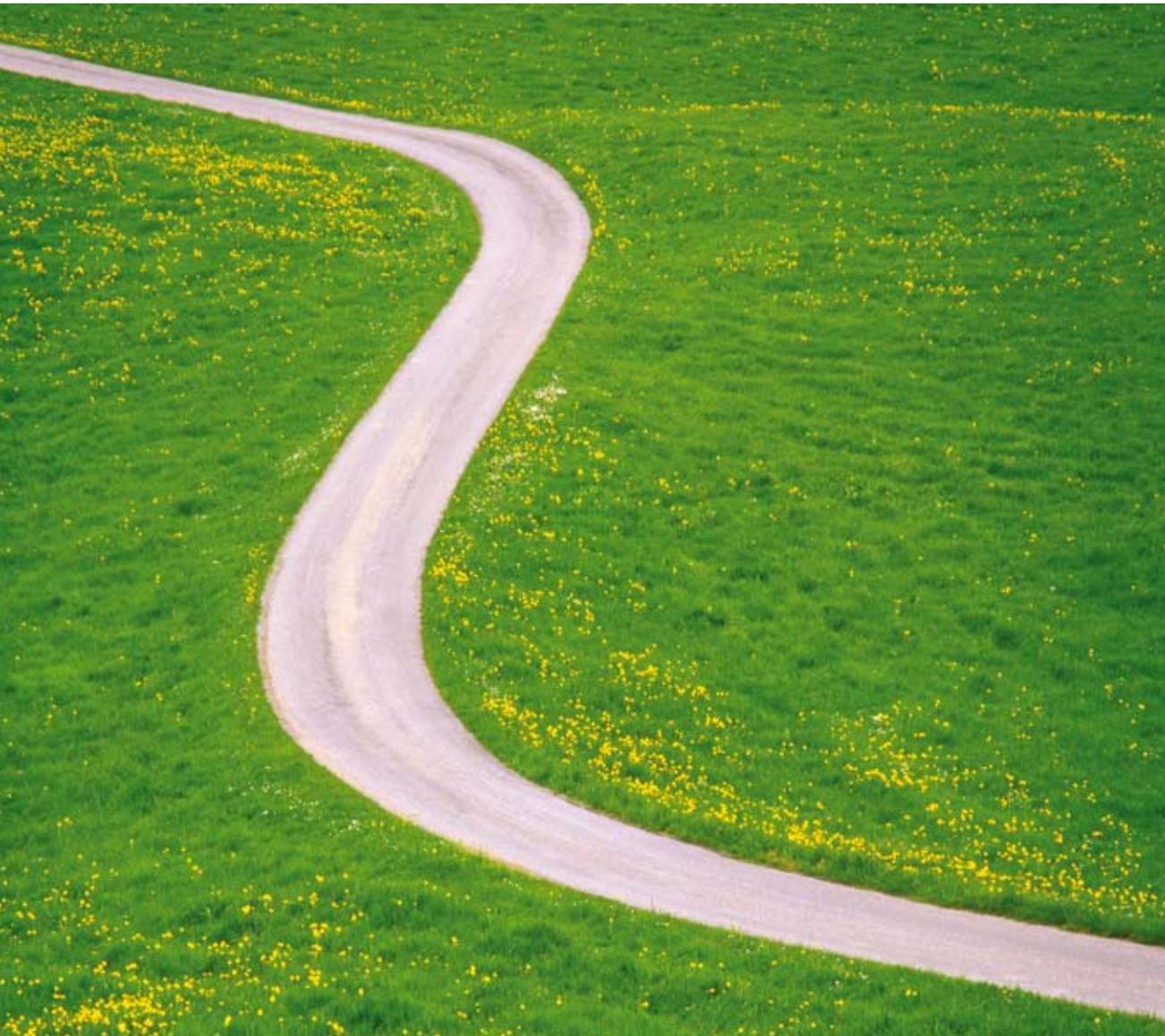


The next phase:
Opportunities in China's
pharmaceuticals market



Contents

1	Foreword
3	China's pharmaceutical market: summary and prospects
3	1. China's healthcare reform and 12th Five-Year Plan (2011–2015)
3	1.1 Healthcare reform overview
4	1.2 Latest developments
4	1.3 The 12th Five-Year Plan
5	2. Growing and distinctive Chinese pharmaceutical market
5	2.1 China's pharmaceuticals market expected to see strong growth overall
7	2.1.1 China has the largest elderly population in the world
8	2.1.2 Healthcare expenditures expected to grow rapidly over the next five years
11	2.1.3 Market opportunities are rising in rural and suburban areas
13	2.2 Generics expected to continue to dominate the market, but patented drugs expected to see significant growth
15	2.3 The OTC sector is expected to see steady growth with the improving health consciousness and promotion of self-medication
16	2.4 China's drug distribution industry continues to see consolidation
17	2.5 China has become one of the top options for global pharmaceutical companies to conduct R&D activities
18	2.6 The biotech sector has been targeted as a key development sector by the government
20	3. Regulatory regime and policy development
20	3.1 National authority & legislation
20	3.2 Drug registration, approval, and manufacturing
22	3.3 Advertising
22	3.4 Pricing
22	3.5 Reimbursement
23	4. Summary
25	M&A highlights
28	1. Domestic M&A surges as pharmaceutical players lead a new wave of consolidation
31	2. Inbound M&A activity making a gradual recovery
34	2.1 Inbound acquisitions
37	2.2 The due diligence challenge
38	3. Outbound M&A
38	3.1 Outbound M&A of China's LSHC industry: historical activity
38	3.2 Looking forward
39	3.2.1 Private equity interest in medical device manufacturers
39	3.2.2 Large-cap pharmaceuticals' expansion abroad
39	3.2.3 Outbound CRO M&A
40	4. China and India LSHC M&A: a giant competition or a giant opportunity?
41	Conclusion
42	Abbreviations
43	Contacts

Foreword



Business activity in the life sciences & healthcare (LSHC) sector in China is growing increasingly robust. Mergers and acquisitions activity is especially active, both domestically and from a cross-border perspective. Top international and domestic Chinese pharmaceutical companies, as well as a host of smaller players, are moving to secure market share along with drug and device development permissions and capabilities in the context of China's evolving regulatory regime. The prospect of greater protection for intellectual property is also a factor in the broader context of what is emerging as the world's next great market for patented drugs. Companies who might have hesitated before now see that China is moving past its phase as a supply market for ingredients and generic finished drugs, and on to a new phase as the world's second-largest LSHC market within this decade.

