceutical industry – poised for the giant leap



**Ed Giniat**

Global Chair, Pharmaceuticals Practice



**Peter Fung**

Partner in Charge  
Industrial Markets  
KPMG in China



**Andrew Weir**

Asia Pacific Chair  
Infrastructure, Government &  
Healthcare



**Norbert Meyring**

Asia Pacific Chair  
Pharmaceuticals Practice

China is steering itself into a new era. The model of high-voltage growth, which the nation followed for three decades, is undergoing a radical shift. The new yardsticks of the future are socioeconomic development and resource sustainability.

This transformation is best exemplified by a fresh set of development goals outlined in the 12th Five-Year Plan (2011-2015) that envisages slower GDP growth rate and greater emphasis on welfare measures, public services and more equitable distribution of wealth.

The new growth model will be powered by innovation and technological superiority rather than cheap labour or unrestricted exploitation of resources. China is now turning away from its export-oriented trajectory. Boosting domestic demand and consumption is a bigger priority for planners rather than the export of cheap goods.

The mechanism for increasing consumption is income growth, urbanisation and releasing the potential of China's vast rural population. The government hopes to achieve this by pursuing a 'new industrialisation path with Chinese characteristics', emphasising the building of a modern industrial structure that utilises more advanced technology which is cleaner and safer. The five-year plan also promotes service-oriented industries in mega-cities like Shanghai, Beijing and other developed hubs along the coastal region.

Thus, China stands at the cusp of a modern society, increasingly affluent and with a growing population, its growing urban population demanding better services and quality of life. The government is also aware of the need to undertake a systematic overhaul of social, economic and financial structures for a more balanced society. One main component of this new agenda is an efficient pharmaceutical value chain.

In 2009, China launched an aggressive healthcare reform plan that aims to bring all its citizens under basic medical coverage, modernise its health infrastructure and improve grassroots healthcare delivery, along with an overhaul of the pharmaceutical industry.

The 12th Five-Year plan focuses on achieving this through continuous reform and policy incentives. From high-end research to affordable drug pricing and sophisticated logistics and distribution, every effort is being made to modernise the health industry.

In fact, consolidating the pharmaceutical distribution sector and biotechnology are the focus areas for the next five years. China hopes to streamline and integrate its drug distribution and bring pharmaceutical production and sales closer together, thereby reducing medicine prices.

Biotechnology has also been singled out as one of the seven 'strategic emerging industries' in the five-year plan. More investment in this sector can help resolve health problems associated with China's rapidly ageing society. The plan will support the development of innovative biotech products, high-end medical devices and patented medicines.

Despite these lofty targets, policy-makers must also achieve a fine balance between their welfare objectives and the profitability of drug companies – domestic and foreign. Even as China works on its ambitious healthcare targets, it is under pressure to rebrand itself as a quality destination internationally.

The pharmaceutical industry is thus caught up in a dynamic environment where China is trying to position itself not only as a vast and unique market, but also as a source and destination for high-quality research and manufacturing.

This report encapsulates the exciting developments that are simultaneously taking place within China's pharmaceutical sector and follows the trends which are likely to affect global multinationals and the local industry in the years to come. There are opportunities waiting to be tapped at all levels, but there are also risks involved in operating in a multi-tiered market where quality and compliance are issues that are just beginning to be addressed.

# 00

## Contents

### Chapter 1 -- The China market: Big, growing and complex

- 1.1 A growing and stratified market
- 1.2 Healthcare reforms dictate industry course
- 1.3 Mega trends driving drug demand
- 1.4 Players race to meet target

### Chapter 2 -- Big players – Changing strategy in the new landscape

- 2.1 Foreign multinationals deepen their footprint
- 2.2 Domestic drug-makers focus on bulk and brand
- 2.3 Biotech firms nurture the future
- 2.4 TCM takes modernisation path

### Chapter 3 -- Trends and opportunities in China's unique market

- 3.1 Outsourcing opens drug discovery options
- 3.2 Quality and compliance to build 'Brand China'
- 3.3 Mergers and acquisitions, a winning formula
- 3.4 Innovation gains industry attention
- 3.5 Funding options and fiscal incentives

### Conclusion -- Incubating a healthy future



# 01

## The China market: Big, growing and complex



China's booming economy and high GDP growth make its pharmaceutical market the fifth largest and one of the most attractive in the world. With its volume and 20 percent annual growth projection, it is set to overtake Japan as the world's second largest market by 2015.<sup>1</sup>

Health spending, which is now only 4.7 percent of GDP and much lower than countries like the US, Germany and Japan, is steadily going up. A RMB 850 billion healthcare package for 2009 to 2011 will take spending up to 5.5 percent of GDP.<sup>2</sup>

With stakes this high, global pharmaceutical companies are strongly focused on China for future growth. However, China's health environment is marked by two distinctive characteristics: severe disparities in rural and urban healthcare systems and growing demand for superior drug quality. Government regulations must manage these aspects, generating challenges and prospects.

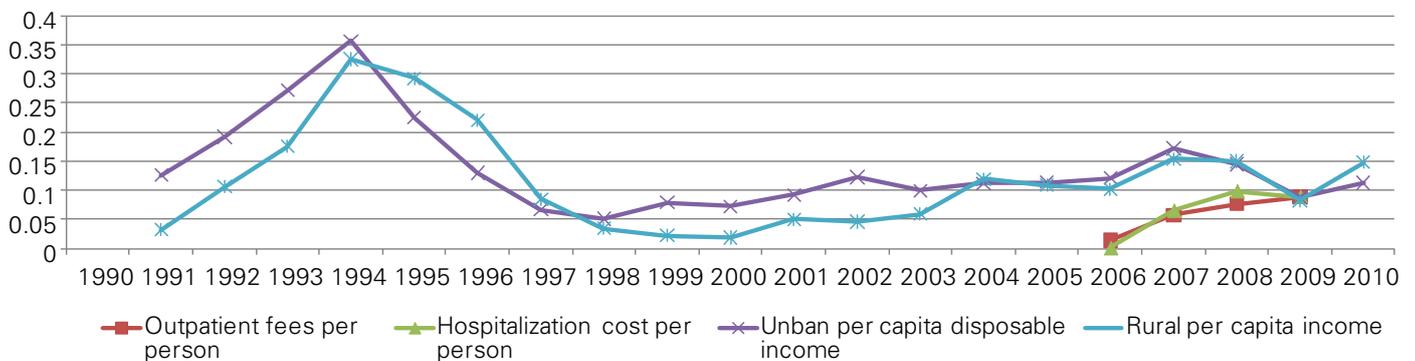
The 2010 KPMG report "The Changing Face of Healthcare in China" highlights the radical advances in public policy brought about by the 2009 Healthcare Reform Plan and the opportunities generated by these reforms.

Success in China thus has much to do with responding to the ambitious targets and swift pace set by policy-makers, managing the complexities of a multi-tiered market and building a portfolio that includes both specialised and generic, low-end products. A strategy to flourish here hinges on identifying risk factors correctly and on time.

#### 1.1 A growing and stratified market

China's status as one of the world's largest markets rests mainly on the size of its population, rather than its maturity. The percentage of healthcare expenditure in GDP may be below five percent, but China's share of spending on drugs out of its total healthcare expenditure is as high as 50 percent, compared with only 13 percent in the United States (US) in 2009<sup>3</sup>. However, in monetary terms, Chinese per capita spending on medicines was among the lowest in the world, at USD 35.1 in 2009.<sup>4</sup>

#### Indexed growth of China healthcare costs



Source: Ministry of health of the People's Republic of China, 2010

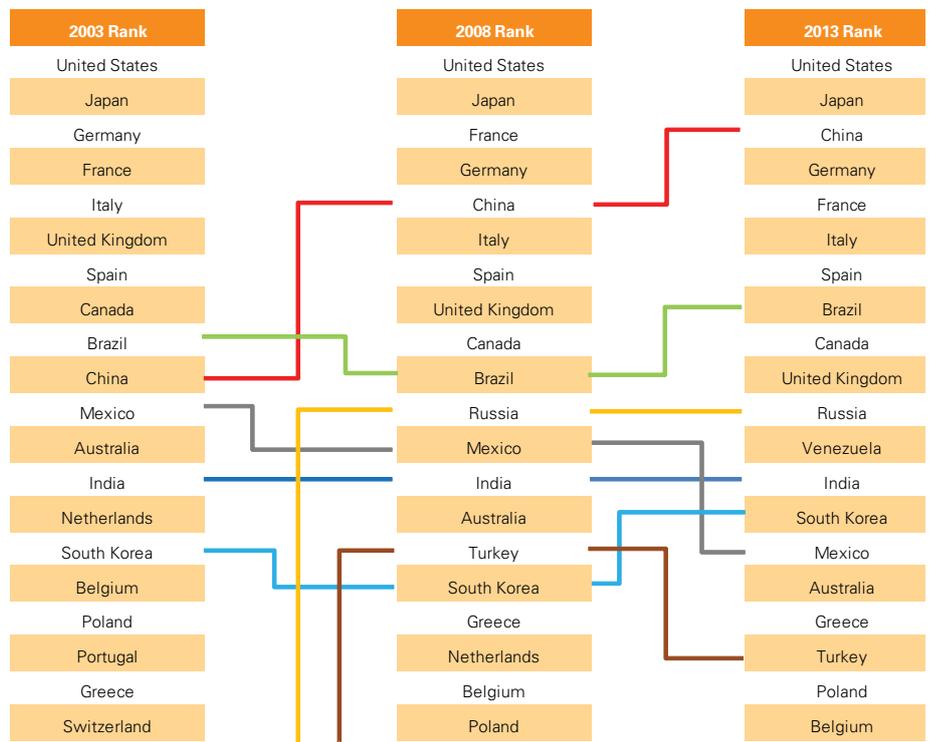
1 China seen as No. 2 drugs market by 2015, 8 Nov 2010, Reuters

2 IMS market prognosis 2010-2014 Asia/Australia/China

3 Is the Chinese market finally ripe for MNC pharma companies 22 May 2009, Pharma News

4 Pharma & Biotech Industry Outlook' 9 November 2010, Zacks Investment Research

### Global pharmaceutical market rank



Source: IMS Health, Market Prognosis, Sep 2009; Includes Preliminary Turkey Forecast

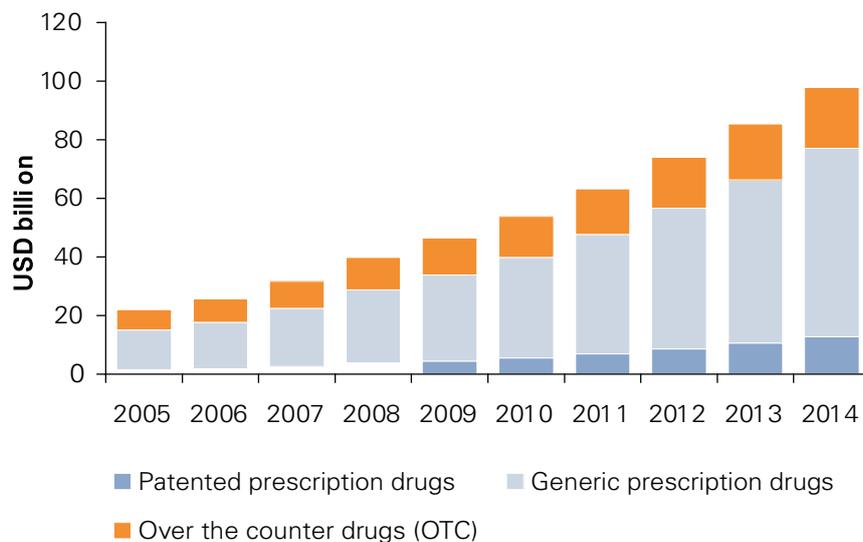
Drug revenue has grown swiftly and the market here may double in size by 2013. Hospital drug sales, retail pharmacy sales and rural drug sales are forecast to grow 20 percent, 13 percent and 40 percent respectively.<sup>5</sup> This contrasts starkly with developed nations which are looking at single-digit growth for the next few years.

A small but rising percentage of the urban population, whose income has grown quickly, is likely to become customers of high-end healthcare products. Even a tiny percentage of China's huge population base is a large number in other markets. The country

already has over one million Chinese with net worth more than RMB 10 million.

However, vast regional and urban/rural differences in economic development exist across China, with rising income disparities among its people. The mainland Chinese drug market comprises a complex system of regional markets where manufacturing is dominated by generics and the majority of sales come from over-the-counter (OTC) drugs.

<sup>5</sup> 'Pharma & Biotech Industry Outlook' 9 November 2010, Zacks Investment Research



Note: OTC includes both patented and generic over-the-counter pharmaceuticals  
Source: CAMDI, SFDA, BMI, China Customs

**OTC options:** The over-the-counter medicine sector, which was RMB 88 billion in 2009 and roughly RMB 96.4 billion in 2010, is set to grow, but slowly.<sup>6</sup> In 2009, the average annual growth was a relatively modest 7.7 percent.

The key driver for the OTC market is the popularity of preventive medicine among Chinese people and the cultural tendency to self-medicate for minor health complaints. The urban population has become increasingly health conscious and an increasing number of people tend to visit drug stores, bypassing doctors.<sup>7</sup>

According to pharmaceutical market research firm IMS Health, a study of the retail pharmacy sector in 13 major cities reveals that OTC sales are led by cough, cold and other respiratory remedies, followed by vitamins, minerals and nutritional supplements, and pain relievers.

Multinational products occupy prominent positions among OTC medicines sold through retail pharmacies. Foreign consumer health companies generally form joint ventures with indigenous players, which dominate this sector. The leading JVs operating in China are Xian-Janssen, Wyeth OTC and Bayer-Beijing. They compete with domestic companies such as Revised Pharmaceutical Group and Harbin Pharmaceutical Group.

Competition in China is likely to become fierce as major global players seek to penetrate this sector. Pricing and intricate knowledge of the regional markets will determine who gets ahead, while newcomers to the sector face increasing risks. The government has adopted an ambivalent attitude toward OTC products and is unwilling to promote self-medication. The hospital market is an important channel for OTC drugs, many of which are covered under the reimbursement list. If the government decides to take OTC products off this list, manufacturers may be left in the lurch.

The prices of OTC medicines are determined by the government or made adjustable to market forces according to law. Product prices are listed in China's national basic health insurance scheme catalogue. By fixing and adjusting medicine prices, the state controls their affordability and thus the profit margins of drug companies.

**Prescription for success:** China is set to become the world's third-largest prescription drug market in 2011, beating Germany, according to IMS Health.<sup>8</sup>

Strong growth in government funding of healthcare and a rise in spending by an increasingly affluent middle class are expected to help China overtake Western markets. An increase in

<sup>6</sup> China Pharmaceuticals & Healthcare Report Q4 2010, Business Monitor International

<sup>7</sup> 2010 Report on China's OTC Drug Market, March 2010, Market Avenue

<sup>8</sup> China could be 3rd largest pharma market by 2011, 16 March 2010, Associated Press

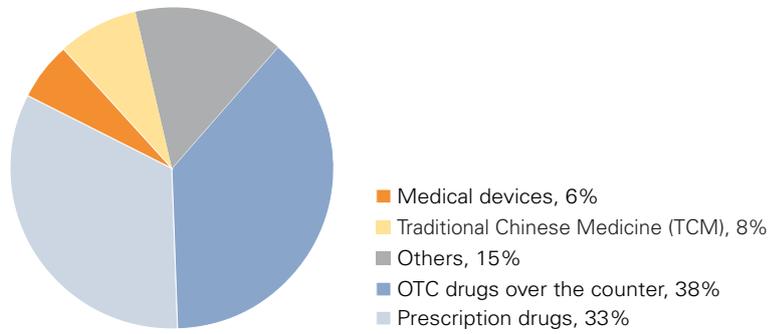
demand for certain treatments, such as cardiovascular and central nervous system therapies, will also be a key driver.<sup>9</sup>

One of the important growth areas will be hypertension drugs, with the market expected to double by 2014, due to greater awareness of the disease, and the increasing prevalence of contributory factors, such as obesity.<sup>10</sup>

Prescription drug sales are set to reach RMB 442.5 billion by the end of 2014. The performance of this sector has been better than that of OTC, with an average annual increase of 27.1 percent in 2009.<sup>11</sup>

The recent pricing reforms remain a cause for concern as they are likely to affect the profitability of the prescription drug market in the short term. Drug revenues are threatened by the government's setting ceiling prices on all such products.

### China's pharmaceutical market – market segments in China



Source: 2009 Information Explorer Ltd. (IEL)/BMI

<sup>9</sup> China to be top three prescription drug market, 7 October 2010, FT.com

<sup>10</sup> China Pharmaceuticals & Healthcare Report Q4 2010

<sup>11</sup> Space for domestic OTC market squeezed, 19 Sept 2010, Article Leader



**Leveraging the generic market:**

Generic drugs are the backbone of China's pharmaceutical industry. China has more than 5,000 pharmaceutical companies — about 98 percent of which produce generic drugs. By the end of 2009, the value of the generic drug sector was USD 29.3 billion, forming 63 percent of the total pharmaceutical market.<sup>12</sup> Analysts estimate that the generic drugs market will boom for the next four years, rising at a CAGR of 12.9 percent to a value of USD 57.1 billion by 2014.<sup>13</sup>

Despite the optimism, generic drugs are the key competitive issue for multinationals. The loss of patent protection for blockbuster drugs between 2011 and 2013 dictates much of multinationals' policies and strategies. Major products' patents expiring has resulted in a loss of nearly USD 137 billion in revenues in 2011, which will limit the growth of the global pharmaceutical market to 5 to 8 percent until at least 2013.<sup>14</sup>

As drug-makers lose some of their monopoly and sales growth in Europe, and as growth in the US and Japan stalls, makers of both prescription and over-the-counter drugs are targeting new markets — particularly in Asia and Latin America. With its rising middle class, China is the biggest prize.<sup>15</sup>

The generic segment in China thus remains attractive to foreign investments, with multinational entities moving towards acquiring generic drug companies to compensate for the loss of income from expiring patents. Generics are expected to capture a larger consumer base owing to the healthcare subsidies put forward by the government since 2009.