Organic market growth, driven by a combination of shifting age, wealth, and urbanisation demographics, is a second factor that has whetted the appetite of LSHC players. Many multinational players who have regarded China only as a source of raw materials or research are now contemplating China market entry. Others who have previously entered the market through joint ventures with Chinese companies and research institutes are now ready to ramp up their growth through drug licensing and acquisitions, where the right matches can be found. Key hurdles remain, among them discerning which targets have the desired capabilities, and which present unacceptable risks discoverable only through professional due diligence.

This report focuses in particular on pharmaceuticals companies, both domestic and foreign, and their activities in the China market—all from the viewpoint of prospective investors.

Yvonne Wu
Partner, Enterprise Risk Services
National Leader, Deloitte China Life Sciences and Health Care
Shanghai, China

China's pharmaceutical market: summary and prospects

China's pharmaceutical market: summary and prospects

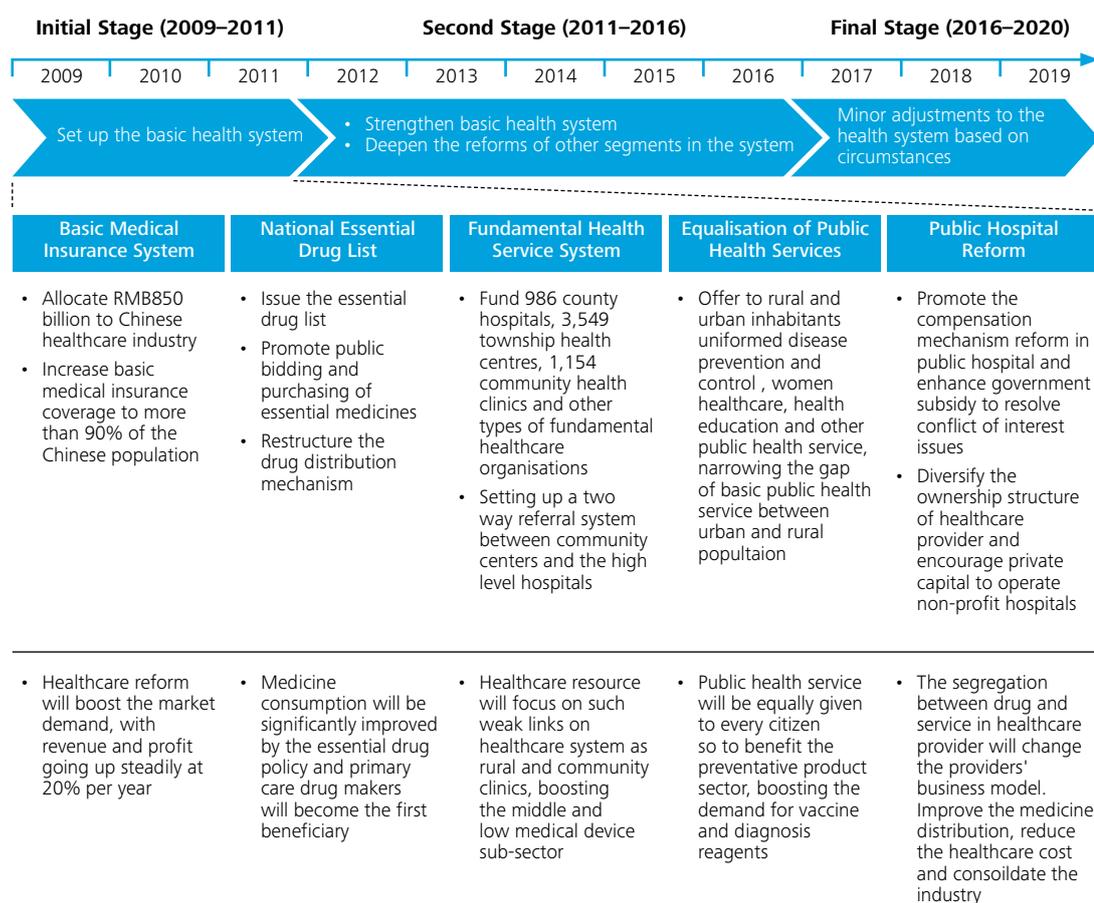
1. China's healthcare reform and 12th Five-Year Plan (2011–2015)

1.1 Healthcare reform overview

In March 2009, China's government revealed plans for a sweeping healthcare overhaul, and committed RMB850 billion to develop the country's healthcare system between 2009 and 2011. Among its provisions were to increase the Basic Medical Insurance (BMI) coverage from approximately 65 percent of the population to 90 percent by 2011;¹ to revise the national Essential Drugs List (the "EDL", medicines reimbursable under BMI); and to allow the National Development and Reform Commission (NDRC) to more strictly regulate pricing. A second phase of the healthcare reform plan, expected between 2011 and 2020, is to involve the establishment of a universal health care system by which all citizens will be able to access affordable drug and medical services.

The proposed plan, titled "*Opinions of the CPC Central Committee and the State Council on Deepening the Health Care System Reform*", is illustrated in the following chart (Figure 1).

Figure 1: Healthcare reform blueprint through 2020



Source: Ministry of Health (MOH), Deloitte Analysis

¹ The State Council of People's Republic of China, *Opinions of the CPC Central Committee and the State Council on Deepening the Health Care System Reform*, April 2009.

1.2 Latest developments

By 2010, the number of urban and rural residents covered by the basic medical insurance scheme had reached 1.26 billion.² According to the 2011 work plan for healthcare reform released by the State Council in February 2011, the maximum reimbursement for urban residents will reach six times their annual disposable incomes in 2011, and no lower than RMB50,000, while annual medical treatment allowances for both urban and rural residents will rise to RMB200 *per capita per annum* from the current RMB120 *per capita per annum*.³

Furthermore, funds from the central government have been allocated to the upgrading and construction of nearly 900 county-level hospitals, 1,620 township health centers, 1,228 urban community health service institutions, and 11,250 village clinics in remote areas.

The public hospital reform, regarded as the most difficult task within the industry and the public, has also begun in 16 pilot cities, including Shanghai, Anshan, and Zhenjiang, to explore a mechanism for partitioning hospital operations and management, as well as separating the duties of medical drug prescriber and dispenser.

In January 2011, the Ministry of Health (MOH) announced the goal of reducing patients' contribution to their personal healthcare by 30 percent over the next five years. The MOH stated that lower drug prices would be the top priority of health authorities in 2011 in an effort to reduce patients' costs. Consequently, with effect from 1 September 2011, the NDRC reduced the prices of 82 drugs by an average of 14 percent, which was the 28th deduction in drug prices since the 1990s.

1.3 The 12th Five-Year Plan

In 2011, the government released its 12th Five-Year Plan (FYP)—the guidance for social, economic and environmental development for the country over the next five years. Like all plans before it, the Five-Year Plan and the objectives it sets will have far-reaching impacts, although it has no specific implication for any single industry itself. However, a few critical implications for Chinese pharmaceutical market can be understood most clearly by examining major themes of the Plan.

- Rising income projected will increase overall healthcare consumption, and the associated demand for high-quality healthcare services.
- Urbanisation and the upgrading of rural infrastructure (including healthcare facilities)—shifting urbanisation demographics will give rise to new pockets of demand for pharmaceuticals.
- As one component of a broader set of national goals to push industry consolidation and industrial advancement, pharmaceutical companies are encouraged to consolidate domestically, eliminating outdated and excessive capacity, solidifying market share and technologies to build their businesses.
- Pharmaceutical manufacturing and distribution may be shifted from the prosperous Eastern provinces to balance the development of Central and Western China.
- In the future, the sector will need significant investments in new and cutting-edge technologies and the know-how they need to grow, either by acquisition or in-house development, funding for which will be drawn from various sources.

China's healthcare reform and the 12th Five-Year Plan exert their influence on what is not only an enormous and growing market for pharmaceuticals, but one which bears its own unique characteristics and constraints.

² The Central People's Government of People's Republic of China, *Review of the Ongoing Progress of Health Care System Reform 2010*, February 2011.

³ Ministry of Health, *The regular press conference of the Ministry of Health on 10 June 2011*.

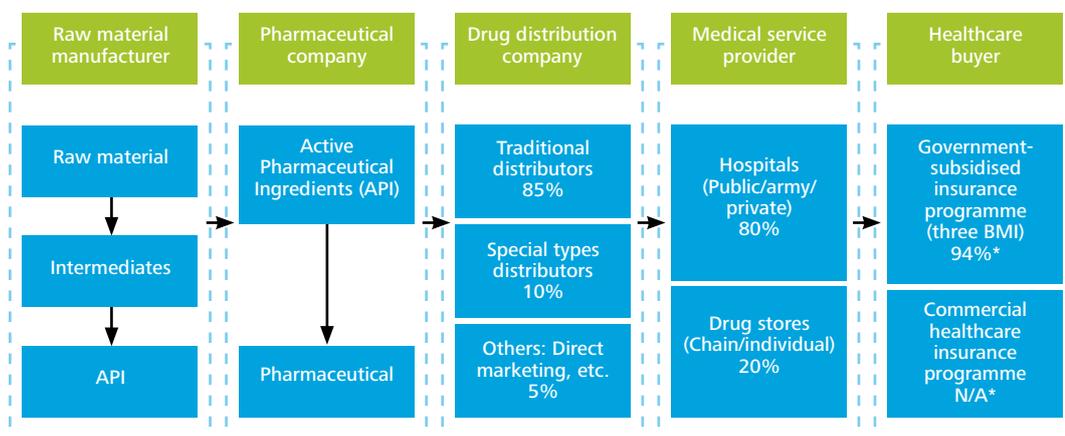
2. Growing and distinctive Chinese pharmaceutical market

China is one of the largest pharmaceutical markets in the world, but the status is arguably due to the size of its population, as the market is not yet mature. The combined forces of economic and demographic development, government stimulus, enhanced health awareness among the public, market consolidation, and improving R&D capability may help the country to grow into a more sophisticated market within the next decade.

2.1 China's pharmaceuticals market expected to see strong growth overall

Observers such as the Economist Intelligence Unit (EIU) and IMS Health are unanimously upbeat about the prospects for China's pharmaceutical market, and the view extends to all points along the value chain (Figure 2), although the growth pace for each one may vary slightly.

Figure 2: Chinese pharmaceutical industry value chain



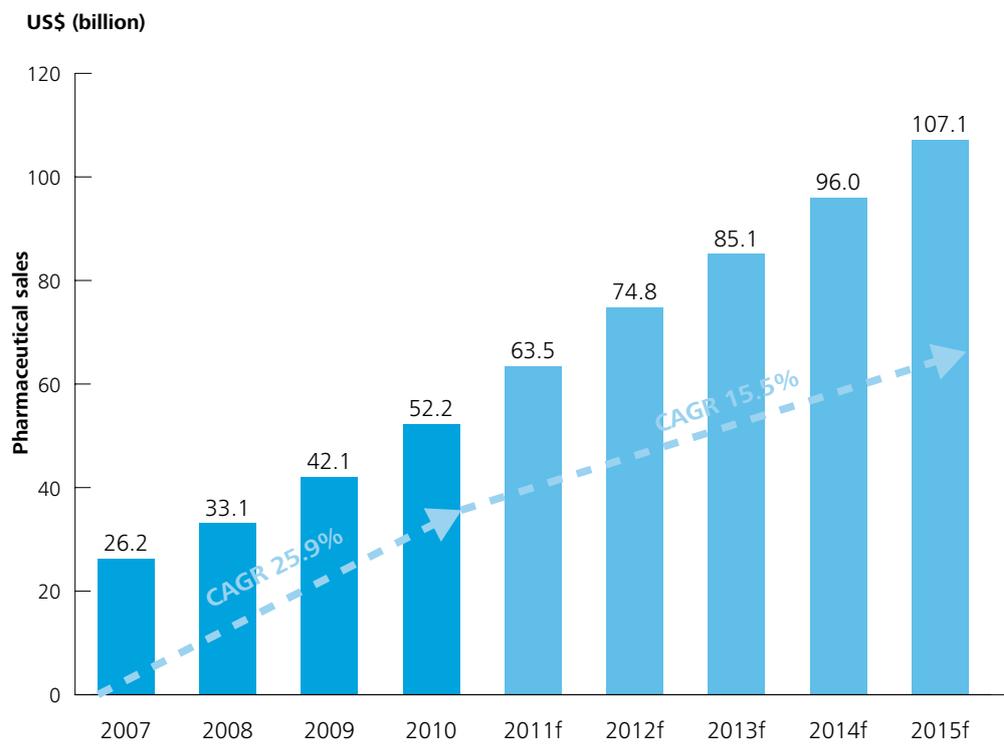
Remark: data with "*" is calculated on the basis of the data from the Sixth National Population Census in 2010.

Source: Deloitte Analysis

Key drivers of market expansion are the rising health care awareness and needs fueled by economic growth, large and aging population, increasing total and per capita health spending, and the ongoing healthcare reform and 12th Five-Year Plan supportive measures.

Pharmaceutical sales growth in China has outstripped that of healthcare expenditures overall. Sales grew at a CAGR of 25.9 percent from 2007 through 2010, and are expected to continue strong but more modest growth from 2010 through 2015, at a CAGR of 15.5 percent (Figure 3).