Major Chinese companies too are waiting in the wings to snap up the market as patents expire. How 'big pharma' turns this to its advantage and spreads its network is the question. In order to offset losses, pharmaceutical companies have established strategic plans to acquire new revenue streams through M&A.

**1.2 Healthcare reforms dictate industry course**

Macro and micro policy changes guide almost every aspect of China's pharmaceutical sector. The single biggest factor shaping the industry landscape and impacting the business models of all enterprises is the radical healthcare reform plan of 2009.

After years of experimenting with a 'cradle to grave' system and then overturning it for crippling market-driven reforms, the administration launched a fresh round of the Healthcare Reform Plan, in April 2009, to fix the ailing medical system for its 1.3 billion citizens.

With accessibility and affordability being the two planks of this reform, the government pledged to invest RMB 850 billion (USD 124 billion) over three years<sup>16</sup>. Changes are being carried out in two steps.

The first phase, to be completed by the end of 2011, aims to increase accessibility. The government is set to build a network of basic healthcare facilities, expand the public medical insurance system to cover 90 percent or more of the population, and reform the drug supply system.

**Drivers of pharmaceutical market growth****Continuous Growth :**

- Rolling out the healthcare reforms and increasing investment by foreign and domestic companies will be the primary growth drivers for the industry in the coming year, especially in the OTC market.
- Forecasting of China to be the world's third-largest pharmaceuticals market in 2011, with a value above USD50 billion.
- Increase of 28 percent during the first six months of 2010 in the value of import and export trade of medicine and health products in China, compared to the same period in 2009.
- Export value of ActivePharmaceutical Ingredients (API) is USD10 billion, growth rate 31percent, accounting for 53 percent of exported pharmaceuticals.

<sup>12</sup> China Pharmaceuticals & Healthcare Report Q4 2010, Business Monitor International

<sup>13</sup> China Pharmaceutical Industry Report 1H11, February 2011, Emerging Markets Direct

<sup>14</sup> Why Generic Drug Companies Will Dominate Future Pharmaceutical Markets, February 1, 2010, BioJobBlog

<sup>15</sup> China seen as No. 2 drugs market by 2015, 8 Nov, 2010, Reuters

<sup>16</sup> China speeds up healthcare reform, 10th Sept, 2009, China Daily

### Healthcare reform – the implications

Reduce the cost of medical services	<ul style="list-style-type: none"> <li>The National Essential Drug List (NEDL) under the National Essential Drug System (NEDS) is applicable to government-funded hospitals, grassroots clinics, and other health institutions. The 2009 list contains 307 drugs — 205 chemical and biological drugs and 102 TCMs.</li> <li>Medicines listed in the NEDS are subject to price control by the government.</li> </ul>
Upgrade Infrastructure and facilities	<ul style="list-style-type: none"> <li>30,000 hospitals, care centers and clinics will be built or modernised by the end of 2011.</li> </ul>
Enlarge insurance coverage	<ul style="list-style-type: none"> <li>More than 90 percent of citizens to be covered by insurance by the end of 2011 and coverage of the entire population by 2020.</li> </ul>
Reform of the distribution model	<ul style="list-style-type: none"> <li>All listed essential drugs are included in China's national Reimbursement Drug List (RDL) and enjoy higher reimbursement rates than non-essential drugs. The national RDL sets the percentage of drug costs reimbursed under national insurance.</li> </ul>

Source: 2009 National Essential Drug List, Healthcare Reform

At least 1,000 county hospitals were modernised in 2009 and another 1,000 upgraded in 2010. Plans are afoot to build a mix of 30,000 more hospitals, care centres and clinics by the close of 2011.<sup>17</sup>

By 2020, the government plans to bring the entire population under public medical insurance, further strengthen infrastructure and streamline drug research and delivery; thus making medicines and medical services accessible to all.<sup>18</sup>

**National Essential Drug List and two sides of affordability:** A key aspect of the healthcare reform is the restructuring of the pharmaceutical industry, for which the government is overhauling the National Essential Drug List and the National Essential Reimbursement Drug List.

One of the major challenges left over from the pre-2009 era is the well-entrenched 'reimbursement schemes', by which hospitals and doctors earn considerable revenue for prescribing medicines. In this practice, hospitals

were paid a commission based on the cost of drugs prescribed, leading to patients being given medicines they may not have needed.

In addition, between 1990 and 2000, drug-makers were free to fix prices and the cost of medicines went sky high. In response to these complaints, the central government sought to impose controls and announced waves of price cuts. China slashed drug prices on 19 occasions from 1996 to 2006. By May 2007, some 1,500 medicines had had their prices fixed by the central government and more than 800 medicine prices had been adjusted by local governments.

Currently, medicines sold in China, primarily those listed on the Essential Drugs List (EDL) and those produced or traded under a monopoly, are subject to price controls by the government. Hospitals and retail pharmacies are not allowed to add margins to drug product sales, rather, a pharmacy fee is added to each physician's prescription. The maximum

<sup>17</sup> Healthcare Reform Aims to Cover 90% of Chinese Citizens by 2011, Nov 12, 2010, 2point6billion.com

<sup>18</sup> China Sees Challenge On Health System, 24 Sept 2010, Wall Street Journal

retail reference price is only applicable to retail outlets that stock the essential drugs, and basic medical insurance packages reimburse drug costs only according to the price of generic products.<sup>19</sup>

In 2007, the National Development and Reform Commission (NDRC) redefined how drugs should be priced, and implemented a new five-step procedure, beginning with the EDL. This was designed to prevent profiteering and benefit patients and generic drug manufacturers.

In 2009, the NDRC drafted a reform for pricing policies that set the threshold for new price controls. On August 18, 2009, the Ministry of Health released a list of 307 essential medicines that would become available at heavily subsidised prices.

By mid-October 2009, the NDRC had slashed the prices of 45 percent of the country's essential medicines, including treatments for common diseases, such as colds, fever, high blood pressure, heart disease and diabetes.

A major shake-up for the global pharmaceutical players came in November 2010, when the NDRC announced plans to curb the prices of essential drugs produced by foreign-capitalised firms. Such products had in the past been excluded from China's regular rounds of price reductions, and their makers had independent pricing powers since 2000 as a way of encouraging R&D.

In the 2010 round, a cap was announced on the retail prices of 174 'self-developed' medicines. A 'self-developed' medicine is one developed by a pharmaceutical company on which the patent has expired.

In China, these medicines are owned mainly by international pharmaceutical giants. Of the 174 capped, 107 were produced by 40 foreign drug-makers, including Pfizer, Merck, Eli Lilly, Novartis and Bayer.<sup>20</sup> According to NDRC, this will help save the public RMB 2 billion annually.<sup>21</sup>

19 China Pharmaceuticals & Healthcare Report Q4 2010, Business Monitor International



**Complex reimbursement regime**

Healthcare in China is governed by diverse and complex reimbursement and insurance policies that entitle patients to compensation. The systems differ greatly between rural and urban populations as local governments are entrusted with significant power to make decisions on the use of drugs.

After the dismantling of the 'barefoot doctors' system and deepening rural healthcare crisis, China established the New Rural Cooperative Medical Scheme (NCMS) in 2003 — one of the largest public sector health insurance programmes in the world.

The system, which has now grown in strength, requires households to purchase health insurance for modest premiums of RMB 10 to 20 per person. Local and central governments each contribute subsidies of RMB 20 to 40 for each enrolled individual. By 2008, NCMS had expanded to include 800 million people in rural China.

The rural medical scheme is administered at the county level and coverage has varied greatly across regions. Although local health administrators are guided by central policies and the national essential drug

list, they are encouraged to define drug reimbursements and benefits on the basis of local needs and resources. This local decision-making has created substantial differences in allocating benefits and reimbursements between villages and counties across China.<sup>22</sup>

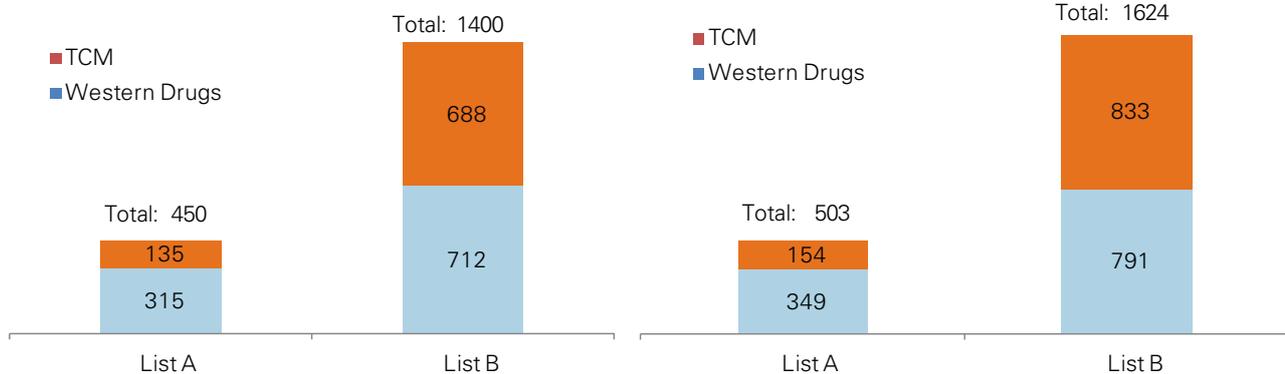
**NRDL for urban residents:** A major change for urban employees came in 2009 when the government revised the National Reimbursement Drug List (NRDL). This list provides the reimbursement framework for the 'urban employee basic medical insurance (BMI) scheme' and 'urban resident BMI scheme.'

The NRDL now includes all the drugs on the Essential Drug List revised in 2009 as part of the healthcare overhaul plan. According to IMS Health, there are more than 2100 products in the latest NRDL — 1140 Western medicines and the rest traditional Chinese medicines. The NRDL is further categorised into two groups of A and B lists.

The A List comprises 349 basic Western drugs. Listed by chemical compound, the drugs are fully reimbursable and are compulsory in all provincial drug reimbursement bulletins.

**2004 National Reimbursement Drug List**

**2009 National Reimbursement Drug List**



A list: Generic, low-cost products, fully reimbursable; decided by central government.

B list: MNC products largely fall into List B, generally higher price than products on List A. Provinces have the flexibility to adjust at provincial level.

Compound drugs not listed in the NRDL, but made up by NRDL - listed drugs, are reimbursable as List B drugs as long as the compound's price is not higher than the sum of its ingredient drugs

Source: MOHRSS Website

<sup>20</sup> 'China plans to curb foreign drug-makers' pricing powers, 29 Nov, 2010, Bloomberg

<sup>21</sup> Drug price cuts not yet felt everywhere, 14 Dec, 2010, China Daily

<sup>22</sup> Impact of China's New Rural Cooperative Medical Scheme and its implications for rural primary healthcare, August 2010, BMJ

The B List comprises 791 relatively innovative and patented Western drugs. The selection of drugs on List B can be adjusted up to 243 molecules/ reimbursement combinations by provinces and municipalities to suit their local economic situation and healthcare needs.<sup>23</sup>

**Implications of the EDL:** A listing on NRDL means the drug is available to large masses of the population, who are covered by the various medical insurance schemes. Reimbursement by the government means drugs are more affordable to patients and there is a high willingness from physicians to prescribe. Drugs on the NRDL are said to be much more easily added to hospital formularies.

On the flipside, drugs on the NRDL are subject to government price control and likely targets for price cuts. This has always been a vexing issue for multinationals as the combined advantages of low-cost production and tax rebates begin to erode when the government caps prices.

However, the impact need not be detrimental. With a relatively low price, drug producers can still earn profits by selling large amounts of medicine. Even as companies agonise over the implications of their products being included on the EDL, it is difficult to ignore that the domestic market for medicinal drugs is expected to expand to RMB 200 billion within three years, a number vastly attractive to foreign manufacturers.<sup>24</sup>

Self-developed medicines being put on the EDL will take foreign pharmaceutical enterprises into China's home market, including second- and

third-tier cities as well as rural regions. As the number of consumers in these areas grows, inclusion of limited brands on the EDL will give foreign companies a much-needed presence in the grassroots market.

The National Reimbursement Drug List also remains uncertain and risky for multinationals. To access the broadest market in China, foreign drug-makers need to have their products on this list; however, the list proposes to cap the sales margin on brand-name drugs at 23 percent.

A number of foreign enterprises are lobbying for the Chinese government to introduce a more balanced system and to reward innovation and quality.

#### **Streamlined purchase process**

In the 1980s, China launched market-oriented medical reforms encouraging hospitals to make money with the aim of mobilising medical staff and improving hospital efficiency.

Long-standing low government funding for public hospitals had resulted in doctors prescribing expensive and sometimes unnecessary medicines to patients in order to make profits for the hospital. This system was too onerous for patients and was heavily criticised.

The authorities are now standardising the purchase of essential drugs at government-funded grassroots medical institutions to establish a transparent purchasing system of essential drugs.<sup>25</sup> Moreover, efforts are being made to instill greater transparency in the hospital tender purchasing system. An open tender and bidding system is now the standard drug procurement mechanism for reimbursed drugs as well as those medicines local authorities purchase in bulk.

---

**“ The cost of building our own distribution network within China would be too high. Therefore, it is our intention to continue using the existing distributor network and partnership to deliver our drugs to our customers over the near and middle term.”**

**China commercial head, AstraZeneca**

---

<sup>23</sup> The 2009 revision of National Drug Reimbursement List, 2009, IMS Health

<sup>24</sup> Foreign companies fight to enter essential drug list, Dec 2, 2010, Economic Observer

<sup>25</sup> Prognosis for medicine costs looking good, 11th Dec, 2010, China Daily

## Besides the policy driven changes, other factors affecting the consolidation in distribution:

- State-backed distribution players like Sinopharm are proactively driving M&A activity
- Enforcement of regulations like the Good Safety Practice certification, makes distribution for start-ups and small players challenging
- Growth of pharmacy chains like Mannings and Watsons
- New distribution models via purchasing platforms, like e-commerce are expected to grow quickly as many provincial governments are promoting online purchasing.

More than 80 percent of all drugs sold through hospitals are now being purchased through the bidding process. The selection of products is made by tendering committees within each province and tenders are generally issued once a year or every two years for clusters of hospitals within a province. The tender system has become more standardised now with manufacturers and distributors more familiar with the system. Widely used drugs can be purchased directly from

pharmaceutical companies, while less commonly prescribed drugs can be ordered from drug wholesalers.

However, reforming public hospitals to reduce their dependence on income from drug sales will be a major challenge. With the goal of eliminating drug mark-ups in government hospitals, a new funding system is being piloted in 100 public hospitals. The success of the policy depends of the availability of government funding to compensate for the loss of income from drugs.

### Distribution

	Number of companies in 2007	Concentration Top 3: Market share	Typical net profit margins
USA	70	96%	1.5-2.5%
Japan	130	70%	1.0-1.5%
China	13,000	21%	0.60%

Note: The Top three US distributors --Cardinal, McKesson and Amerisource Bergen  
Source: "China Healthcare Industry Research", UTIC, August 2007



### Consolidation of the distribution sector

China's reform policy is geared towards greater consolidation and swift developments are taking place in the drug delivery and distribution sector.

Efforts first started in April 2009, with the CPC Central Committee and State Council launching the 'Deepening the Medical and Health System Reform' to encourage major consolidation of the pharmaceutical industry. By 2010, the focus had shifted to overhauling the distribution and logistics network.

The first national drug circulation industry management policy, released in March 2010, encourages enterprises to "spontaneously merge, restructure and eliminate systems and mechanisms that hinder fair competition, so that the drug distribution enterprises can select the superior and eliminate the inferior and eventually improve industry concentration."<sup>26</sup>

As part of the 12th Five-Year Plan (2010-2015), the Ministry of Commerce came out with the National Pharmaceutical Distribution Industry Development Plan (Draft), which encouraged big Chinese pharmaceutical companies to achieve more than RMB 100 billion annual sales by 2015.<sup>27</sup>

But consolidation of the USD 44 billion pharmaceutical distribution market in China is fraught with challenges. Of the more than 7,000 distributors in China, 80 percent are considered small. The top three distributors — Sinopharm, Shanghai Pharmaceutical and Jointown — accounted for about 20.7 percent of market share, far lower than 90.7 percent for the three biggest companies in the US.<sup>28</sup>

The degree of fragmentation is apparent from the fact that the top 100 firms accounted for about 67 percent of the market and the first 500 composed 85 percent in 2009.<sup>29</sup> These small, local distributors lack both the scale to automate and the logistical expertise of distributors in developed countries.

It is now left to China's largest pharmaceutical players to move quickly

to integrate resources and step up the pace of mergers and acquisitions to consolidate the industry. In this, they have full government support.