Figure 3: Pharmaceutical sales in China, 2007–2015



US\$1 = RMB 6.79

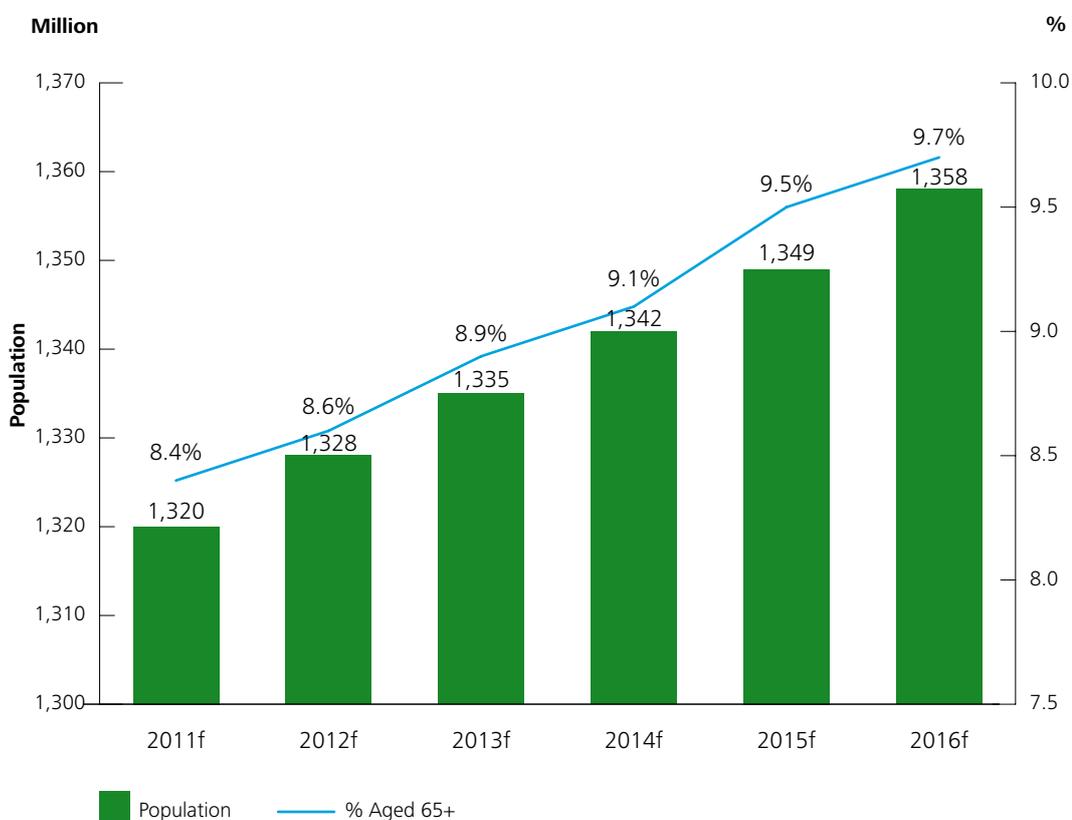
Source: Southern Medicine Economic Institute (SMEI), Association of the European Self-Medication Society (AESGP), BMI

2.1.1 China has the largest elderly population in the world

By 2016, EIU projects that the population of China will reach 1.36 billion, the largest in the world, slightly larger than India's. The senior population (over 65 years) will still remain proportionally smaller, but in 2016 it is expected to be 9.7 percent, rising from 8.4 percent in 2011 (Figure 4).

The aging population will generate higher demand for health care services, since elderly groups have weaker immune systems, resulting in a higher incidence of illness. Currently, the elderly population makes up 23 to 40 percent of the prescription drug market and 40 to 50 percent of the over-the-counter (OTC) drug market.⁴

Figure 4: Aging Chinese population



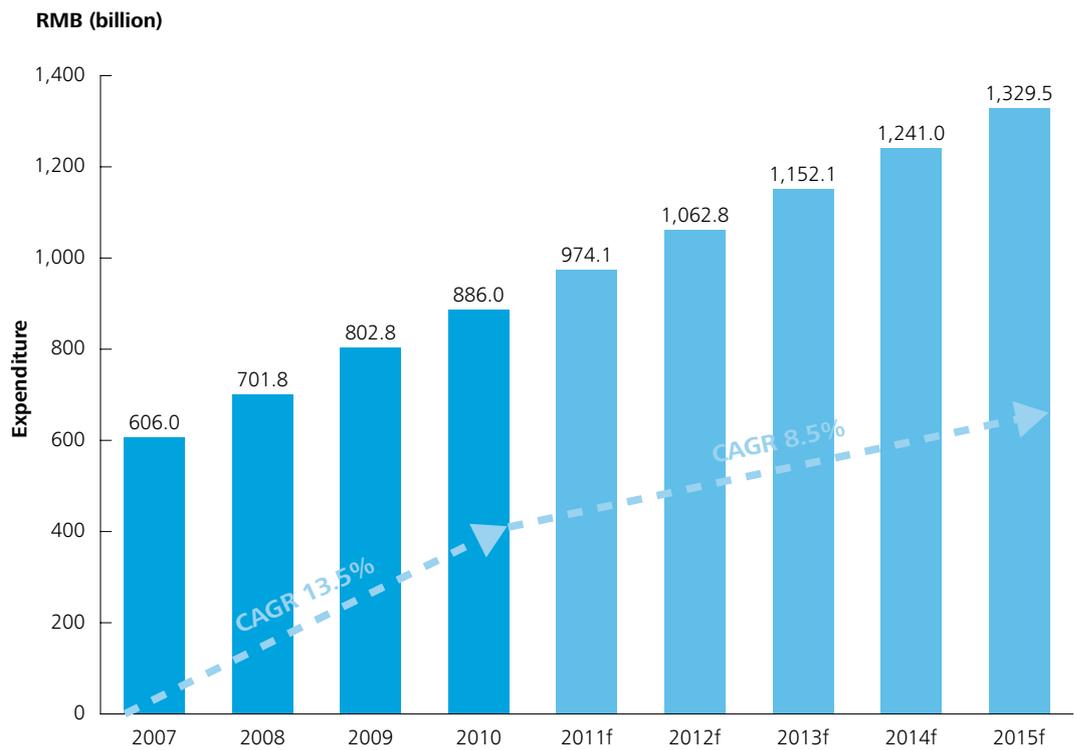
Source: EIU, Espicom

⁴Deloitte research, *The Life Sciences and Health Care in China: Opportunities, challenges and implications*, p.2

2.1.2 Healthcare expenditures expected to grow rapidly over the next five years

Out-of-pocket and private insurance healthcare payments rose steadily from 2007 through 2010, at a CAGR of 13.5 percent. These payments are expected to continue rising, but at a lower rate of 8.5 percent through 2015 (Figure 5).