For the past two years, the top five domestic distributors — China National Pharmaceutical Group, Shanghai Pharmaceutical, Jointown Pharmaceutical Group, Nanjing Pharmaceutical and Guangzhou Pharmaceutical — have seen robust growth. M&As were key to the increase in concentration among distributors. This trend is likely to continue and the practice of providing more sophisticated and integrated logistics services will phase out smaller players.<sup>30</sup>

One of the most aggressive players is Sinopharm, a leading drug distribution company with strong government ties. In January 2011, Sinopharm announced the establishment of Sinopharm Tangshan Newland Company in Tangshan city, Hebei province, a new joint venture (JV) with local pharma unit Tangshan Newland. Sinopharm will initially invest RMB 21 million in the Tangshan JV and further earmark RMB 100 million for the construction of a Tangshan-based pharmaceutical logistics centre. This new JV deal could generate a dramatic change in the country's domestic drug distribution market.<sup>31</sup>

Shanghai Pharmaceuticals, the country's second-largest drug company by revenue, also announced the acquisition of a 65.2 percent stake in China Health System Ltd., the third-largest drug distributor in Beijing, for RMB 2.33 billion.<sup>32</sup> The company has been actively striking deals in recent years as it seeks to accelerate its expansion. Since 2010, it has acquired or signed agreements to acquire nine companies in its effort to expand the geographical footprint of its distribution business.

Foreign enterprises are yet to gain a firm foothold in this sector, but the possibilities are immense. US drug wholesaler Cardinal Health Inc. made a start with buying Chinese distributor, Zuellig Pharma China, known locally

<sup>26</sup> Large-scale restructuring kicks off in pharmaceutical industry, 11 March 2010, HuaXia Healthcare Holdings Ltd website  
<sup>27</sup> Sinopharm's continued expansion: harbinger of change in China's pharmaceutical distribution industry, 25 Jan 2011, GBI Analysts Inside

<sup>28</sup> China Pharmaceuticals and Healthcare Report 2010 report, Business Monitor International

<sup>29</sup> Large-scale restructuring kicks off in pharmaceutical industry, 11 March 2010, HuaXia Healthcare Holdings Ltd website

<sup>30</sup> China's pharma industry consolidation, concentration on the rise, 7 June 2010, Interfax

<sup>32</sup> Sinopharm's continued expansion: Harbinger of change in China's pharmaceutical distribution industry, 25 January 2011

---

“ The number of mental health cases has increased over recent years, especially for neurosis. This increase cannot simply be attributed to urbanisation. In my opinion, other reasons include more accurate diagnosis by medical workers and greater awareness of neurosis in wider society.”

Lu Zhi De, Associate Dean, Minhang District, Shanghai Mental Health Center

---

as Yong Yu, in a USD 470 million deal in late 2010.<sup>33</sup> The acquisition marked the first move by one of the big three US drug wholesalers, which also include McKesson Corp and AmerisourceBergen Corp, outside of North America.

### 1.3 Mega trends driving drug demand

The pharmaceutical market will experience explosive growth in the coming years, fuelled not only by healthcare reform but several macro trends taking place within China's socio-economic structures.

Chronic diseases such as cancer and respiratory and heart conditions are China's biggest health problems, according to the health ministry, which is urging citizens to change their lifestyle habits.

**Impact of lifestyle diseases:** China will complete the urbanisation process in a few decades — it took Western countries 300 to 400 years. The country's urbanisation rate was about 43 percent in 2005 and is expected to rise to well over 50 percent over the next 10 to 15 years.

The consequences of this trend on the pharmaceutical sector will be mixed. On the one hand, urban populations, with higher cash incomes, will benefit from better access to health services, information and education. On the other hand, the rapid environmental, economic and social changes that follow urbanisation will increase the prevalence of major risk factors for chronic diseases.

In particular, urban areas in China are moving through a rapid nutritional transition towards Western-style diets, dominated by more processed foods and a higher fat content. Increasing urbanisation also leads to equally rapid shifts toward more sedentary occupations through the acquisition of new technology. In China, these transitions have contributed to stark increases in obesity and hypertension, especially among male, urban and high-income groups.<sup>34</sup>

The emergence of these conditions is a major health threat in a country still coping with infectious diseases and malnutrition. Forecasts estimate that China will lose USD 556 billion to the costs of heart disease, stroke, and diabetes in the period 2005–2015.<sup>35</sup>

### Unique disease profiles drive MNC research:

Pharma companies have adopted careful strategies while pouring in funds for R&D. Given China's market size, multinational firms are starting to analyse each region's specific medical needs for potential sources of profit.

In the next 10 to 15 years, China's urbanisation rate is expected to rise to more than 50 percent. Rapid environmental, economic and social changes have contributed to stark increases in obesity and hypertension.<sup>36</sup> These 'diseases of affluence' have opened up a big market for pharmaceutical companies, particularly because China is still ill-equipped to deal with the rise in non-communicable diseases.

According to the World Health Organization, China has the world's second largest incidence of cancer. The country has 2.2 million new cancer patients each year, accounting for about 20 percent of the total number of cancer patients. Major menaces are liver, stomach and lung cancers.<sup>37</sup>

With the domestic drug industry unable to keep pace with the increase in occurrences and complexity of the disease, foreign manufacturers see potential in the anti-cancer drug market in China. MNCs have shifted focus to conducting clinical trials for ailments more common to ethnic Chinese.

---

33 Cardinal buys Zuellig Pharma China with \$470m, 30th Nov, 2010, Agencies

34 China battling with lifestyle related diseases, 19 March 2010, Reuters

35 Urbanisation and the spread of diseases of affluence in China. October 2008, University of York

36 Urbanisation and the spread of diseases of affluence in China. October 2008, University of York

37 Foreign competition for China to accelerate R & D cancer drug market, December 2010, EzineMark.com

In 2009, Pfizer, the world's largest drug company by sales, began work in China on an anti-inflammatory compound to treat liver disease. Pfizer is seeking collaboration with partners in China on liver diseases, such as cirrhosis and cancer. It is also going for 'external innovation' — teaming up with local biotech companies and research institutes to share risks and costs.

Novartis has a research centre in China studying gastric, liver, naso-pharyngeal and esophageal cancer and hopes to test its first experimental drug specifically tailored for Chinese cancer patients in 2013. It will spend USD 1.25 billion on R&D centres in Shanghai that will be pillars of its drug development.

Diabetes, too, is reaching epidemic proportions, with an estimated 92 million adults — 10 per cent of the adult population — now affected. Eli Lilly plans to open a diabetes research centre in China in the second half of 2011. It has committed about USD 2.5 million over three years to support collaborative diabetes programmes between Chinese and European academic centres.<sup>38</sup>

**Ageing population:** China's ageing population is another significant factor for the industry. The population aged 60 and above in China reached 167.14 million in 2009, which is 12.5 percent of the total population. In 2009, the population aged above 80 in China reached 18.99 million.

Senile dementia is a common disease among the elderly in China and its incidence rate has risen continuously in recent years. According to the findings of a report by Research and Markets, about four to five percent of people above the age of 65 suffer senile dementia, it afflicts ten percent of those in the group aged above 75, and 20 percent in the group who are aged more than 85. According to conservative estimates, the number of senile dementia patients (including Alzheimer's disease, vascular dementia, mixed dementia..) totalled six to eight million.<sup>39</sup>

With the improvement of China's living standards, common diseases in the elderly are gradually attracting closer attention. Though the Chinese anti-senile dementia drug market is in the initial stages, it has witnessed strong growth

in recent years. In 2009, the value of the Chinese anti-senile dementia drug market rose by about 30 percent year-on-year. This sector is forecasted to maintain the annual growth rate of 20-30 percent seen in recent years.

#### 1.4 Players race to meet target

So far, China's pace has matched its goals on healthcare reform. The government now plans to accelerate this process and make better quality drugs accessible and affordable for all at the end of the ten year reform period.

The players competing for space in the country's dynamic pharmaceutical market include thousands of domestic companies and a handful of foreign enterprises which account for only ten to 20 percent of drug sales.

There is, however, immense potential to grow in this policy-driven country. The industrial environment is transforming swiftly, focusing now on quality as much as quantity. Chinese companies are investing heavily in both regulatory compliance and research and development. Non-compliant plants are shutting down as newer facilities adhere to good manufacturing practices.

The government has begun to be a catalyst in helping upgrade China's pharmaceutical value chain. An important strategy is to increasingly involve foreign multinationals because the 'go-it-alone' power of domestic companies remains limited. For the many domestic companies aspiring to be globally competitive, more mergers and acquisitions, exports and research provide a straighter and faster route to their goals.

Foreign companies on their part hope to leverage the accessibility target of the health reforms and spread their network into rural areas and second- and third-tier cities. Mergers with local companies have become a central part of the pharmaceutical industry's growth strategy given the need to extend 'geographic footprint'.

Thus, in time to come, domestic and foreign players are likely to consolidate and collaborate, finding innovative strategies to survive, profit and effectively meet China's extensive health goals.

<sup>38</sup> Lilly to open diabetes research center in China, 2 Nov, 2010, Company website

<sup>39</sup> Chinese anti-senile dementia drug market will grow 20-30 percent, Sept 21, 2010, The Pharma Letter



# 02

## Big players – Changing strategy in the new landscape



In China's complex pharmaceutical market, global and domestic players operate in an extremely crowded and competitive environment. More than a thousand international enterprises vie for space, along with in excess of 5,000 domestic players.<sup>40</sup> The world's top 20 multinational medicine makers have extensive operations in the country, including R&D facilities, joint ventures and wholly owned companies.<sup>41</sup>

Multinationals, most of which have had bases here for more than a decade, continue to view China as a leading overseas market with dazzling growth potential. US and European drug-makers have invested more than a billion dollars since 2009 into building R&D and manufacturing facilities.

In addition to facing severe competition from domestic firms, foreign companies investing in China face considerable risks due to a strong regulatory regime and price controls. MNCs can achieve differentiation and competitive advantage by cultivating a diverse portfolio, ranging from generics to niche biotech drugs.

Big domestic players, on the other hand, have formidable distribution networks and a meticulous knowledge of the different tiered markets of China. Eager to be major players in the international markets, local companies are aggressively consolidating and no longer want to be known as manufacturers of generic drugs.

This competitive landscape has thrown up an industry canvas that is uniquely Chinese. Innovative research in biotechnology now vies with traditional Chinese medicine companies eager to adopt modern scientific standards.

### 2.1 Foreign multinationals deepen their footprint

Global market leaders face multiple pressures on their margins, especially the loss of patent protection on blockbuster

drugs. Companies such as Pfizer, Sanofi, Bristol-Myers Squibb and GlaxoSmithKline stand to lose their best-selling products within the next five years, as generic versions of popular drugs get ready to flood the market as soon as patents expire. In 2011, products worth more than USD 30 billion will lose patent cover.

Pfizer's 20-year patent for its popular cholesterol medicine Lipitor, which saw USD 11.8 billion in sales in 2010, expires in 2011.<sup>42</sup> Plavix Clopidogrel, used to treat blood clots, brought its joint developers, Sanofi and Bristol-Myers Squibb, about USD 9 billion in annual sales since 2008. Its patent expires in November 2011.

Such high-profile ageing patents join a long list of medicines by multinationals that have expired over the past decade — with more, worth about USD 77 billion — to come between 2011 and 2015.<sup>43</sup> After patent expiry, generic versions are estimated to take over 50 percent of the market in the first year and as much as 70 to 80 percent of sales in the second.<sup>44</sup> The year 2012 will be a challenging one for several companies<sup>45</sup>. Patent losses now drive much of MNC strategies and policies. High research costs and a long incubation time make it increasingly difficult to bring new drugs to market. New products may not generate the same level of sales as those losing patent protection. Thus, foreign firms

40 China's booming pharma sector welcomes western investors, 4 April 2011, InPharmaTechnologist.com

41 China Booms: The new superpower, January 17, 2011, BioSpectrum

42 Bitter pill for multinationals as top drug patents expire, 30 March 2011, China Daily

43 Pharma & Biotech Industry Outlook, Zacks Investment Research, November 9, 2010

44 Pharma & Biotech Industry Outlook, Zacks Investment Research, November 9, 2010

45 Why generic drug companies will dominate future pharmaceutical Markets, February 1, 2010, BioJobBlog

must strategise effectively to make up for the loss of revenues that arises from losing intellectual property exclusivity.

Companies, however, need to make fundamental changes in their strategies for China to deal with the crisis of patents. This could be through internal restructuring to hire the most effective team of salespersons, or by opting for mergers and acquisitions that bring niche advantages. For instance, strategic alliances with local companies help share costs, bridge the revenue gap and also help make inroads into the fast growing rural market.<sup>46</sup> In addition, multinationals should consider investing in disease-driven research. Specialised research and product launches tailored for China's unique demands and market are fast becoming the norm.

#### Restructure to survive

Almost half of the top 10 pharmaceutical companies in China are multinationals but none of them controls more than 2.5 percent of the total market.<sup>47</sup>

Now, driven by the urgency to make up for the loss of patent rights and cash in on China's burgeoning healthcare market, global companies are executing drastic internal restructuring. In coming years, competition for talent and market share will intensify in China among multinational

and domestic pharmaceutical companies. Enterprises are racing to streamline every department, from R&D to sales. Western drug firms have been expanding aggressively in China, hiring thousands of salespersons besides researchers.<sup>48</sup>

For the multi-billion renminbi pharmaceutical marketing industry, keeping up with the fast expanding interior markets requires increasing agility, skill and knowledge. Sanofi has reduced its staff in the US and Europe and is expanding its Chinese workforce by one-fifth each year. It plans to recruit thousands of new sales representatives who will fan out across mainland China in pursuit of untapped markets.<sup>49</sup>

Corporations like Pfizer and GSK are also renovating by diversifying, laying off employees in the West and executing mergers —all while bidding to develop the China market, which will soon have hundreds of millions of citizens able to purchase more expensive prescription drugs.

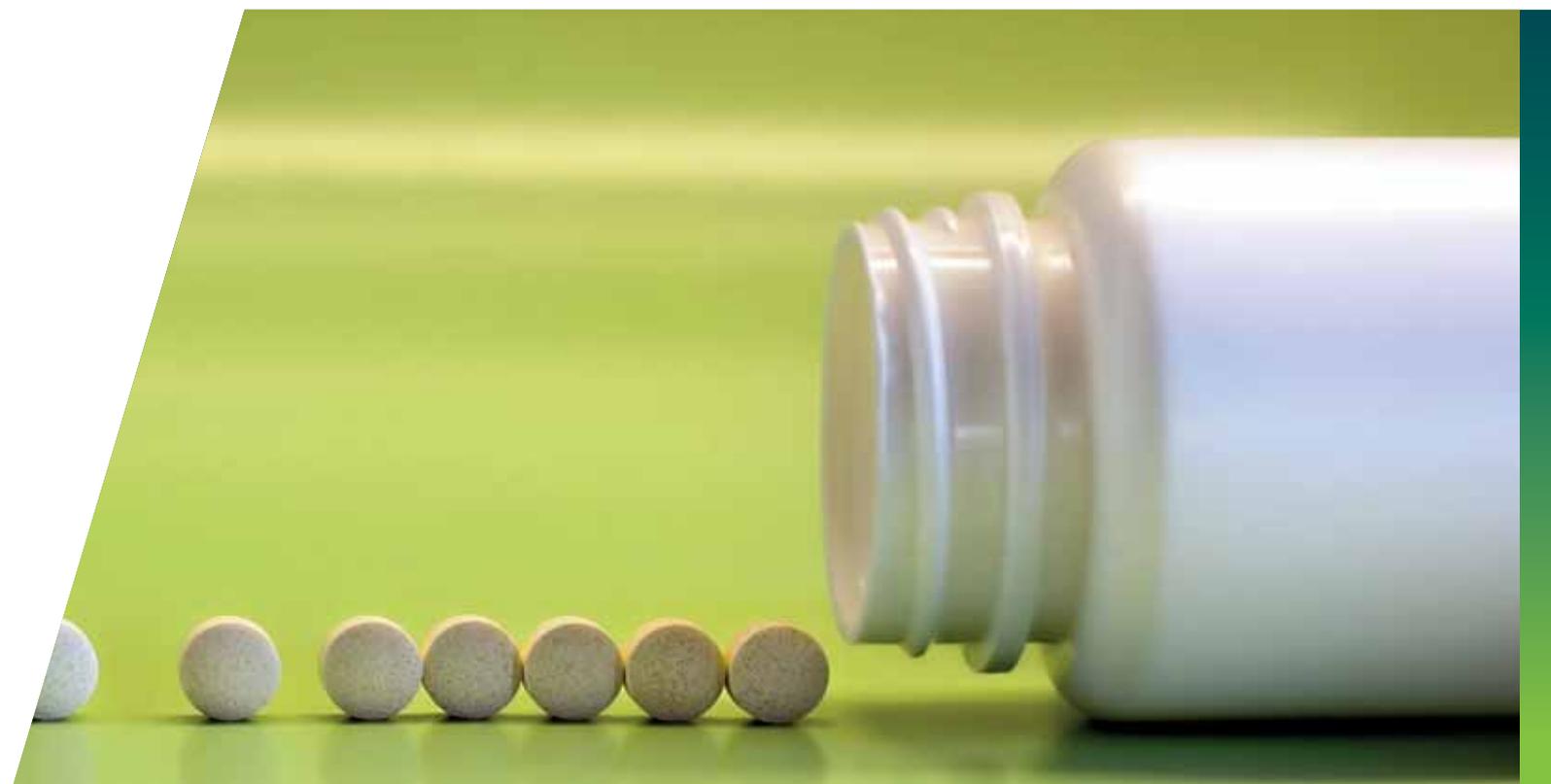
Pfizer will slash about 1,100 R&D jobs in the US in 2011 and close down its research centre with 2,400 employees in Britain before 2013. The company plans to increase its representatives in China — many of them trained doctors — by 39

46 Pharma & Biotech Industry Outlook, Zacks Investment Research, November 9, 2010

47 Global drug firms take aim at made-for-China healthcare, 16 September 2010, Reuters

48 Global drug firms take aim at made-for-China healthcare, 16 September 16 2010, Reuters

49 Big Pharma's Challenge: Figuring out China, 23 September, 2010



percent to 3,200 in 252 cities by 2012. According to Pfizer, many reps are medical information specialists, trained in biosciences.<sup>50</sup>

GSK, too, has been steadily escalating its sales force numbers in China and as at March 2010, more than 2,500 reps were working across the country.<sup>51</sup>

Swiss pharmaceuticals group Roche decided to increase its employee strength in China by 25 percent back in 2009, even at the cost of trimming jobs in the US and Europe. The company is working on a complete value chain in China, and the new jobs cover pharmaceutical research, clinical development, production, marketing and sales. Roche has invested more than USD 1.5 billion in China and realised double-digit growth in the past few years. China also accounted for more than 40 percent of its total turnover in the Asia-Pacific region.<sup>52</sup>

Merck has announced it will reduce its staff by 15 percent, a total of about 16,000 lost jobs across the globe. At the same time,, it is substantially increasing its presence and field force in emerging markets, like China, Brazil and Russia.<sup>53</sup>

Major drug companies also say intense competition and high costs make it harder to support the old way of drug research of keeping large teams of in-house researchers and waiting for results.

Sanofi is restructuring to close 20 of its 30 labs in Europe, a move expected to save EUR 2 billion (USD 2.8 billion) this year. Its R&D spending for 2012 is projected at USD 6.5 billion to USD 7 billion, much less than the USD 9.4 billion in 2010.

London-based AstraZeneca also unveiled a plan to further cut labour costs after 12,600 employees were let go over the past two years. The pharma industry's rush into China has led to more than a battle for market share. It has created a parallel battle for good employees. Drug-makers are faced with a war for talent, particularly in marketing and sales. Every year, about 20 percent of GSK's sales force quits to take jobs at rival firms, which is the average for the pharma industry in China and India.<sup>54</sup>

Companies like Takeda Pharmaceuticals, which has faced sales-rep turnover of up to 60 percent annually, brought in new management to focus specifically on the attrition problem, figuring that if it could fix its sales turnover, it could boost sales in the country tenfold within five years.

#### Expansion a common strategy

Foreign enterprises have one strategy for China in common — all have expanded heavily in recent years and expect the country to bring in much of their future growth. Chinese consumers have greater faith in multinational products, but foreign companies need more visibility.

In recent years, Western pharmaceutical players have stepped up their presence in China — be it in manufacturing, marketing or research. One immediate advantage is lower costs. The cost of developing a new drug in the West is higher than ever — about USD 1.3 billion.<sup>55</sup> It is also difficult for companies to predict which drugs will become blockbusters that yield an annual revenue of at least USD 1 billion. In this context, China remains a cost haven. Based on their China projections, each company has worked out its own unique strategy.

#### Top 10 multinationals MNCs in China in 2011 Q1

Company	Sales (US\$m)	Growth (%)	Share (%)
Pfizer	835	31	8.32
AstraZeneca	749	32	7.47
Bayer HealthCare	663	20	6.61
Sanofi	620	31	6.18
Roche	531	31	5.29
Merck	443	15	4.42
Novartis	440	25	4.39
GlaxoSmithKline	378	30	3.77
Novo Nordisk	359	30	3.58
Johnson & Johnson	288	30	2.87

Source: BMI China Pharmaceutical report, 2011 Q1

<sup>50</sup> Pfizer sees strong growth in China, 4 April 2010, China Daily

<sup>51</sup> Merck, GSK expand sales forces in China, 13 January 13, 2011, Medical Marketing & Media

<sup>52</sup> Roche to boost China headcount by 25%, Sept 9, 2009

<sup>53</sup> Merck, GSK expand sales forces in China, January 13, 2011, Medical Marketing & Media

<sup>54</sup> GSK suffers sales-rep poaching in China, India, April 4, 2011, Fierce Pharma

<sup>55</sup> Drug developers are changing the way they do R&D, 5 January 2011, Tufts Center for the Study of Drug Development

### Pfizer

Ever since entering the China market in the 1980s, Pfizer has introduced a broad product portfolio in the country. It has invested USD 1 billion in China and has business operations in more than 200 cities with 9,000 employees distributed across the country. It has established eight state-of-the-art plants in Dalian, Suzhou and Wuxi that manufacture products for the pharmaceutical, nutrition, consumer healthcare, animal health and capsule users sectors.

After Pfizer's merger with Wyeth, its China business was divided into two units, the bio-pharmaceutical business (WBB) and the diversified business (PDB). Through the WBB, the company introduced more than 50 innovative drugs into China.

Its showpiece is the China Research and Development Center (CRDC), a state-of-the-art facility in Shanghai, established in October 2005. The CRDC provides global drug development support capabilities, research collaborations and strategic alliance opportunities to China and the Asia region.

The Shanghai centre also collaborates with leading academic researchers and top institutions in China including Peking University, Tsinghua University, Fudan University, Institute of Biophysics of the Chinese Academy of Sciences, and the Shanghai Institute of Biochemistry and Cell Biology.

Pfizer has also been partnering aggressively with local companies. In April 2011, it signed an MoU with Shanghai Pharmaceuticals to jointly pursue potential business opportunities in China.<sup>56</sup>

### AstraZeneca

Anglo-Swedish company AstraZeneca is one of the largest multinationals operating in the prescription market in China, with headquarters in Shanghai and 23 branch offices in major cities across the mainland. The company deals in a variety of therapeutic classes, with the main focus on cardiovascular, respiratory, anaesthetic, oncology and central nervous system medicines, apart from some OTC medicines.

<sup>56</sup> 2010 Company Annual report available on website



AstraZeneca entered China in 1993 and was one of the first multinationals to establish a local clinical research base. At present, most of AstraZeneca's business comes from big hospitals in 200 of the largest cities. The company is now trying to boost its sales capabilities in an additional 100 cities and build a sustainable business in the broader rural market. AstraZeneca has more than 3,500 employees working in manufacturing, sales, clinical research and new product development.

In 2001, the company inaugurated the AstraZeneca China Supply Point in Wuxi New District, Jiangsu Province. The site, the largest manufacturing investment for the company in Asia, is authorised to export products to the European Union (EU). The company opened the Innovation Center China in Zhangjiang Hi-tech Park, Shanghai, in 2007, now one of its main R&D facilities.<sup>57</sup>

---

**"Our revenue growth last year was 6% above benchmark of China market growth, thanks to healthcare reform that continues to expand medical insurance coverage and newly approved reimbursement list implementation."**

China commercial head, Astra Zeneca

---

### **Bayer**

Bayer HealthCare has maintained a presence in China since 1936. In 1997, it began producing drugs in Beijing and now manufactures and markets a wide range of products. One of its most popular products is Glucobay, China's best-selling diabetes medication. In 2005, it acquired Roche's OTC business and two years later, Bayer HealthCare and Schering Pharmaceuticals completed a merger to form Bayer Schering Pharma. In 2009, this joint venture launched a EUR 100 million investment for a global scale R&D centre in Beijing.

The company proposes to add 2,500 new jobs in emerging markets, particularly China, by 2012. A key element of Bayer's strategy in Asian countries is selective expansion of

super-specialised drugs. In 2010 it launched Betaferon in China to treat multiple sclerosis.<sup>58</sup>

### **Sanofi**

For this leading French company, emerging countries are a major focus area. Sanofi has grown swiftly in China, employing 6,000 people in more than 200 cities. It specialises in key therapeutic areas such as cardiovascular/thrombosis, diabetes, oncology, internal medicine and the central nervous system.

In 2010, Sanofi took two decisions — it acquired local company BMP Sunstone Corporation and formed a joint venture Hangzhou Sanofi Minsheng Consumer Healthcare. This now enables the group to position itself as a leader in two growth markets — vitamins and mineral supplements with Minsheng, and cough and cold drugs with BMP Sunstone.

Sanofi currently has six manufacturing facilities in Beijing, Hangzhou,

Shenzhen and Tangshan, in order to meet the increasing demand of the Chinese market. The company is also engaged in integrated R&D in China from drug target identification to late stage clinical studies.<sup>59</sup>

### **Roche**

Swiss multinational Roche is focusing on emerging markets, which are expected to generate 50-60 percent of its overall sales growth over the next two to three years. Like its competitors, Roche too is banking on China's healthcare reforms, but its strategy differs. Unlike other companies, the Swiss drug-maker will not pursue branded generic products in the emerging markets. It will instead focus on innovation and differentiated medicines, and leveraging pharma and diagnostics to develop personalised healthcare strategies.

Roche's recent cost-cutting exercise will result in 4,800 job cuts worldwide, or 6 percent of the workforce. In China, however, the company scaled up its field force from 960 sales reps in 2009 to 1,300 in 2010. The majority of this force is responsible for selling Roche's speciality-care products to the Chinese market. For China,

<sup>57</sup> AstraZeneca Website news

<sup>58</sup> Bayer website and 2010 Annual Report

<sup>59</sup> 2010 Company Annual report

the company is working out a multi-disciplinary approach to marketing with scientists, key account management and reimbursement teams working with sales reps.<sup>60</sup>

In April 2011, Roche announced that it will make Shanghai its third strategic operations centre in the world, after Basel, Switzerland, and San Francisco in the US. The company completed the Roche Shanghai expansion (RoSE) project at Zhangjiang Hi-Tech Park in Shanghai's Pudong New Area — a major step since its Asia-Pacific headquarters moved to the city in 2009.<sup>61</sup>

Roche Pharma China has also obtained approval from the US Food and Drug Administration to export China-made Xeloda (Capecitabine, a drug used in the treatment of metastatic breast and colo-rectal cancers) to the US. In 2011, at least 50 percent of the Xeloda made in China will be exported to the EU and the US, an important step towards upgrading the entire Chinese pharmaceutical industry chain.

Like its multinational peers, MSD is also aligning with local companies. In March 2011, it signed an agreement with Chongqing Zhifei Biological Products to promote its vaccines in China. The promotion will involve RMB 220 million worth of products made by MSD. The company plans to launch more advanced products in the Chinese market with its local partner.<sup>63</sup>

### Novartis

The Swiss company has been continuously expanding in emerging markets and is conducting extensive research in China.

At the Novartis Institutes for BioMedical Research (NIBR) in Shanghai, scientists are focusing on liver cancer while building broad expertise about other forms of liver disease prevalent in Asia. Novartis has also undertaken joint development of a pioneering medicine against malaria with Chinese partners, the Shanghai Institute of Materia Medica (SIMM), which played a key role in discovery of the antimalarial medicine Coartem.

In 2001, Novartis and SIMM announced a collaboration on drug discovery based on natural products. Under the agreement, SIMM has isolated hundreds of new compounds from medicinal plants known in traditional Chinese medicine. In return, Novartis has provided financial support, and shared natural product research and advanced drug discovery techniques.

Novartis is now expanding its vaccine business in emerging markets. The planned acquisition of a majority holding in Zhejiang Tianyuan Bio-Pharmaceuticals will pave the way for local production of vaccines in China.<sup>64</sup>

### GlaxoSmithKline

GlaxoSmithKline (GSK) was one of the first foreign pharmaceutical companies to establish successful joint ventures in China. With five manufacturing sites, of which three are joint ventures, GSK's total investment in China now exceeds USD 400 million.

“Innovation is the key success factor in the pharma sector. Increasingly more returnees are bringing their innovative projects to China — and bringing the results to market. That's great for China's pharmaceutical market.”

Frank Grams, Executive Director, Roche Partnering, Roche

### Merck

Merck, which came to China in the 1900s, has undertaken wide-ranging operations through its various subsidiaries. Merck Sharp & Dohme, which is the trademark of US-based Merck & Co Inc, has been expanding its investment in China in recent years. The unit started work on a new manufacturing site in Hangzhou in July 2010. With a total investment of RMB 1.1 billion, this is one of the largest pharmaceutical packaging projects undertaken by Merck in recent times. The unit is expected to start production by the first quarter of 2012 and will have an annual packaging capacity in excess of 300 million packs.<sup>62</sup>

60 Re-engineering Roche, Interview of Pascal Soriot, COO of Roche Pharmaceuticals, Scrip 100, June 2010, available on Roche Website

61 Roche sees new Shanghai center one of its hubs, 15 April 2011, China Daily

62 Merck begins work on new unit, 13 July 2010, China Daily

63 MSD to promote vaccines through, Chongqing Zhifei, 9 May 2011, China Pharma Review

64 Novartis Website and 2010 Annual Report

The company employs about 5,000 people in China and has offices in major cities. Its business units here include prescription medicines, vaccines, over-the-counter drugs and consumer healthcare, headquartered separately in Shanghai, Beijing and Hong Kong.

In 2010, GSK signed important strategic alliances with major local pharmaceutical companies and acquired Nanjing MeiRui Pharma Co. MeiRui is a leading Chinese pharmaceutical business with a strong portfolio of urology and allergy products. GSK will gain these as well as MeiRui's established sales and marketing platform and a manufacturing facility in Nanjing City.

GSK also has a strong research and development presence in China with more than 200 drug development projects conducted in collaboration with in excess of 30 leading medical universities/hospitals. It is developing medicines for hepatitis, asthma, diabetes, oncology and mood disorders in China. Recently, GSK boosted its R&D investment with an emphasis on cancer prevention and treatment. The company has an OTC research centre in Tianjin and a global R&D centre in Shanghai.<sup>65</sup>

#### **Novo Nordisk**

Novo Nordisk has been operating in China for nearly 50 years and was one of the first international biopharmaceutical companies to establish its R&D presence here in 1997. The Novo Nordisk R&D Centre China in Zhongguancun Life Science Park in Beijing specialises in molecular biology, protein chemistry and cell biology. By 2015 it will expand this centre and double staff strength from 100 to 200 employees. China is Novo Nordisk's third largest market.

The Danish company, headquartered in Beijing, has two production plants in Tianjin and local offices at Shanghai, Guangzhou, Shenyang, Wuhan, Jinan and Hong Kong. In China, it conducts a holistic diabetes programme that includes physician training, patient and public awareness, strengthening the healthcare system, local production and R&D.<sup>66</sup>

Novo Nordisk currently holds 63% of the total insulin market and 70% of the modern insulin market of China.

#### **Johnson & Johnson**

Emerging markets are an important focus area for J&J. The company hopes to leverage China's healthcare reforms and enhanced spending power. In order to tap the mass market here, J&J is focusing on smaller and more rural healthcare settings. The company will also beef up on research and development centres.

It will launch a medical devices and diagnostics R&D centre in Suzhou in 2011 and has also entered into pharmaceutical research partnerships that connect biotech, medical and academic communities to its global research centres. In 2008, it tied up with Tianjin Medical University Cancer Hospital, while in November 2010, a research collaboration between Tsinghua University and Janssen Pharmaceutica was announced.<sup>67</sup>

#### **Eli Lilly**

Eli Lilly has been building its organisation in China for two decades. Eli Lilly (China) R&D Co. Ltd. was officially launched in Shanghai on 14 March 2011, to develop medications for diabetes patients in China and the rest of Asia. Lilly has invested more than RMB 2 billion in China — including an R&D centre in Zhangjiang Hi-Tech Park in Shanghai — and built strategic partnerships with more than 10 local companies and academic institutions since the late 1990s.

According to the company, it is the first global pharmaceutical player to create a venture capital fund focused on the biopharmaceutical industry in China. The fund, known as Lilly Asian Ventures, has made six investments and deployed more than RMB 250 million since it was established in 2007.

Eli Lilly is now in the process of losing important patents that will hurt its top-line and bottom-line. One of the strategies to counter the loss is to focus on the emerging markets.

65 2010 Company GSK Annual report

66 2010 Novo Nordisk Website news

67 Johnson & Johnson Website

Since 2008, the company has doubled its sales force in China and increased its presence through a growing network of alliances and external partnerships, venture capital investments and more clinical trials.<sup>68</sup>

## 2.2 Domestic drug-makers focus on bulk and brand

Unlike the streamlined foreign enterprises, China's domestic industry is dotted with major and minor players, numbering more than a whopping 5,000 companies. Although lacking in the administrative and research sophistication of their foreign counterparts, local companies make up for it by their sheer scale of operations and penetration into the hinterlands.

The strength of domestic companies lies in manufacturing generics and active pharmaceutical ingredients (API) for export.<sup>69</sup>

Chinese companies have managed to maintain a high momentum of

growth in recent years in the chemical pharmaceutical segment. In 2009, the number of chemical pharmaceutical manufacturers reached 2,434, up 7.5 percent year-on-year.<sup>70</sup>

As at August 2010, China had roughly 1,200 API manufacturers, capable of producing more than 1,500 categories of active pharmaceutical ingredients. It was ranked first in the world in terms of output of ingredients for penicillin, vitamins and antipyretics and analgesics. China has also become the world's biggest exporter of active pharmaceutical ingredients, with the export volume nearly half of the domestic output of API. These ingredients also accounted for 80 percent of China's total pharmaceutical export value in 2009.