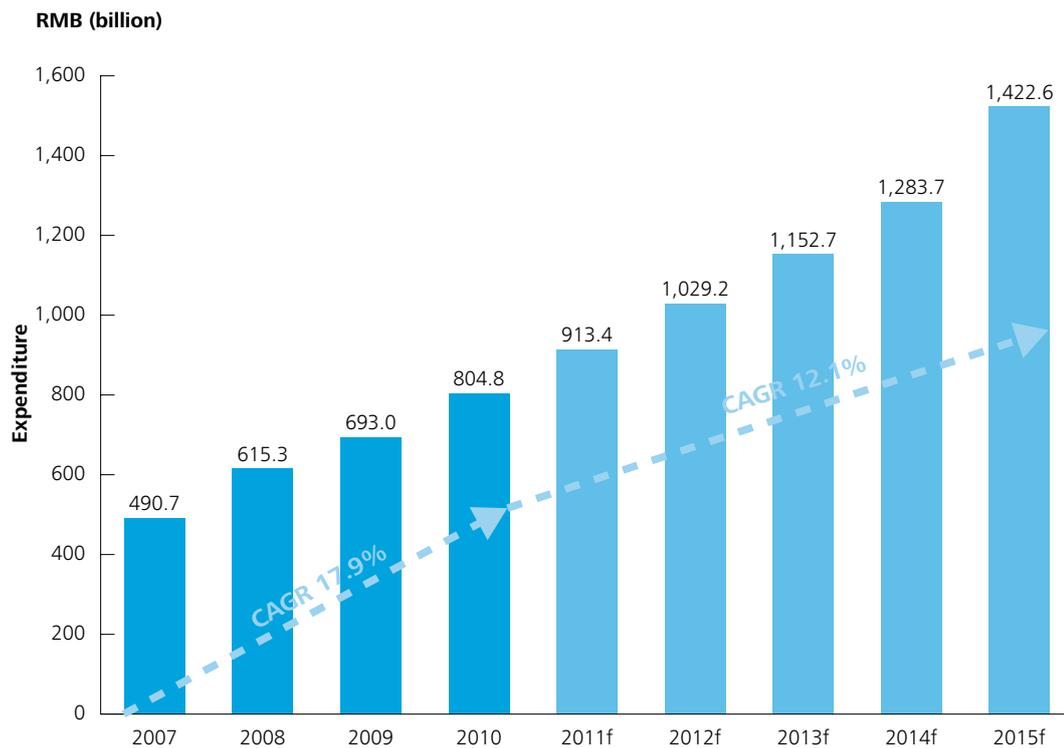
Figure 5: Private healthcare expenditure in China, 2007–2015



Source: World Health Organisation (WHO), BMI

Historically, government healthcare payments in China have been lower than personal and private-sector payments, but they have been rising more rapidly, and are forecast to equal or exceed private payments in 2013. The CAGR for government payments was 17.9 percent from 2007 through 2010, and they are forecast to grow at 12.1 percent from 2010 through 2015 (Figure 6).

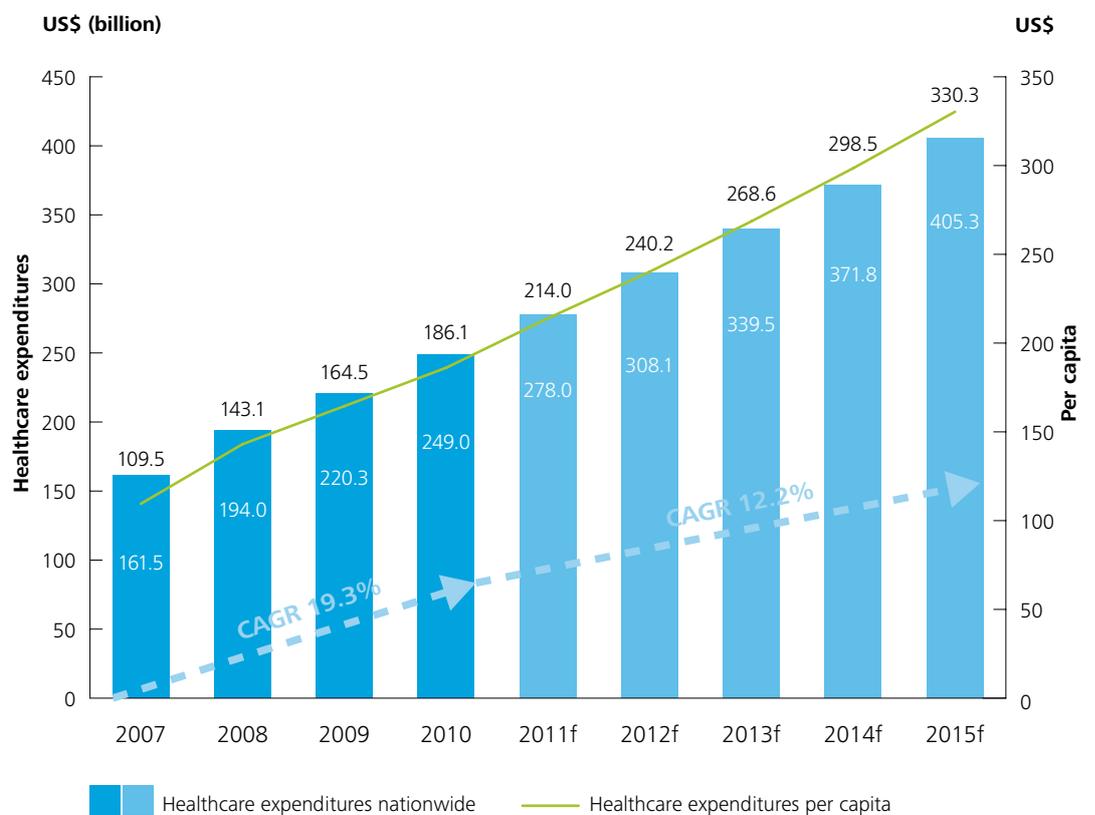
Figure 6: China government healthcare expenditure, 2007–2015



Source: WHO, BMI

China's *per capita* healthcare expenditures, having grown at a CAGR of 19.3 percent from 2007 through 2010, are forecast to continue rising at a CAGR of 12.2 percent through 2015 (Figure 7), reaching US\$437 per head in 2016. In the Asia-Pacific region, this figure places China ninth, between Malaysia (8) and Thailand (10), and far behind Australia at US\$6,185 *per capita* for healthcare. However, due to China's world-leading population, her projected overall healthcare expenditures of US\$593.4 billion in 2016 are forecast to top all other Asia-Pacific nations.⁵ Second is Japan, whose *per capita* expenditures of US\$4,656 are forecast to exceed a multiples of 10 times the expenditures per person in China.