The government is reportedly drawing up a plan to invest USD 761 million for API manufacturers, with the goal of raising the country's export value of products by USD 4 billion annually.<sup>71</sup>

<sup>68</sup> Eli Lilly company Website

<sup>69</sup> Specialty Drugmaker Sinobiopharma Takes on Big Pharma in China, Nov 13, 2010, Bloomberg

<sup>70</sup> China's chemical pharmaceutical industry in 2010, Dec 13, 2010, Research and Markets

<sup>71</sup> China, week in review, 1 March 2011, China Venture



### Building up trust

Despite significant headway in the chemical manufacturing sector, the domestic industry is yet to mature and consolidate — nearly 90 percent of China's pharmaceutical manufacturers are small or medium-sized enterprises — and the 10 largest companies generate only 13 percent of the industry's overall revenue.<sup>72</sup>

However, their aspirations are high. Many companies are aiming to go overseas for their next growth opportunities. The main motivation for them to go abroad is a deep concern for building brand awareness and a trusted image domestically. It is important for local companies to work on the trust factor because Chinese consumers tend to have more faith in foreign brands.

Local drug-makers understand that they operate in a low trust environment so building a strong brand is a sound strategy for increasing market share.

For the past three years, Chinese companies have established a presence in emerging markets such as Russia, Central and Southeast Asia, and Africa. These markets are a popular destination, at times, due to their less-strict product requirements and regulatory mechanisms.

However, developing a profitable presence in the American or European markets remains the ultimate goal. Chinese companies are keen to gain entry into Western countries because product standards and regulations are higher. Acceptance in the West remains a way of proving the quality of their drugs, strengthening their brand image and increasing credibility in other markets worldwide.

### Collaborate and consolidate

Expanding overseas follows a variety of strategies. Many of the Chinese industry leaders develop partnerships in their target markets, usually via joint venture or collaboration with research institutions or other MNCs or set up production and R&D centres abroad. This makes it easier to access

worldwide markets, allowing them to understand the regulatory environment and local consumer demand without having to start from scratch.

Zhejiang Hisun Pharmaceutical, a leading pharmaceutical group based in Zhejiang, made a USD 5 million investment in Photolitec of Buffalo, USA, in March 2011 for cancer treatment. The partnership with Photolitec is a strategy adopted by Hisun to transform itself into a global company. Hisun also has licensing agreements with Roswell Park and Cleveland BioLabs Inc. in the US and has opened its American headquarters in Princeton.<sup>73</sup>

The main challenge facing Chinese companies is obtaining official drug certifications in the developed markets of Europe and the US. Drug-makers have to go above and beyond what is necessary to meet the standards of China's own State Food and Drug Administration in order to gain a foothold in the West.

Together with the government's dedication to improving the R&D capabilities of Chinese universities and research institutions, domestic pharmaceuticals companies have shown the potential for becoming the leaders of innovation in the near future.

Continued partnerships with MNCs and leading research institutions will offer them insight into the workings of international pharmaceutical markets and access to advanced technology and resources.

### The local champions

While the Chinese pharmaceutical industry is still quite young and in many ways underdeveloped, it has begun to invest heavily in innovation and research. In the meantime, it continues to build its distribution and supply chain networks, thus providing formidable competition to multinationals.

<sup>72</sup> Chinese companies go abroad, 12 January 2009, Seeking Alpha

<sup>73</sup> Chinese investments boost WNY biotech companies, 28 March 2011, bizjournals.com

### Top listed local pharmaceutical companies according to market capitalisation

Company Name	State related	Market capitalization (USDbn)	Revenue T12M(USDmn)
Sinopharm	√	8.20	6,886.52
Shenzhen Hepalink		8.13	325.41
Jiangsu Hengrui Medicine	√	6.52	544.95
Shanghai Pharmaceuticals	√	6.35	5,512.73
Yunnan Baiyao Group	√	6.12	1,044.34
Sichuan Kelun		5.52	590.32
Shandong Dong-E E-Jiao	√	4.88	301.72
Kangmei Pharmaceutical		4.88	346.98
Harbin Pharmaceutical	√	4.09	1,552.77
Hualan Biological Engineering		4.07	178.25
Shanghai Fosun	√	3.74	563.60

Source: BMI China Pharmaceutical report, 2011 Q1

#### Sinopharm

Sinopharm Group, the largest distributor of pharmaceutical and healthcare products in China, is now working on extending its distribution network. It is targeting nationwide coverage by the end of 2012 from its current level of 40 percent.<sup>74</sup>

In 2010, the company extended its presence to provinces such as Jilin, Jiangxi, Guizhou and Gansu primarily through acquisition of distribution businesses in those places. Distribution of pharmaceutical and healthcare products accounted for 93.4 percent of the company's revenue for 2010.

With presence in 29 provinces, Sinopharm supplies about 56.76 percent of all hospitals on the mainland and some 77,087 pharmaceutical distributors, retail pharmacies and other healthcare institutions. By the end of 2012, the company's distribution network will cover all 333 cities at or above prefecture-level in China, compared with 133 cities as of now.

In 2010, the retail business at Sinopharm recorded revenue of RMB 1.72 billion, a rise of 23.74 percent compared with 2009, during which the company opened another 447 drug stores,

bringing the total number of retail pharmacies it operates to 1,394. The company is headquartered in Beijing.

#### Shenzhen Hepalink Pharmaceutical

Shenzhen Hepalink is one of the world's largest producers and sellers of heparin sodium active pharmaceutical ingredients, as well as China's only American FDA and European Union CEP certified company. The company's clients include leading global pharmaceutical companies.

Hepalink's main product is highly purified heparin, a substance made from the mucous membranes of pig intestines. Heparin is a blood thinner used to prevent clots. The company has been focusing on the production of injectable grade heparin products since 1986 and is compliant with the latest cGMP regulations.

With more than 500 employees, Hepalink has experienced huge growth in recent years. In 2007, Goldman Sachs bought a 12.5 percent stake in the company for USD 4.9 million.

In May 2010, it had a successful IPO launch at the Shenzhen stock exchange.<sup>75</sup>

<sup>74</sup> Sinopharm aims for nationwide presence, 26 March 2011, China Daily

<sup>75</sup> In China, strong debut for supplier of heparin, 6 May 2010, New York Times

The company also announced plans to establish a subsidiary in Hong Kong and a joint venture in Chengdu City, Sichuan Province, with Chengdu Tongde Pharmaceutical.

#### **Jiangsu Hengrui Medicine**

Jiangsu Hengrui Medicine, established in 1970, is principally engaged in the manufacturing and distribution of pharmaceutical tablets, injections and raw materials in the domestic market.

The company provides drugs for a range of treatments including cardiovascular disease, endocrine ailments, antibiotics and for infusions during surgery. With more than 1,500 employees, Jiangsu Hengrui now plans to boost research and development investment to about RMB 430 million in 2011, almost 10 percent of its projected revenue for the year.<sup>76</sup>

Jiangsu Hengrui is one of the few Chinese companies to get approval from the US Food and Drug Administration for clinical trials to treat Type II diabetes.

#### **Shanghai Pharmaceuticals**

Shanghai Pharmaceuticals is the only integrated drug company in China that leads both in product development and distribution. The company, with its headquarters in Shanghai, engages widely in research and development. Its strength, though, lies in distribution, warehousing, logistics and value-added pharmaceutical supply chain solutions

to drug manufacturers and dispensers, such as hospitals, distributors and pharmacies.

It has a network of retail pharmacies across nine provinces, municipalities and autonomous regions. The company also has collaborations with various multinationals. In April it signed an MoU with Pfizer. The collaboration is meant to leverage both companies' strengths, matching Pfizer's global capabilities in developing innovative medicines with Shanghai Pharmaceuticals' capabilities and reach in the China market. The companies are currently exploring potential cooperation for the registration, commercialisation and distribution in China of Pfizer products. They are also looking at equity investment opportunities.<sup>77</sup>

#### **Yunnan Baiyao Group**

Yunnan Baiyao Group, is a Kunming-based company engaged in the research, development and manufacture of pharmaceuticals as well as the wholesale and retail distribution of drugs produced by other companies.

The company is one of the most influential Chinese traditional medicine manufacturing enterprises with GMP certified plant operations.

It has 18 subsidiaries in China and has been listed on the Shenzhen Stock Exchange since 1993. The company has an impressive sales network throughout China and is also venturing abroad. Its trademark product 'Yunnan Baiyao' is said to be effective for clotting and healing wounds.<sup>78</sup>

### **2.3 Biotech firms nurture the future**

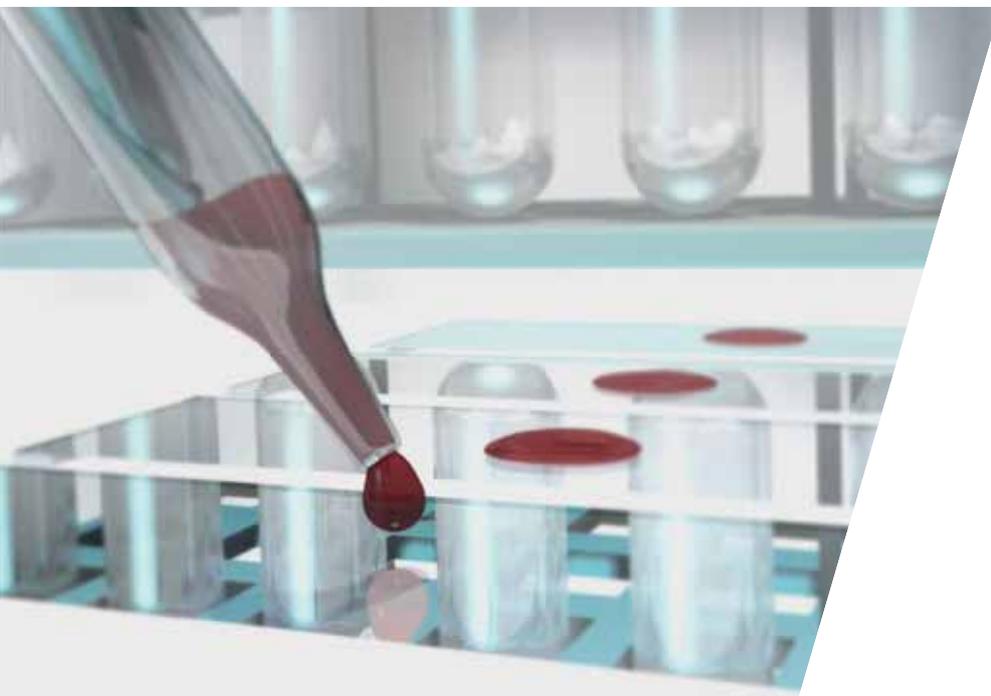
The strength of China's pharmaceutical players lies in their new-found willingness to invest in innovative drug research and biopharmaceuticals. This is now a high-priority sector within the pharma industry, which has gained extraordinary momentum during its short lifespan.

In fact, the Chinese biotechnology scene has transformed from an initial collection of companies with mixed innovator/service business models to a differentiated landscape with an international impact.

<sup>76</sup> Company profile, Reuters website

<sup>77</sup> Pfizer and Shanghai Pharmaceutical sign memorandum of understanding for potential strategic partnership, 20 April 2011, 4-Traders

<sup>78</sup> Company website profile



Until now, the US had been the most active country in research and innovation, holding nearly 60 percent of the world's biotechnology patents. In comparison, China is still at a nascent stage but is fast catching up, with more than 700 companies in the biological and bio-chemical sector and sales revenue forecast to grow at a CAGR of about 23 percent over 2010 - 2012.<sup>79</sup>

According to Henry Lee, CEO, Techpool BioPharmaceutical Co, "The bio-technology sector is not limited by traditional chemistry and provides mind-boggling options. It is a platform for the next-generation medicines. For example, my company is in the process of extracting compounds from human urine to convert to medical products. If this is successful, the possibilities are immense, as it is possible to extract compounds from animal blood as well."

Several factors make China a good place for biopharmaceuticals to flourish. Better IP protection, strengthened over years of awareness and law enforcement, has improved China's image, making it more attractive for global companies to harness the country's biotech services. Additionally, governments at various levels strongly encourage and support the development of this industry.

The sector has been accorded the status of 'strategic industry' in the 12th Five Year Plan, ensuring that tens of millions of renminbi in government funds flow into this segment.

Rapid innovation in biotechnology is also expected to spur the growth of the entire pharmaceutical industry as traditional drug companies increasingly collaborate with these firms to leverage their expertise.

China's biotech industry is providing one of the most effective solutions for beleaguered global drug companies, now under pressure to make their operations more efficient and cost effective. It is likely that pharma-biotech mergers will increase in the next few

years. By 2015 big pharmaceutical companies may be supported by a networked R&D organisation, consisting of multiple long-term relationships with these new firms.

For instance, Swiss-based Nycomed acquired a majority stake in Guangdong Techpool Biopharma in late 2010. Techpool, founded in 1993, specialises in the research, manufacturing and marketing of biologic drugs derived from natural sources. The Chinese company has a number of innovative protein drugs, including Ulinastatin for the treatment of sepsis and multiple organ dysfunctions.<sup>80</sup>

Biotech companies also attract generous funds. Five Chinese biopharma companies went public in the first five months of 2011 and raised an average of USD 172 million in their debuts on the Shenzhen Stock Exchange.<sup>81</sup>

#### China's prospects in biosimilar sector

Biosimilars are the closest that the biotech world has to generic drugs. However, because biotech drugs are grown in cultures, rather than constructed out of chemicals like traditional pharma drugs, it is impossible to have a generic version that is an exact reproduction of the original. This makes biosimilars difficult to produce and they are regulated under stringent guidelines.<sup>82</sup>

Biotech drugs are the most expensive drugs in the world and the price model for the 'blockbusters' is fundamentally different from traditional pharma big-sellers. For example, the world's biggest selling cholesterol drug, Lipitor's cost per patient is extremely low. The same is not true for biotech drugs that address cancer. Biologics are taken only by people who are seriously ill and there are never enough people suffering from these diseases to make for a traditional blockbuster product such as Lipitor. So to get a blockbuster in biologics, the drug needs to be sold for a lot of money.

This price model is the reason why making generic versions, or biosimilars, is an attractive proposition for companies. According to a report by the IMS Institute for Healthcare Informatics,

79 Global and China bio-pharmaceutical industry report, Sept 2010, Research in China

80 Nycomed expands China presence with Techpool stake, 2 Nov 2010, InPharm

81 IPO Update, 5 April 2011, Bio Generics and Biosimilars Initiative

82 Biosimilars and China: A natural combination, but will it happen, 15 June 2007, Seeking Alpha

by 2015, spending on biosimilars is expected to exceed USD 2 billion annually, or about 1% of total global spending on biologicals.<sup>83</sup>

Under an agreement with US in 1993, China has been making generic versions of biological products patented before 1985, including insulin. Since then, Chinese authorities have been revising various laws and regulations on patents, trademarks and copyrights to conform with international standards.

Some of the major local biosimilar companies are - Beijing Tiantan Biological Products, Chengdu Rongsheng Pharmaceuticals, Shanghai Institute of Biological Products, Changchun Institute of Biological Products and Shengyang Sunshine Pharma.

The future looks bright for biosimilars. In May 2011, Shanghai Celgen Bio-Pharmaceutical received approval from Chinese authorities for Qiangke—a biosimilar version of etanercept. Qiangke is a recombinant human tumour necrosis factor receptor-IgG fusion protein for injection. It is used for treatment of ankylosing spondylitis. Pfizer/Amgen has the originator version, Enbrel, which posted record sales in 2010. The US patent on Enbrel expires in October 2012, which opens up the market for biosimilars, such as Shanghai Celgen.<sup>84</sup>

#### 2.4 TCM takes modernisation path

Traditional Chinese medicine (TCM) generally refers to the comprehensive Chinese medical system based upon the body's balance and harmony. It is widely used in China, and policy makers are promoting it to reduce burdensome medical costs and allow universal access to healthcare. However, the share of TCM in the global medical market, which is dominated by Western medicine, remains low.

More people globally now think Chinese herbal medicines have few side effects, and the World Health Organization has accepted it as a method to treat illness and protect health. With its growing popularity, the Chinese government has stepped in to streamline the sector.

In 2009, China spent RMB 10.97 billion supporting TCM, an increase of 165 percent over 2005. From 2005 to 2009, the number of TCM hospitals grew 9.6 percent to 3,299 with 449,000 beds, 42.6 percent higher than in 2005.<sup>85</sup>

The government will now help upgrade TCM research and development in 2011 by improving the systems for historical research and innovation. The sector is being urged to establish databases of ancient, traditional Chinese medicine publications and to study its basic theories. Innovation is also being promoted to build a clinical R&D system, setting up key TCM labs, facilitating technology transfers into the industry and improving R&D management and quality control.

An interesting and uniquely Chinese development is the growing use of biotech in traditional Chinese medicine. Since TCM has demonstrated its effectiveness in the treatment of various diseases over a long period in history, a large group of experts believe they are likely to possess natural products that can be isolated for their therapeutic value.

Hong Kong based Biotechnology Research Institute or BRI is involved in evaluating the efficacy of TCM products, identifying those with therapeutic potential and discovering promising compounds for new drug development.

BRI utilises biological assays to screen TCM products and botanicals for therapeutically active compounds. Its focus areas are neurodegenerative diseases, such as Alzheimer's, Parkinson's, Amyotrophic Lateral Sclerosis, stroke, epilepsy and also cancer.

TCM enterprises like Chengdu Kanghong Group are also involved in combining biotechnology and TCM. The company has been researching, producing and selling traditional Chinese medicines as well as biotechnology products. Its subsidiary, Kanghong Sagent (Chengdu) Pharmaceutical is a 50:50 joint venture formed in December 2006 with US-based Sagent. The company has built an FDA-approvable, sterile manufacturing facility in Chengdu

83 Generics and biosimilars to drive down drug spending, 20 May 2011, Seeking Alpha

84 TNF biosimilar approved in China, 23 May 2011, Generics and Biosimilars Initiative

85 China to strengthen TCM research and development, 14 January 2011, China Daily

and operations are expected to commence in 2011 in preparation for an FDA inspection, possibly in 2012.<sup>86</sup>

Other innovative measures to upgrade TCM include a new index of Chinese herbal medicines published in Chengdu, the capital of Sichuan province, launched in April 2011. This will help both the government and businesses in the field understand trends and promote further development of the industry.

Authorised by the Ministry of Commerce, the Chengdu Index carries prices and purchase data on medicines reflecting the overall commerce in traditional Chinese medicines.

TCM herbal treatments received a major blow when they were made illegal in the EU in May unless they registered their products under the European Union Traditional Herbal Medicines Registration Scheme. The European market consumes about one fourth

of the total TCM exports from China according to statistics from China's State Administration of Traditional Chinese Medicine. The new legislation is likely to cost the industry USD 500 million a year and put about 100,000 practitioners out of work.<sup>87</sup> The EU's Traditional Herbal Medicinal Products Directive prohibits selling any traditional herbal medicines that have not received official approval. So far, none of the TCM products that had been sold in the EU have been approved.

<sup>86</sup> Sagent launches initial public offering, 11 May 2011, The Pharmaceutical News

<sup>87</sup> EU's rules on traditional treatments to cost millions, 14 April 2011 China Daily



# 03

## Trends and opportunities in China's unique market





The policy-driven pharmaceutical industry of China is in a race to meet the twin targets of quantity and quality set by the ambitious health reform plan of 2009. The industry finds itself well-positioned to support the reform and leverage the opportunities that abound here.

A combination of traditional and next-generation advantages is turning China into a haven for pharmaceutical manufacturers. From drug development to delivery, every segment of China's pharmaceutical industry is seeing vast and simultaneous transformation. The country is building an environment ideal for MNCs, where five major trends converge to give drug companies, struggling with cost-containment strategies, a base for their future.

First, the outsourcing sector is evolving in a sophisticated manner, and is capable of handling the complex demands of Western biotech companies. Second, the government's stand on quality and compliance should go a long way towards improving trust in China's drugs. In addition, international companies can also benefit from the higher quality standards. Third, mergers and acquisitions and greater collaboration between multinationals and domestic companies are an important development. Fourth, heavy investment in innovative research, tailored to diseases prevalent in Asia and specifically China, are helping to drive this industry.

The fifth trend revolves around funding this vast scale of business change, new sources of capital need to be tapped, creating great potential for venture capitalists and market investors. Both domestic and foreign investments can

contribute significantly to upgrading the overall quality of healthcare in China.

### 3.1 Outsourcing opens drug discovery options

Foreign companies plagued by pressures to reduce costs increasingly view outsourcing to China as a sound strategy. China is now a top pharmaceutical outsourcing destination, especially for drug discovery.

Throughout 2010, the demand for Chinese outsourcing services remained strong and the sector grew about 23 percent year-on-year. The current market size of the local outsourcing industry is valued at about USD 2.05 billion, crossing the USD 2 billion mark for the first time.<sup>88</sup> It is likely to grow at an approximate rate of 25.2 percent in 2011.<sup>89</sup>

China has a number of compelling strengths that make it a leader in the global outsourcing industry. Foreign companies can tap a less expensive patient pool and talented scientists and can easily access animals for research programmes — all supported by government regulators anxious to foster the industry.

**Unique patient pool:** A major attraction of outsourcing in China is its vast patient pool. Studies that require patient stratification are difficult to pursue in the US, hence countries such as India and China are ideal locations due to the availability of large numbers of

<sup>88</sup> China Pharma Outsourcing Annual Review - Latest Development Trends, 10 March 2010, Research and Markets

<sup>89</sup> China Pharma outsourcing annual review - Latest development trends, 10 March 2010, Research and Markets

suitable, receptive patients. Unlike the US and EU, China has a pool of highly desirable 'treatment naive patients' for conducting clinical studies. For cultural reasons, patients in China tend to be more compliant with their medical care, resulting in lower attrition rates in clinical trials. Studies in China have demonstrated, on average, a 70 percent cost savings over those done in the US due to lower per patient costs.<sup>90</sup>

In addition, the presence of unique gene pools in China's population is valuable for pharmacogenomic studies. Certain patient populations are more easily accessible here than in other countries, providing an opportunity for the focused development of niche markets. Examples include gastrointestinal cancers (esophageal, gastric, and liver); hepatitis; nasopharyngeal cancers; and neural tube defects.<sup>91</sup>

**Talent pool:** China offers a large pool of talented people in the sciences, including an increasing number of Western-educated graduates. Global pharma firms have been forced to slim down and cut research staff, so many now see China as a compelling destination to conduct cutting edge research. At least 80,000 PhDs in the life sciences from Western institutions have returned to China to work in the industry or in academic institutes, bringing with them leading skills and knowledge. This trend, combined with state-of-the-art research facilities and infrastructure, positions China as a leader of the outsourcing industry.<sup>92</sup>

**Integration through Contract Research Organisations:** Assured by these advantages, drug companies are increasingly turning to contract research organisations in China and (CROs are by definition outsource). Industry estimates suggest that the global CRO market is expected to reach USD 24 billion by 2012, with the majority of this growth coming from India and China.

### Upcoming trends – the CRO market in China

The 400 CRO companies in China mainly focus on the pre-clinical and clinical testing of new drugs.

About 1/3 of China's CRO companies are in Beijing due to incentives from the local government. Another fast growing market is Shanghai.

It is estimated that the Asia Pacific CRO market for clinical services (excluding drug discovery) generated approximately USD1.0 billion in revenues and is projected to grow at a CAGR of 20% to reach close to USD2.5 billion by 2015.

PE and VC have been active in the domestic CRO field, despite historic profitability challenges, they are attracted by double and triple digit growth figures as China's credentials as an R&D and trial hub develops.

Recent examples of CRO activity include:

Charles River Laboratories International's USD1.6 billion buyout of China's Wuxi Pharmatech in 2010

Partnership between the multinational CRO ICON with local Tigermed Consulting in 2010.

Source: Frost & Sullivan

<sup>90</sup> Global Outsourcing: Defining China's Leading Edge Frank L. Douglas and Gigi Hirsch, 2008

<sup>91</sup> Global Outsourcing: Defining China's leading edge Frank L. Douglas and Gigi Hirsch, 2008

<sup>92</sup> China to become life science powerhouse by 2010, 17 November 2010, Monitor Group

The Chinese CRO market is expected to flourish at a compound annual growth rate of 33 percent.<sup>93</sup>

Leading Chinese CROs offer research services at significantly lower costs and are increasing their ability to meet Western standards in drug quality and safety.

The first CROs focused largely on standardised chemistry-based studies. Initially big pharma was reluctant to outsource its chemistry-based operations as these were seen as a core function. Compound chemistry, which is basic to the drug discovery process, held some of the company's most sensitive intellectual property. These notions have changed fast, largely due to the scarcity of chemists and demand for new compounds exceeding the supply. Companies simply couldn't hire enough chemists to get the job done.

While 60 percent of Chinese professional service providers are still chemistry-focused, enterprises are now moving up the R&D value chain. The number of firms that are able to offer services with biotech capabilities has increased significantly, from only about 10 percent three years ago to now about 40 percent.<sup>94</sup>

**Future of outsourcing:** Local authorities in China have been quick to accommodate the needs of outsourcing companies. Major Chinese CROs are located primarily in two centres: Shanghai Zhangjiang Biopharmaceutical Park and Beijing Zhonguancun Life Science Park.

While ShangPharma remains one of China's earliest providers of chemistry outsourcing services, Wuxi PharmaTech is the poster boy of the CRO industry. The company showed a solid 24 percent growth in revenues during 2010, with sales totalling USD 334.1 million. The company predicts it will reach about USD 400 million in 2011. Wuxi's contract manufacturing segment provided the biggest percentage gains in revenue.<sup>95</sup>

Outsourcing of biopharmaceutical R&D has mostly been tactical to date, as opposed to strategic. Tactical

outsourcing tends to be a fall-back position when in-house resources unexpectedly prove inadequate to complete a project and the company turns to short-term solutions. Strategic outsourcing, on the other hand, employs a deliberate mix of in-house and external resources with a view toward long-term cost and resource management.

The strategic model prioritises longer term collaborative partnerships over short-term project tasks with a vendor. This allows companies to focus on building core areas of excellence internally, while establishing reliable external partnerships to meet temporary needs. They can thus optimise productivity.

Although the prospects for the market look upbeat, there are some challenges clouding its landscape. With economic reforms and the expected inflation in China, labour and raw material costs are increasing. Furthermore, cost differentials between inland-based CROs and coastal-based CROs now have to be considered. Inland-based CROs may now be able to compete more effectively on costs, perhaps by as much as 20–30 percent.

**Check-list for companies:** Foreign firms need to track several aspects when entering into a CRO arrangement because local CROs have been developing and bringing their own new drugs to market. They must take proactive measures to ensure intellectual property (IP) protection, pick suppliers with whom strong and stable relationships can be developed and understand and check for potential conflicts of interest.

93 Considerations in Pharmaceutical Outsourcing in China, 1 December 2010, DCAT-ISM Sourcing Summit: Forward Thinking Sourcing Summit

94 China Pharma Outsourcing Annual Review - Latest Development Trends, 10 March 2010, Research and Markets

95 WuXi PharmaTech on the Right Track With 24% Growth in Revenues, 10 March 2011, Seeking Alpha

## How KPMG can help — the benefits of outsourcing among pharmaceutical firms

Pharmaceutical firms across the globe are facing many different challenges, ranging from operational efficiency issues to competitive pressures and regulatory matters. The situation becomes all the more alarming as patents expire and the new drugs pipeline shrinks. In response, pharmaceutical players have adopted outsourcing, allowing them to make their operations more cost efficient, gain access to new ideas and maximise their use of existing resources.

Strategic considerations -- such as growth prospects, IP protection and legal infrastructure -- have become just as important as costs in the outsourcing decisions of pharmaceutical firms. The shifting of the global economic balance from the developed economies to emerging economies became visible in the current decade. Emerging markets are extremely important to many pharma companies, with China being a main focus. Pharmaceutical firms have made huge investments and are conducting a wide variety of activities in the country. China's growing pool of scientists is leading to the rapid development in the life sciences area in general.

Pharmaceutical firms have adopted various different models in China. One global pharmaceutical player has joined forces with Chinese partners, both to leverage existing R&D advantages and resources in China and also to collaborate with various local drug research institutes and CROs. This strategy allows sharing the risks inherent in R&D. Another multinational pharmaceutical firm is looking to establish its own R&D centre in China to take advantage of the country's low costs and rich talent pool. It plans to locate research activities in Shanghai and to build a fully integrated R&D centre.

In order to gain a significant cost advantage in pharmaceutical manufacturing, another global pharmaceutical player is planning to increase its API sourcing from China and the rest of Asia. The company has also decided to produce its entire API externally within a decade as a part of their long-term strategy.

### Benefits of outsourcing

In order to remain competitive in the high-risk, high-reward pharmaceutical industry, companies need to constantly innovate. Many pharmaceutical firms are now more willing to engage in outsourcing, recognising its numerous advantages. The key benefits include cost efficiency, access to skills, process improvement, avoidance of capital cost and the opportunity to focus on core competence.

Outsourcing can bring significant benefits to a company as long as it is able to answer some basic questions. Is the company's outsourcing strategy effective? Is the company well prepared to embrace outsourcing? Does the company have a strategic intent to outsource research and development as well as manufacturing? Is the company in a position to maximise opportunities for collaborative networking?

The business potential of outsourcing in the pharmaceutical industry is clear: outsourcing is playing a growing and increasingly important role in defining the next generation of pharmaceutical businesses and operating models. With continuous growth in the pharmaceutical sector, as well as in CRO and MRO, China offers many strengths, including cost advantages, a large talent pool, and end user market potential. It is perfectly positioned to become a world class player in providing outsourced pharmaceutical services.

### Upcoming trends – growing importance of GMP

On February 12, 2011, the Ministry of Health of China (MOH) published the final version of China's new drug GMP (GMP 2010).

GMP 2010 demonstrates the Chinese Government's determination to upgrade China's drug quality system and advance Chinese drug companies' competitiveness in the international market.

With drug manufacturing standards significantly raised, manufacturing costs will increase and some small-sized companies could be eliminated from the market.

Multinational drug companies need to review their manufacturing practices in China comprehensively to ensure full compliance with GMP 2010.

Multinational drug companies also need to take new GMP standards into account in their M&A and joint venture projects in China to ensure their acquisition targets or joint venture partners comply with GMP 2010.

### 3.2 Quality and compliance to build 'Brand China'

Reshaping the pharmaceutical industry's quality standards is currently a top priority for the Chinese government. With the country becoming a major hub for the world's drug industry, lapses in quality are a matter of international concern.<sup>96</sup>

The State Food and Drug Administration has been making constant efforts to upgrade quality, and the newest set of standards for drug production is

expected to bring quality on par with international standards.

Good manufacturing practices and their implications: Since 1998, China has experimented with and streamlined its quality norms as part of its Good Manufacturing Practices (GMP). A new set of GMP 2010 rules which significantly elevates drug quality standards in China came into effect on 1 March 2011. The regulations contain more detailed requirements for key aspects of the drug manufacturing

<sup>96</sup> The problems and potential of China's pharmaceutical industry, April 2009, AEI Outlook Series



process. They introduce the concept of quality risk management, and encourage the use of standard operating procedures and efficient management of manufacturing records.

The new standards codify in great detail the responsibilities of 'key personnel' in the manufacturing process and quality control of drugs. The definition of 'key personnel' has been expanded to include the company head, and persons responsible for manufacturing management and quality management.<sup>97</sup>

Existing drug manufacturers, depending on the risks of the products they manufacture, will be given a grace period of up to five years to comply with GMP 2010. Companies that fail to bring manufacturing sites into compliance within the deadlines will no longer be permitted to continue making their drug products at the facilities.

However, elevated standards under the new GMP will mean higher manufacturing costs for drug companies. Industry employees are now required to receive periodic training and the drug production process — including purchasing, processing and packaging — will have higher standards. The new GMP standards also require manufacturers to set up a drug recall

system — a first in China — and each step of the drug production process will be recorded in order to monitor quality.<sup>98</sup>

Although analysts agree that the new standards are the best way to build China's international reputation, they warn that the changes are expected to be met with some resistance from the industry. While the changes are likely to benefit big enterprises with resources, particularly those that have already adopted higher GMP standards, many smaller companies will likely be eliminated.

The State Food and Drug Administration estimates that the new regulations could shut down as many as 500 small and medium-sized drug producers, which will be hardest hit by rising operational costs. Nearly 80 percent of blood products manufacturers will not be able to live up to the new GMP standards.<sup>99</sup>

The latest norms contain numerous requirements that are different from US and EU standards, and multinational drug companies need to comprehensively review their manufacturing practices in China to ensure full compliance with GMP 2010. Moreover, foreign companies also need to ensure that acquisition targets or joint venture partners comply with the new standards.

## Emerging trends in the pharmaceutical industry – Quality

Quest for Quality:

- The Industry and Commerce Administration Department will issue a 'business license' only after the related pharmaceutical regulatory department (SFDA or its local branch) has approved the 'pharmaceutical manufacturing license' or 'pharmaceutical distribution license'.
- Pharmaceutical manufacturing or distribution enterprises must obtain an industry compliance certification.
  - Manufacturing enterprises must obtain GMP ('good manufacturing practices') certification.
  - Distribution enterprises must obtain GSP ('good supply practices') certification.
- In addition to the GMP and Pharmaceutical Production License 'must-haves', a variety of accreditation and quality standard 'good-to-haves' impact future domestic license applications, customer confidence and export licenses.
  - These include: ISO14001 for international exports, COS for Europe, FDA and CGMP for the US etc.

<sup>97</sup> China's new drug GMP significantly raises drug manufacturing standards, 17 February 2011, Global Life Sciences

<sup>98</sup> Quality updates for drugmakers, 14 February 2011, Global Times

<sup>99</sup> New version of GMP in China released, 14 February 2011, china.org.cn

### Compliance: Shaping future value chain

The issue of quality has always dogged China's international reputation. Now, with the country becoming an outsourcing hub, there is pressure to adhere to increasingly stringent domestic and international regulatory and compliance requirements.