Figure 7: Healthcare expenditure per capita in China, 2007–2015



US\$1 = RMB6.79

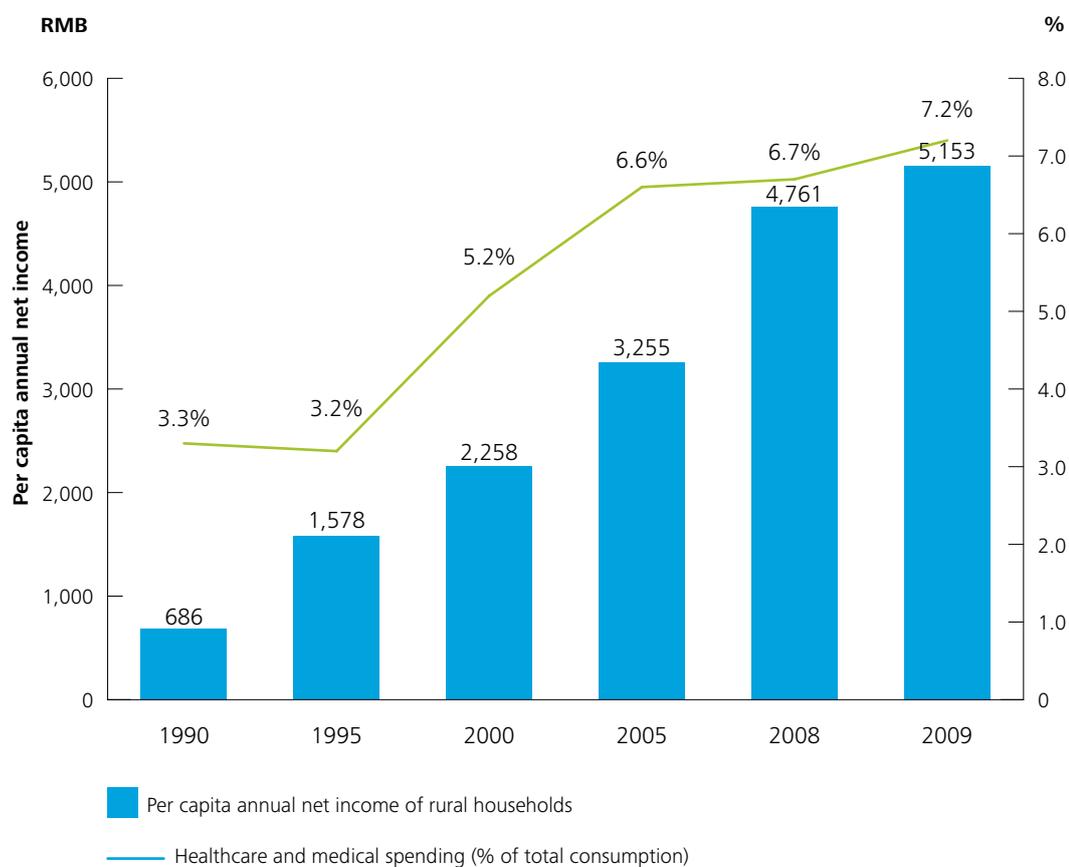
Source: WHO, BMI

⁵ Espicom Business Intelligence, *World Pharmaceutical Market—China, Q2 2011*.

2.1.3 Market opportunities are rising in rural and suburban areas

Although healthcare infrastructure expansion and the hiring of physicians have lagged, the net income and private healthcare expenditure of rural households have grown sharply over the past two decades. In 2009, the average annual net income was RMB5,153, 7.5 times that in 1990. The proportion of expenditure on healthcare and medical services rose from 3.2 percent to 7.2 percent over the same period (Figure 8).

Figure 8: Rising net income and healthcare spending of rural households



Source: National Statistics Bureau of China (NSBC)

The New Co-operative Medical Scheme (NCMS), first introduced in 2000, is a public insurance plan to provide healthcare coverage to around 80 percent of the rural population by 2010. The scheme covered 179 million people in 2005, which was equal to just 76 percent of the population in the rural counties covered by the NCMS in the same year (Figure 9). The coverage was expanded to 94 percent in 2009,⁶ and 96 percent in 2011 according to the latest news release by the MOH.⁷ According to a Ministry of Finance official, central and local government subsidies will be raised from the current RMB120 to RMB200 *per capita* in 2011.

Figure 9: New Cooperative Medical Scheme

	2005	2006	2007	2008	2009
Number of counties implementing the NCMS	678	1,451	2,451	2,729	2,716
Number of enrollees (millions)	179	410	726	815	833
Enrollment rate (%)	76	81	86	92	94
Total fund raised at current year (RMB billion)	7.5	21.4	42.8	78.5	94.4
Per capita premiums (RMB)	42.1	52.1	58.9	96.3	113.4
Payout at current year (RMB billion)	6.2	15.6	34.7	66.2	92.3

Source: NSBC

In addition, the NDRC and the MOH jointly launched a rural health service system enhancement plan, in which RMB36 billion will be invested over the next three years, to support construction of 2,176 county-level hospitals nationwide. As of now, RMB31.4 billion in funds are in place to upgrade and build 1,877 county-level hospitals, with additional funds set aside for construction of 29,000 township hospitals, and the upgrade of another 5,000. The infrastructure improvements and covered treatment of underserved populations are expected to boost the pharmaceutical market in China's rural and suburban areas.

Some observers might think that the drugs prescribed in rural areas differ greatly from those in urban areas. On the contrary, according to the data from the National Statistics Bureau of China (NSBC), malignant tumors, heart disease, and cerebrovascular disease were the top three causes of death in both urban and rural areas in 2009 (Figure 10). That said, deaths caused by heart disease and cerebrovascular disease in rural areas increased notably from 2008 to 2009, which may suggest changes to product marketing strategy options for pharmaceutical companies who want to further explore rural areas.

Figure 10: Leading causes of death (crude mortality rate per 10,000 population)

	Urban area		Rural area	
	2009	Change 08-09	2009	Change 08-09
Malignant Tumour	167.6	0.6	159.2	2.4
Heart Disease	128.8	7.8	112.9	25.8
Cerebrovascular Disease	126.3	5.5	152.1	17.9
Diseases of the Respiratory System	65.4	-7.8	98.2	-6.0
Trauma and Toxicosis	33.5	2.2	54.1	1.1
Endocrines, Nutritional & Metabolic Diseases	20.3	-0.8	11.3	0.2
Diseases of the Digestive System	16.6	-1.0	14.6	-1.8
Diseases of the Genitourinary System	7.3	0.4	7.2	1.5
Diseases of the Nervous System	6.9	0.6	5.1	0.7
Infectious Disease (not including Respiratory Tuberculosis)	4.4	-0.3	5.0	0.3

Source: NSBC

⁶ NSBC

⁷ Ministry of Health, *The regular press conference of the Ministry of Health on June 2011*.