Compliance, especially for multinationals operating in China, is particularly challenging. Domestic anti-bribery and anti-corruption laws in particular are stringent and becoming more so every year. Just recently for example, the Chinese government has moved to regulate gift cards which have become a common substitute for cash payments in illegal transactions<sup>100</sup>, and in February 2011 issued its own version of foreign anti-bribery legislation<sup>101</sup>. Similarly, at the end of last year the Chinese government released its first ever White Paper on China's Efforts to Combat Corruption and Build a Clean Government.<sup>102</sup> But, what of foreign bribery and corruption laws with extraterritorial reach such as the US Foreign Corrupt Practices Act (FCPA) and the recently enacted UK Bribery Act (UKBA)? Both laws carry with them

severe consequences for corporations and individuals if successfully prosecuted for violating them. Domestic companies with global ambitions are also taking note and considering these laws as part of their outbound investment and growth strategy.

Entities conducting business in China need to keep compliance with domestic and relevant foreign anti-bribery and corruption laws on their radar for a multitude of reasons. Under the FCPA companies are normally jointly prosecuted under civil and criminal regulations by the US Department of Justice (criminal) and the US Securities and Exchange Commission (civil). Individuals can serve time in jail and receive fines while corporations can be held accountable for the actions of their employees which can result in significant monetary fines and disgorgement of profits earned as a result of the illegal activity. If a company is publicly listed on a US exchange its shares can also be suspended, or possibly delisted.

Notably, the FCPA only applies to bribery of foreign government officials to gain or retain business and is normally prosecuted not on actual evidence of bribe payments – but rather on the lack of appropriate books and records and proper accounting for the illegal payments. This is particularly relevant in China given the common lack of transparency in business transactions and less than complete or meaningful business records to support corporate payments. It becomes even more murky and ambiguous in the healthcare, medical device, and pharmaceutical sectors given the significant use of distributors, agents, and other third-parties that are viewed as an extension of the company under the law but typically do not have the internal controls in place to adequately maintain their own books and records to the standard required by the FCPA.

<sup>100</sup> China regulates gift cards to prevent corruption, 25 May 2011, [www.Gov.cn](http://www.Gov.cn)

<sup>101</sup> A foreign corrupt Practices Act with Chinese Characteristics, 1 May 2011, [www.chinasignpost.com](http://www.chinasignpost.com)

<sup>102</sup> China's Efforts to combat Corruption and Build a Clean Government, 29 December 2010, [www.chinadaily.com.cn](http://www.chinadaily.com.cn)



## How KPMG can help — a business strategy

For pharmaceutical companies, implementing adequate measures to counter corruption and bribery and eradicating costs associated with such practices should be a fundamental norm. Corruption charges can damage a firm's reputation, add significant ongoing costs, impair overseas expansion plans and cripple staff morale.

Companies unable to demonstrate a track record of compliance with anti-bribery or anti-corruption legislative and regulatory requirements may have difficulty seeking audit or regulatory approval necessary for public listing and may limit or debar them from public contracts. Adherence to anti-corruption practices not only adds value to a company's reputation; it also extends tangible and intangible benefits in terms of cost efficiency and brand leadership.

It is a business imperative for companies to develop strong anti-bribery and anti-corruption policies given the increasingly stringent legislation either in place or being developed by various governments across the globe. The reach of such legislation, too, may affect various individuals and/or a company as a whole, irrespective of the country in which the business is operating, and the country of origin of such legislation.

KPMG can help companies navigate the current regulatory environment while maintaining profitability and adhering to their ethical standards and value systems in three principal ways:

**Compliance:** Providing practical and cost effective advice to companies looking to develop compliance strategies that will allow them to operate profitably and ethically around the world.

**Due diligence:** Providing targeted due diligence in pre- and post-acquisition phases of investments and in support of organic growth strategies to enhance knowledge and comfort relating to business partners and operations, and to identify, mitigate, and remediate regulatory compliance risks.

**Investigations:** Providing customized approaches to understanding the specific facts and circumstances pertaining to issues or allegations raised through internal or external channel (e.g., whistleblowers), and working with the company and its legal advisors to respond to regulators' and other third-parties' request for information in administrative, civil, or criminal proceedings.

### **A call for transparency**

As governments continue to focus their efforts on reducing corruption both at home and abroad, a company's level of compliance with anti-corruption or anti-bribery legislation will inevitably be reflect in its shareholder value.

Companies that fail to implement such policies or measures to mitigate corruption and bribery, decline to comply with such legislation or neglect to propagate a transparent track record of such compliance, do so at their own peril.

Although newly enacted, with an effective date of 1 July 2011, the UK Bribery Act is already being touted as even more stringent than most countries' domestic anti-bribery laws, and has a scope that exceeds that of the FCPA and extra-territorial reach that will affect any corporation with a "close connection" to the United Kingdom.<sup>103</sup> The UKBA's offenses includes commercial bribery as well as bribery of foreign officials; carries with it severe criminal consequences for individuals and corporations including potential debarment from all European Union public contracts; and has only one corporate defense – Adequate Procedures. The UKBA has yet to be tested but the UK government has persistently advised that it intends to enforce the Act starting on its effective date – 1 July 2011.

Monetary penalties and potential debarment aside, the negative publicity and brand damage associated with non-compliant activity, particularly for publicly listed companies, makes compliance with domestic and foreign anti-bribery laws a business imperative. In many companies where a compliance culture is thriving the bottom line improves because the cash leakages are plugged or significantly reduced through adequate monitoring, investigation, and remediation of non-compliant behavior.

Compliance provisions will go a long way in redefining China's own quality chain due to more on-the-spot inspections. For instance, the Bulk Pharmaceutical Task Force of the Society for Chemical Manufacturers and Affiliates (SOCMA) and the European Fine Chemicals Group (EFCG) of the European Chemical Industry Council (CEFIC) are calling on the US Food & Drug Administration to mandate inspections of foreign active pharmaceutical ingredient manufacturing sites.

The FDA has been unable to keep up with globalization of the drug industry, as a result, inspections in high-risk regions like China and India are much less stringent when compared to the US and Europe. Both SOCMA and EFCG have indicated a willingness to pay fees for these inspections when performed on their member-owned facilities that are located outside the United States. (SOCMA and EFCG urge for reform in FDA inspections of foreign drug-manufacturing facilities, Mar 17, 2011, InPharma). Such inspections will compel Chinese companies to measure up to international standards and streamline their own manufacturing.

### 3.3 Mergers & acquisitions, a winning formula

As pharmaceutical companies struggle with the pending loss of patent protection on their popular drugs, different business strategies have taken shape to deal with the crisis. Mergers and acquisitions and partnerships are highways on an essential but tricky roadmap. China now ranks as one of the most attractive M&A destinations for foreign drug-makers in Asia from the perspectives of cost, risk and market opportunity.

Multinationals tend to team up with domestic medicine producers to expand scale. Companies penetrating the China market have tended to acquire local manufacturers and generics firms that provide a quick, cost-effective point of entry from which to launch more expensive, branded products. Since late 2009, there has been a strong recovery in mergers and acquisitions after the global financial crisis eased in Asia.

#### Sample M&A transactions in China in 2010

Buyer	Seller	Amount	Comments
GSK	Nanjin Meirui Pharmaceutical company	USD70M	GSK will enlarge the China drug market through M&A
Sanofi	Minsheng Pharma	n/a	OTC drug market
Nycomed	Guangdong Tianpu pharma	USD214M	51.34% stock for entering the market in China and set the relationship with Shanghai Pharma (the stockholder of Tianpu)
Sanofi	BMP	USD520M	OTC drug market
Shanghai Pharma	China Health System Ltd	RMB2.328 (USD339M)	65.24% stock for market consolidation
Shanghai Pharma	Xinya pharma	RMB1.48B (USD217M)	Expand production line and enhance distribution

Source: Giant CRO Ltd.

<sup>103</sup> The new UK Bribery Act 2011, June 2011, www.british-legal-centre.com

Foreign enterprises such as Abbott, Bayer HealthCare, Roche, GSK, Sanofi, Pfizer and Novartis have greatly expanded their businesses in China over the years and 'aligning with locals' has turned out to be a winning strategy for them, as well as local drug-makers.<sup>104</sup>

Acquisitions have been taking place in all kinds of companies — from manufacturers of generics to those making extremely specialised drugs to distribution firms. The start of 2011 has seen some significant deal activity involving big pharma in China.

Pfizer has signed three deals with a China focus in 2011. The first was with Shanghai Pharmaceutical for the distribution and marketing of Pfizer products in China. The partnership is intended to leverage both companies' strengths, matching Pfizer's global capabilities in developing innovative medicines with Shanghai Pharmaceutical's distribution network in the China market.<sup>105</sup> Pfizer's second deal was with Daiichi Sankyo for the co-promotion of the latter's olmesartan medoxomil in the country.<sup>106</sup>

Other global companies have been busy, too. Merck KGaA acquired Beijing Skywing Technology, a leading provider of cell culture media products and bioreactors for the Chinese biopharmaceutical industry. The acquisition allows Merck to quickly establish a presence in this market segment in China. Novartis acquired an 85 percent stake in Zhejiang Tianyuan Bio-Pharmaceutical — a fast-growing developer, producer and distributor of bio-pharmaceutical products in China.

GlaxoSmithKline is taking over Nanjing MeiRui Pharma for USD 70 million. Sanofi bought BMP Sunstone Corporation, a Beijing-based specialty pharmaceutical company, for about USD 521 million, the largest M&A deal in China's pharmaceutical industry.<sup>107</sup> In March 2011, research-based Japanese drug firm Takeda teamed up with China Medical City in Taizhou to make a significant investment to build R&D,

manufacturing, and marketing facilities in China.

More significantly, multinationals are starting to trust local companies with production. In the niche sector, Nasdaq-listed SciClone Pharmaceuticals acquired NovaMed Pharmaceuticals, a China-based specialty pharmaceutical company in April 2011. NovaMed, backed by foreign venture capital, has a portfolio of 18 drug products spanning major therapeutic areas including oncology, cardiovascular disease, central nervous system disorders and urology/infection. SciClone stated the acquisition would give it a formidable sales and marketing network, nearly 20 commercial stage products and an expanded Shanghai-based management team with significant pharmaceutical industry experience.<sup>108</sup>

Yet another trend is the practice of large companies to go in for unconventional acquisitions. Rather than focus on traditional mergers that lift gross margins and cost savings, a number of enterprises prefer to buy firms that have unique uses for drugs. The industry now feels there is a better business model in zeroing in on the end customer rather than on bulk manufacturers of generics.<sup>109</sup>

Moreover, heavyweight Chinese companies are also wooing multinationals with a vengeance. Shanghai Pharmaceutical announced in April 2011 that it will ink more than RMB 20 billion worth of procurement contracts with 69 multinational pharmaceutical companies in 2011. The overseas drug makers involved include giants such as Pfizer, Sanofi, Merck and Novo Nordisk. Their contracts are estimated to account for about 60 percent of Shanghai Pharmaceutical's total procurement of medicines and medical devices in its domestic pharmaceutical distribution business.<sup>110</sup>

**Anti-monopoly hitch for foreign firms:** Although the Chinese government welcomes Western investment in pharmaceuticals, the road is not always easy for aggressive

104 M&As in Asia Pacific remain steady: July 2010, BioPharma

105 Pfizer and Shanghai Pharmaceutical sign MoU for potential strategic partnership, 8 May 2011, 4-Traders

106 Big pharma increases activity in China, 2 May 2011, Partnering News

107 China lures global drug makers, 20 September 2010, Reuters

108 SciClone acquires NovaMed Pharmaceuticals, 19 April 2011, MarketWire

109 Novel M&A paths gain acceptance, 4 April 2011, Reuters

110 SH Pharma inks \$20 bln in deals, 14 April 2011, Global Times

## How KPMG can help: Focus on integration

It's been a busy decade for pharma deal-making. In the 10 years up to 31 December 2009, a total of 1,345 mergers and acquisitions of pharmaceutical assets and companies were announced. Disclosed prices totalled more than USD 694 billion, according to DealSearchOnline.com.<sup>111</sup>

Many of the leading global R&D pharmaceutical companies have established a significant footprint in China and are constantly on the lookout for solid M&A targets to increase revenue/growth rates, enhance product portfolio and to expand routes to market.

While in general multinational companies have increasingly come to appreciate the importance of sound integration planning — and strong implementation of an integration plan to help capture value in a transaction — the pharmaceutical industry presents a unique set of challenges, including, but not limited to:

- sustaining the target company's revenue growth
- leveraging and/or augmenting the target company's current and pipeline drugs
- ensuring compliance with anti-corruption legislation – FCPA in the US, the Bribery Act in the UK etc.

In order to manage the above complexities, KPMG recommends companies consider:

- performing an issue-driven commercial and operational due diligence on the target company before closing the deal to identify the issues as early as possible
- developing an integration programme that focuses on risk mitigation, synergy identification and realisation, and value creation.

players. There is a risk of multinationals running into the 2008 PRC Anti-Monopoly Law that regulates all M&As — domestic, as well as cross-border.

Under this law, Pfizer had to sell its Chinese swine-vaccine business to a subsidiary of a Harbin Pharmaceutical Group in 2010. The transaction was done to comply with a Ministry of Commerce (MofCom) anti-monopoly review of Pfizer's merger with Wyeth. The ministry determined that the combination of the two US pharmaceutical makers would leave the merged firm in control of nearly half the Chinese market for certain swine vaccines, a lucrative niche in a country with many pig breeders.<sup>112</sup> The Pfizer deal is believed to be the first in which China required divestment of a local business.

Authorities have made it clear that the Anti-Monopoly Law of 2008 is not intended to excessively interfere in international M&A transactions. The trend in fact has been for China to align its approach with international practices

and remain open to foreign investment. However, the fundamental principle is that foreign investment is expected to contribute something new. If nothing new is to be contributed, that is, if the investment is purely for 'speculative' purposes, then the investment may not be approved.

### 3.4 Innovation gains industry attention

Although China has enjoyed the benefits of an expansive market for pharmaceutical production, the industry suffers from minimal innovation and investment in research and development. The 2009 health reform plan aims to correct this with the government encouraging foreign companies to bring in capital, state-of-the-art research and training of personnel.

Of late, China has been at the centre of a trend for the globalisation of research, a slow shifting away from countries like the US that have dominated the research scene for the past 40 years.

<sup>111</sup> quoted from <http://www.fiercepharma.com/story/pharma-m-10-years-1-345-deals-694b/2010-03-26>

<sup>112</sup> Pfizer deal highlights China's clout, 29 May 2010, Wall Street Journal

China's overall R&D investments are growing at a rate that closely matches the country's 9 percent to 10 percent annual economic growth. This means that in dollar terms the growth in China is roughly the same as that in the US — about USD 10 billion per year.<sup>113</sup>

The 2008-2009 recession helped level the distribution of global research. Emerging nations like China were less affected by the recession and could continue to invest in their R&D infrastructures at relatively high levels. Many multinational companies opted for basing some of their operations here.

In June 2010, China's State Food and Drug Administration asked domestic pharmaceutical companies to increase their investment in R&D in order to remain competitive. The government, for its part, plans to invest USD 1.5 billion in new drug development between 2011 and 2016.<sup>114</sup>

**Holistic strategies:** Another approach adopted by multinationals is the research and sale of drugs that tackle entire lifestyle issues rather than simply marketing medication for specific diseases.

Novo Nordisk has displayed remarkable success with its strategy to market insulin. Its plan was to enter the diabetes market in China not just with products but with a long-term, comprehensive approach to patient care and education of physicians and patients that focused on managing diabetes effectively.

Novo recognised that it could only achieve this level of change and strengthen China's healthcare system by working together with a wide variety of stakeholders, including the Chinese government and physicians. They built diabetes clinics, invested in community diabetes prevention programmes, and launched several public-private initiatives in partnership with the Chinese Ministry of Health to develop diabetes guidelines, training, and health systems integration.

Today, China is the third biggest market in Novo Nordisk's business and the second largest insulin market. In 2010, Novo Nordisk had 63 percent of the insulin market in China.<sup>115</sup>

**Partnership approach:** Drug companies are exploring every resource in China to strengthen and increase the relevancy of their research. Collaborations between multinationals and local universities are on the rise, signifying a partnership approach to drug R&D.

Johnson & Johnson has collaborated with Tsinghua University to tackle diseases like hepatitis B, tuberculosis and bird flu and this has paved the way for new therapies.<sup>116</sup>

Scientists from the University of Bradford in the UK, and Jilin University and the Shanghai Institute of Materia Medica in China are working with Chinese scientists to carry out innovative research and deliver a new product with a potentially huge health benefit to millions of people.

At least 3.3 billion people — half of the world's population — are at risk of malaria, with about 250 million new cases each year and nearly one million deaths, mostly in the developing world.<sup>117</sup> Artemisinin, based on TMC, is the leading treatment on the market to combat malaria, but a more effective form of the drug is urgently needed.

In another instance, the National Center for Drug Screening, affiliated with the Shanghai Institute of Materia Medica, is opting for an innovative drug discovery model that involves scientists and partners in developing and developed countries. According to the scientists, this is a new process, collaboration not only at the multinational level but with different partners.

The Center provides a wide-range of drug screening services and technical consultation to universities, research institutions and pharmaceutical companies across China. Using a donated

113 2011 Global R&D Funding Forecast: The Globalization of R&D, 15 December 2010, R&D

114 China readies \$1.5B plan to bolster biotech, 10 August 2010, Pharma News

115 Novo Nordisk's Blueprint for Changing Diabetes in China, 13 April 2011, The Business of a Better World

116 Companies face accusations of exploiting rare disease price structures, December 2010, Reuters Health e-line

117 Grass looking greener for malaria patients in UK-China joint research, 5 October 2010, ScienceDaily

library of chemical compounds and the associated database from Novo Nordisk's Copenhagen base, the Center is tackling diseases prevalent in Africa, such as malaria, tuberculosis, African sleeping sickness, dengue fever, Chagas disease, leishmaniasis, schistosomiasis and filariasis.<sup>118</sup>

**Bio-medical clusters:** With most multinationals now aware of the advantages of investing in research in China, the top 10 foreign drug companies are either building R&D centres or renting space for research operations. Research facilities have received government support in the form of dedicated parks.

Park features ranging from proximity to suppliers and customers to tax and rental incentives can help businesses grow along with China's medical industry. Most of the bio-medical parks have made large investments in infrastructure, including first-rate buildings and advanced equipment and instruments.<sup>119</sup>

US and European drug makers have invested more than a billion dollars since 2009 in building R&D and manufacturing capabilities tailored to local needs.

Companies like Bayer and Merck see China as a combination of a growing and increasingly affluent market and an ideal research facility for the vast array of health problems.

GSK and Johnson & Johnson have also been operating domestic drug research facilities, with Shanghai emerging as an important destination for long-term investments by foreign players.

Pudong Zhangjiang Hi-Tech Park in Shanghai has attracted Roche, GSK, Beecham, Boehringer Ingelheim, Medtronic, Nycomed and other multinational pharmaceutical companies. GSK has unveiled a 10-year plan to establish one of its largest research centres in Shanghai. While GSK intends to draw upon local talent, it also plans to recruit between 50 and 100 top international scientists and employ more than a 1,000 researchers at the new facility by 2017.

US-based Genzyme is the latest biopharmaceutical company to increase its presence in China. The firm has a USD 100 million R&D facility in Beijing which will house 350 researchers specialising in chemistry, biology and pharmacology. The company will recruit local scientists recruited and strive to develop therapies tailored to the regional population. Completion of the plant is expected by 2012.

## Emerging trends in the pharmaceutical industry — Innovation

Innovation:

- 2010-2015: CNY10 billion in investment is earmarked for the biopharma sector.
- IPR protection is improving but enforcement remains an issue
- China ranked number one in patent-filing in 2010.

Innovation:

- Policy driven — such as numerous tax incentives to attract multinationals.
- Talent pool — 5 million new graduates available in China.
- Industrial park and bio-tech clusters set up by local governments.

## R&D centers on the rise in China

Company	R&D location	Details
Pfizer	Southern	Set up in an industrial park
Roche	Eastern	Focuses on cancer
Novartis	Eastern	Focuses on bio-tech
Bayer	Northern	R&D center covers four big main businesses: heart disease, women's diseases, diagnostic imaging and cancer
GSK	Northern & Eastern	Shanghai has a R&D focus
AstraZeneca	Eastern & Southern	Both R&D centers focuses on clinical medicine
Sanofi	Northern & Eastern	Positioned Shanghai as the ASPAC R&D center, setting up co-study center with universities in Beijing
Johnson & Johnson	Eastern	Cooperates with local companies
Merck	Eastern, Southern & Northern	Cooperates with local companies and hospitals
Eli Lilly	Eastern	Founded an R&D center in Shanghai and also cooperates with other local companies

Source: Giant CRO Ltd.

<sup>118</sup> TDR and China initiate new drug discovery research training, 27 July 2010, TDR enews

<sup>119</sup> Bio-Medical Parks in China Reach Out to Pharmaceutical Investors, 6 August 2010, RightSite.Asia



### 3.5 Funding options and fiscal incentives

China offers a combination of cheaper labour and laboratory set-up costs, as well as strong government incentive programmes to support and foster the domestic pharmaceutical and biotechnology industry. These incentives include tax relief as well as direct funding opportunities.

China's last incentive plan was offered and implemented in 2008.<sup>120</sup> Effective January 1, 2008, the new Corporate Income Tax (CIT) Law and other regulations provided tax incentives/schemes to encourage R&D activities in China. R&D centres which provide research services to overseas companies can enjoy preferential income tax rates and turnover tax exemptions. Manufacturers of pharmaceutical products are also eligible for a reduced income tax rate if they qualify as an 'Advanced and New Technology Enterprise.' The key

<sup>120</sup> Can an R&D tax credit expand investment in product development for global health? 28 February 2011, Center for Global Health R&D Policy Assessment



income tax incentives available to pharmaceutical companies carrying out research in China are included the High/ New Technology Enterprise (HNTE) incentive.

The criteria for qualifying as an HNTE include ownership of core proprietary intellectual property rights and having products/ services which fall under the scope of "encouraged" domains. Enterprises that qualified as HNTEs are entitled to a reduced CIT rate of 15 percent compared with the standard CIT rate of 25 percent. In addition to the reduced tax rate, newly established HNTEs in the Five Special Economic Zones (Shenzhen, Hainan, Zhuhai, Xiamen, and Shantou) and the Pudong New Area within Shanghai can enjoy a tax holiday of two years' full exemption followed by three years of a 50 percent reduction in CIT.

Under the 'CIT super-deduction', companies are also allowed an extra 50 percent expense deduction for eligible R&D costs, including expenses incurred through the development of new technology and products, salary expenses for R&D personnel, and the depreciation of instruments and equipment used for research purposes.

Companies can also avail themselves of an income tax exemption for the transfer of technology. The portion of income derived from the transfer of technology during a tax year not exceeding RMB 5 million can be exempt from CIT. The portion exceeding RMB 5 million is eligible for a 50 percent reduction in CIT.<sup>121</sup>

#### **Venture capital and IPO options :**

Spurred by prospects of massive growth in the pharmaceutical sector, healthcare companies are increasingly attractive to domestic and foreign venture capital (VC). Despite their size, the 'go-it-alone' power of domestic companies is limited. If they are to be globally competitive, as many of them aspire to be, access to funding is imperative.

China's pharmaceutical sector can be broadly classified into three categories: firms that are backed by the government with strong financial support, forming 30 percent of the market; joint ventures and foreign companies with 60 percent of the market; and relatively small companies that have been spearheading R&D and have attracted venture capital.<sup>122</sup>

Despite the potential, healthcare venture capital investment has remained modest until now. Investments to date have focused on relatively lower risk areas, such as clinical research, manufacturing and distribution companies. In 2009, 47 transactions took place in the healthcare sector; aggregating USD 416 million, or contributing 11 percent more than in 2008.<sup>123</sup>

Venture capital owners are optimistic about China's pharmaceutical prospects but the industry should look to vigorously implement strategic restructuring of its enterprises. Such enterprises should become wholly owned listed companies and shut down units to eliminate losses.

Domain Associates, one of the most active US healthcare venture firms, is scouting opportunities in China. Its first investment was made in Eddingpharm,



<sup>121</sup> Investing in China's pharmaceutical industry, 2nd Edition, PwC

<sup>122</sup> M&A Analysis and Research Report on Pharmaceutical Industry of China in 2010, Asia Consulting

<sup>123</sup> China Booms: The New Superpower, September 2010, BioSpectrum

## How KPMG can help: Challenges of the tax environment

Tax considerations are an important aspect for multinationals extending their footprint into China. Various incentive policies have been provided to the pharmaceutical industry, much of it geared to encourage multinationals to shift more of their business functions into China.

Despite the attractiveness of various favourable tax treatments, multinationals should address the challenges posed by tax authorities on transfer pricing arrangements between related parties on cross-border transactions. The new transfer pricing documentation rules require a company's management to develop and maintain detailed information on the transfer pricing strategy and justify the reasonableness of the transfer price.

With tax and customs officials becoming increasingly aware of transfer pricing risks, foreign-invested

pharmaceutical companies in China should be well prepared for audit by the authorities.

Tax authorities have identified the pharmaceutical industry as a major target for audit exercises. Their audit focus would cover different sectors within the industry, such as R&D, manufacturing, distribution and logistics.

In order to eliminate potential exposure, companies should document their compliance with the requirements in China. In particular, supporting vouchers and accounting records should be consistent and well documented to substantiate the validity of the business transactions. Sales rebates, commissions, meeting and conferences, and advertising and promotional expenses, are some of the key areas which are most likely to be reviewed under a tax audit.

a Shanghai-based company focused on medical-nutrition products and cancer therapies. It teamed up with OrbiMed Advisors and Sequoia Capital to provide USD 24 million in Series B financing to Eddingpharm (Cayman) Inc. The firm intends to use its connections to help Eddingpharm forge deals with US drug companies looking to enter the Chinese market.<sup>124</sup>

Pharma retailer and distributor China BCT Pharmacy secured a USD 30 million investment from Milestone Longcheng, a private equity firm, to fund drugstore acquisitions in the Guangxi Zhuang Autonomous Region and neighbouring provinces.<sup>125</sup> The Influx of foreign venture capital is expected to play a positive role in improving the technical level, management, products, corporate ownership structure and industrial structure.<sup>126</sup>

**Funding future lies in IPO:** The local pharma industry should now create a virtuous circle for raising capital. The industry should expand its channels for financing operations including venturing into the capital markets more often.

Chinese companies are increasingly looking at IPOs for funding. Shanghai Fosun Pharmaceutical, already listed in Shanghai, plans to float shares on the Hong Kong Stock Exchange. This is intended to make the company globally competitive and increase the company's financing channels.<sup>127</sup>

Fosun Pharma's Hong Kong IPO reflects the domestic industry's trend toward making strategic adjustments in order to become more internationally competitive. In December 2010, it announced the formation of a joint venture to explore the domestic medical-device market with Chindex International, a leading independent US-based provider of Western healthcare products in China. Fosun will hold a 51 percent stake.

Shanghai Pharmaceuticals, now listed on the Shanghai exchange, plans to raise funds from Hong Kong, too, in order to extend its capital base for its M&A plans.<sup>128</sup> China's securities regulator has approved a plan by Shanghai Pharmaceuticals Holding to issue up to 763.8 million H shares in an initial public offering in Hong Kong.

China NT Pharma Group, a major vaccine and pharmaceutical product distributor in China, launched an IPO in Hong Kong in April 2011. About 25 percent of the IPO proceeds will be used to expand the distribution network through organic growth and also by acquiring other vaccine supply chain service providers. Since 2008, the company's revenue has grown at a compound annual growth rate of 37.4 percent.<sup>129</sup> The company will spur growth along two tracks: network expansion and product diversification.

124 Domain Associates Tiptoes Into China, 22 September 2010, Venture Capital Dispatch, Wall Street Journal

125 BCT Pharma clinches \$30 million private equity investment, 19 January 2011, Interfax

126 Foreign venture capital bullish on China's pharmaceutical industry, Business Standard, 16 December

127 Fosun Pharma to float shares in Shanghai, 2 March 2011, China Daily

128 Regulator Clears Shanghai Pharma IPO Plan, 13 April 2011, Wall Street Journal

129 China NT Pharma Group seeks HK\$2.14b from IPO, 4 April 2011, China Daily

## How KPMG can help: the IPO process opens funding options

From Hong Kong to New York, Chinese drug companies are venturing out to get themselves listed. Local enterprises now want to buy up domestic and foreign drug producers and expand their sales networks as widely as possible. IPOs are becoming an increasingly popular instrument to raise funds to expand operations.

### Benefits of launching an IPO

- Access to capital for growth - Opportunity to raise funds both at the time of listing and at later stages
- Broader shareholder base - Potential to tap into a more liquid market by trading a company's shares
- Employee incentives and commitment - Granting options to the company's key staff can prevent attrition
- Greater visibility and profile - An IPO has the potential to generate confidence among the company's customers and suppliers

- Increased corporate transparency - Possibility of getting more credit at competitive terms from the company's bankers
- Greater efficiency and transparency - Rigorous disclosure standards that are required of listed companies should lead to more efficient information systems and to improvement in the information management and operating systems of companies

### KPMG's role in initiating an IPO

- Senior management should focus on the strategic elements of the IPO process where its input is critical. They should not underestimate the time required of senior management, especially while marketing the IPO with the help of roadshows to institutions.
- KPMG offers multi-disciplinary teams with extensive experience in capital market requirements, accounting and financial reporting. Our team can help with a coordinated, global approach to an IPO.





# Conclusion: Incubating a healthy future

Combining market-driven policies with state control, China has improved the health status of its population – lowering mortality rates and increasing life expectancy over the years. Much, however, remains to be done as health services still remain inaccessible to large sections of society.

The radical healthcare reform of 2009 and the 12th Five Year Plan gave a final push to the modernisation of China's health structure, with a focus on hospital reform, an essential medicines system and basic insurance coverage.

This ambitious quest for universal healthcare by 2020 requires vast mobilisation and upgrade of the pharmaceutical industry and provides immense opportunities for domestic and foreign companies to fill in the quality and quantity gaps along the entire value chain.

The Chinese government remains determined to transform the industry from a generic drug-focused sector to an innovation-driven drug development powerhouse. Securing pharmaceutical supply lines, funding research, eliminating bottlenecks in distribution and making drug quality compatible with global standards remain essential targets for China.

Sensing significant growth opportunities, most multinationals are in the process of extending their footprint in China, concentrating on prescription and high end medicines, research and better distribution networks. Domestic companies, on the other hand, are building on their generic strength and extensive distribution networks to cater to a growing and more affluent market. Chinese outsourcing companies, too, have carved a niche for themselves, becoming essential extensions for 'big pharma.'

Along with quality, innovation and affordability, the focus on biotechnology and the modernisation of traditional Chinese medicine are key drivers of growth, creating virtually endless possibilities from the combination of the best of the East and the West.

Over the next few decades, China has the potential to become as one of the leaders of the pharmaceutical world. With every big company in the sector focusing on this region as a source of growth, the country is likely to play an increasingly significant role in the way drugs are invented, tested and perhaps even regulated.





# Acknowledgements

This report was developed by KPMG's China Pharmaceutical team, with contributions from a number of KPMG subject matter experts. We gratefully acknowledge the following team members who contributed their knowledge, experience and administrative support for this report – Grace Xie, Miguel Montoya, Brian Wilson, Jason Lin, Candice Zhang, Henry Ngai, Tina Liao, Joicy Zhang, Vibhash Ranjan, Merry Newman, Joanna Wells, Limin Tang, Malcolm Parker, Dong Mei and Nick Lindsey. In particular, we thank Harry Law and Suranjana Roy Bhattacharya who wrote and edited the majority of this report.





## KPMG's Global Pharmaceuticals Practice

### Ed Giniat

Global Chair,  
Pharmaceuticals Practice  
T: +1 312 665 2073  
E: [eginiat@kpmg.com](mailto:eginiat@kpmg.com)

### David Blumberg

Global Advisory Leader,  
Pharmaceuticals Practice  
T: +1 267 256 3270  
E: [dblumberg@kpmg.com](mailto:dblumberg@kpmg.com)

### Frank Mattei

Global Tax Leader,  
Pharmaceuticals Practice  
T: +1 267 256 1910  
E: [fmattei@kpmg.com](mailto:fmattei@kpmg.com)

### Chris Stirling

European Chair,  
Pharmaceuticals Practice  
T: +44 20 7311 8512  
E: [christopher.stirling@kpmg.co.uk](mailto:christopher.stirling@kpmg.co.uk)

### Norbert Meyring

Asia Pacific Chair,  
Pharmaceuticals Practice  
T: +86 (21) 2212 2707  
E: [norbert.meyring@kpmg.com](mailto:norbert.meyring@kpmg.com)

### Merry Newman

Global Executive  
Pharmaceuticals Practice  
T: +1 201 505 3599  
E: [mnewman@kpmg.com](mailto:mnewman@kpmg.com)

### Peter Fung

Partner in Charge  
Industrial Markets  
KPMG in China  
T: +86 (10) 8508 7017  
E: [peter.fung@kpmg.com](mailto:peter.fung@kpmg.com)

### Andrew Weir

Asia Pacific Chair  
Infrastructure, Government &  
Healthcare  
T: +852 2826 7243  
E: [andrew.weir@kpmg.com](mailto:andrew.weir@kpmg.com)

### Khoonming Ho

Partner in Charge, Tax  
KPMG in China  
T: +86 (10) 8508 7082  
E: [khoonming.ho@kpmg.com](mailto:khoonming.ho@kpmg.com)

### Ning Wright

Partner, Advisory  
KPMG in China  
T: +86 (21) 2212 3602  
E: [ning.wright@kpmg.com](mailto:ning.wright@kpmg.com)

### Mark Bowra

Partner, Advisory  
KPMG in China  
T: +86 (21) 2212 3883  
E: [mark.bowra@kpmg.com](mailto:mark.bowra@kpmg.com)

### Ricky Wong

Partner, Advisory  
KPMG in China  
T: +86 (20) 3813 8833  
E: [ricky.wong@kpmg.com](mailto:ricky.wong@kpmg.com)

[kpmg.com/cn](http://kpmg.com/cn)

The information contained herein is of a general nature and is not intended to address the circumstances of any particular individual or entity. Although we endeavour to provide accurate and timely information, there can be no guarantee that such information is accurate as of the date it is received or that it will continue to be accurate in the future. No one should act upon such information without appropriate professional advice after a thorough examination of the particular situation.

© 2011 KPMG Advisory (China) Limited, a wholly foreign owned enterprise in China and a member firm of the KPMG network of independent member firms affiliated with KPMG International Cooperative ("KPMG International"), a Swiss entity. All rights reserved. Printed in China.

The KPMG name, logo and "cutting through complexity" are registered trademarks of KPMG International.

Publication number: CN-IM11-0001

Publication date: May 2011