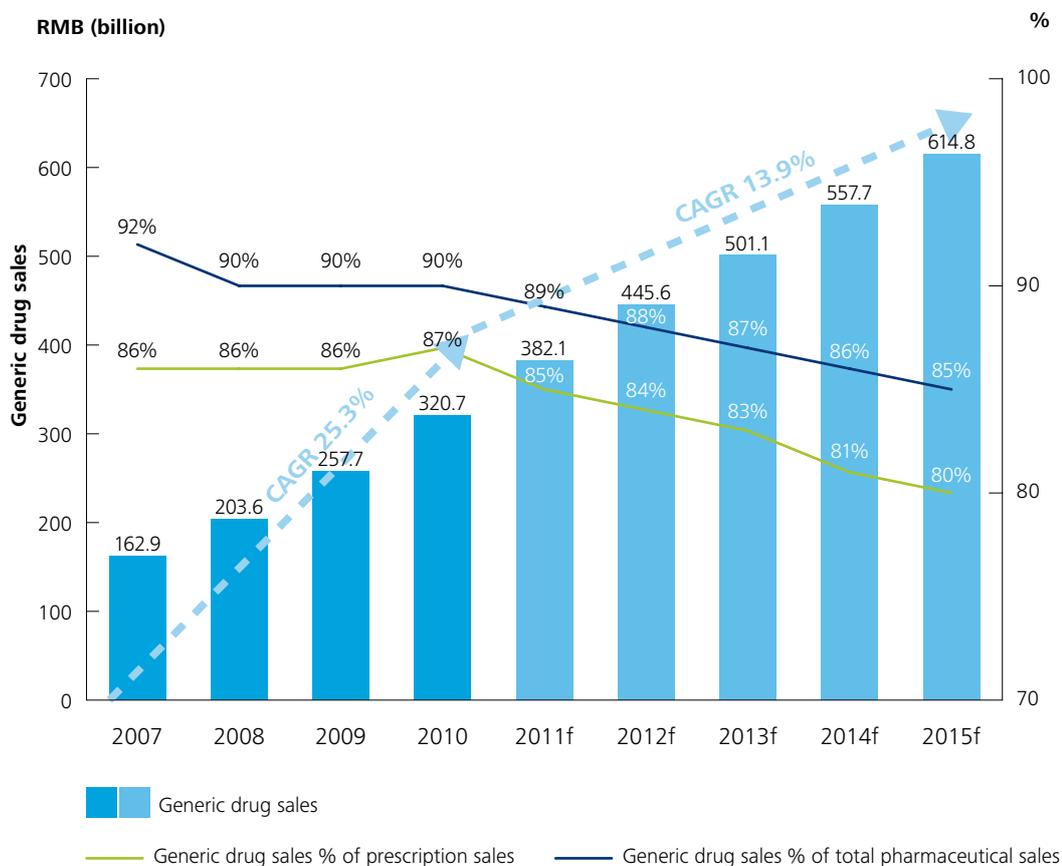
2.2 Generics expected to continue to dominate the market, but patented drugs expected to see significant growth

More than 10 of the world's best-selling drugs, including Pfizer's cholesterol-lowering Lipitor and Lilly's antipsychotic Zyprexa, will lose patent protection in 2011. This is expected to directly result in a nearly US\$5 billion reduction in those global pharmaceutical companies' revenue. Furthermore, it is estimated that more drugs valued at about US\$77 billion in total are going off patent within the next five years.⁸

Although those pharmaceutical giants have never given up developing new drugs to replace these top sellers, the result has been frustrating. For example, Pfizer has invested millions of dollars in R&D to develop substitutes for Lipitor, but has failed in clinical trials. Meanwhile, generics can consume 50 percent of the market of patented drugs within one year after the patent expires, a figure which rises as high as to 70 percent to 80 percent in the second year.⁹ The wave of patented drug expirations will significantly boost manufacturing and sales of the related generics.

In fact, generic drugs are the mainstay of China's pharmaceutical industry, and are likely to remain so for a long time (Figure 11). While the government encourages and relies upon innovation to meet industry targets, China will probably continue to rely upon widespread prescription of generics in the public insurance plan to hold down the overall healthcare expenditures, and the current R&D capability also limits the possibility of launching domestic patented drugs in the near term.

Figure 11: Generic drug sales in China, 2007–2015

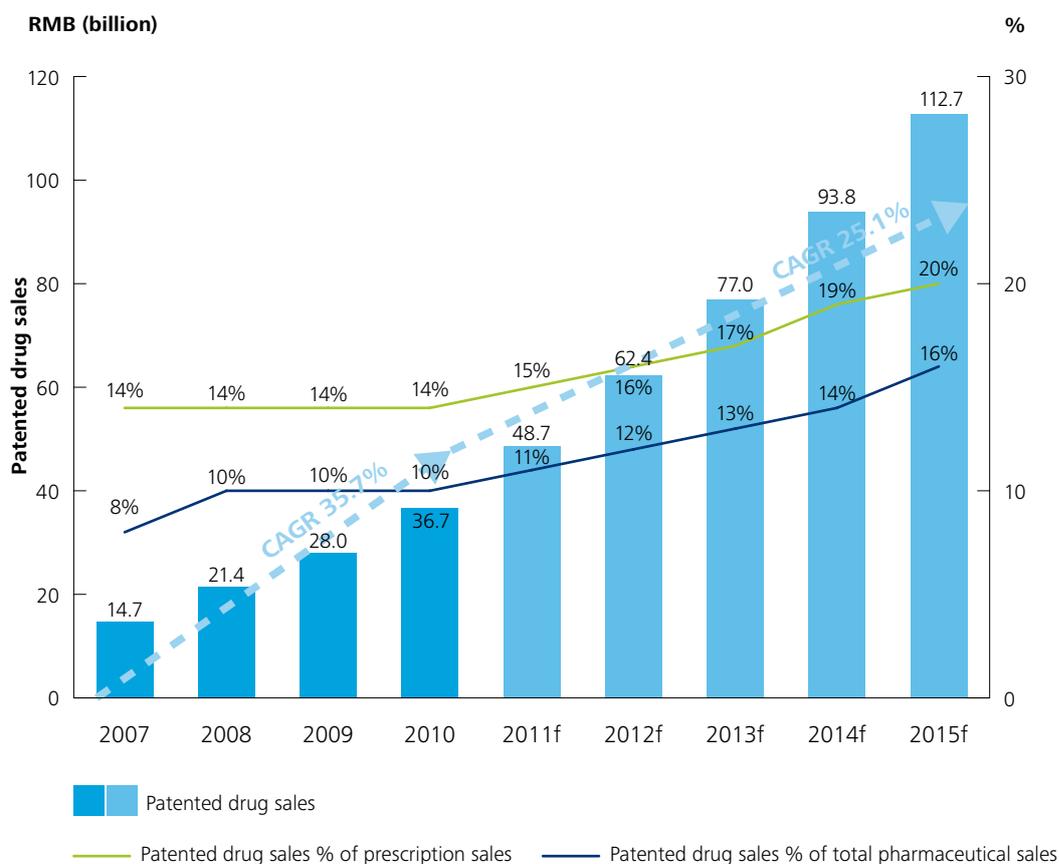


Source: SMEI, AESGP, BMI

⁸ China Enterprise News
⁹ Ibid

At the same time, improved IP protection is expected to draw in more global pharmaceutical players seeking to tap latent demand in the Chinese patented drug market. As Chinese consumers have high confidence in foreign brands, those brands are expected to win drug customers away from the domestic generic brands, causing their proportional market shares to shift accordingly. Sales of patented drugs, which rocketed upward at a CAGR of 35.7 percent from 2007 through 2010, are forecast to continue growing at just over 25 percent from 2010 through 2015 (Figure 12).

Figure 12: Patented drug sales in China, 2007–2015



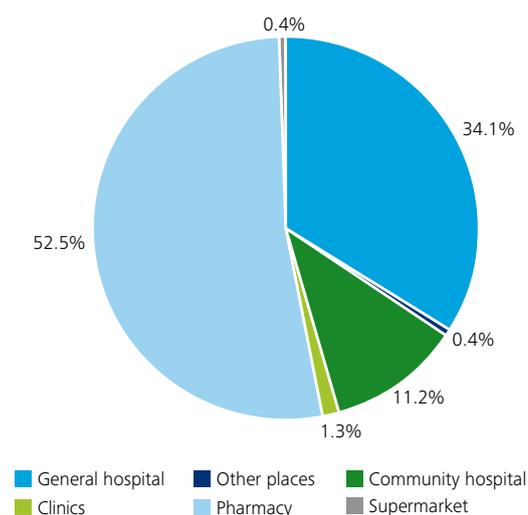
Source: SMEI, AESGP, BMI

2.3 The OTC sector is expected to see steady growth with the improving health consciousness and promotion of self-medication

China's OTC market is growing quickly—around 17 percent per annum in recent years—according to the China OTC Association's statistics, and faster than anywhere else in the Asia-Pacific region. At this rate, observers at Espicom expect China to become the world's largest OTC market by 2020. In 2009, the total OTC drug market was RMB121 billion, with a split of RMB49 billion and RMB72 billion being sold in hospitals and retailers, respectively. Although OTC drugs only account for a minority of the Chinese pharmaceuticals market, their sales are growing in increasing proportion to sales of prescription drugs.

A survey conducted by IMS Health in 2010 shows that 53 percent of respondents preferred to self-treat using OTC drugs purchased at the pharmacy or supermarket (Figure 13). More people are choosing to treat themselves rather than go to the hospital for relatively light symptoms, such as influenza and mild intestinal disorders, thereby raising demand for OTC drugs.

Figure 13: Venues for purchasing remedies for common illnesses



Source: IMS Health, *Healthcare Executive Magazine*, July 2011

The structure of the Chinese OTC market has not changed since 2007, with cold, cough, and allergy treatments accounting for a 30 percent market share; and another 10 percent comprising vitamins, minerals and tonics, anti-inflammatory, gastrointestinal, and gynecological treatments.

So far, the government has completed a basic selection of OTC drugs for the EDL. In the six iterations of the OTC drugs list, there have been more than 4,000 varieties, and this figure is likely to increase as the healthcare reform progresses. Within the EDL, traditional Chinese medicines (TCM) account for about 80 percent of OTC drug sales, and these are often the first option for many Chinese consumers for reasons of cultural familiarity, and perceptions of lower toxicity and side effects.

In 2010, China's top three pharmaceutical companies for domestic OTC sales were Xiuzheng Pharmaceutical Group, Harbin Pharmaceutical Group and China Resources Sanjiu Pharmaceutical Ltd, while Johnson & Johnson and GlaxoSmithKline ranked fifth and sixth, respectively. In fact, more and more foreign drug companies are entering or expanding their presence in China with OTC drugs. In October 2010, Sanofi acquired the U.S.-based BMP Sunstone Corporation for US\$520.6 million. Because of BMP Sunstone's joint-venture with Minsheng Pharmaceutical, the acquisition makes Sanofi a leading consumer healthcare company in China, with a strong position in vitamin and mineral supplements, as well as cough and cold remedies—the two largest categories of OTC drugs.

2.4 China's drug distribution industry continues to see consolidation

Pharmaceutical distribution in China is highly fragmented, and often criticised for its inefficiency and lack of transparency. To illustrate the fragmentation by way of comparison, China's top three distributors—Sinopharm Group, Shanghai Pharmaceutical, and Guangdong Jiuzhoutong Pharmaceutical—had in combination less than 20 percent of overall market share in 2009; while in the U.S., the top three pharmaceutical commerce companies together held a 96 percent market share.

Concentration has been slightly improved. Large companies are gaining more market share through acquisition, with a view to improving operational capabilities and cost effectiveness. For example, Sinopharm completed 24 acquisition-related transactions in 2010, including three stake-raising investments, which together brought the company a nearly RMB4.7 billion increase in sales.¹⁰ In January 2011 alone, Sinopharm completed another 12 acquisitions.

The sector will see continuous consolidation in 2011. This is part of the central government's 12th Five-Year Plan to strengthen the national drug distribution industry by actively supporting acquisitions, mergers, and reorganisations. The scheme includes the establishment of one or two leading national drug distribution companies, each with annual sales of over RMB100 billion (US\$15.1 billion), and the creation of 20 regional drug distribution companies, each with sales of over RMB10 billion (US\$1.5 billion).¹¹

However, mere consolidation can only improve the concentration rather than the efficiency and effectiveness of the distribution system. Without the thorough reform of public hospitals—who still prescribe and sell more than 70 percent of drugs, although their role in drug procurement has diminished due to the hospital tendering process and introduction of the EDL—the result of the consolidation might not mean meaningful change.

As for retail markets, many relatively large chain stores have been forced to consolidate, exit the market, or create larger chains. In general, strong competition in the pharmaceutical sector and low profit margins are driving the segment consolidation. Nepstar Chain Drugstore, the largest pharmacy chain in China, is a model for successful retail operations. It opened 556 new stores in 2007, reaching a total of 2,002 outlets in 62 cities by the end of 2009.

Of the foreign companies participating in China's retail pharmacy sector, both Watson's and Walmart have established a noticeable footprint in wealthy cities and provinces such as Beijing and Guangdong.

¹⁰ 21st Century Business Herald.

¹¹ There have already been several acquisitions in the drug distribution sector in the first half of 2011: Jiangbo Pharmaceuticals announced the signing of a letter of intent to acquire Shandong Xinkangqi Medical Company; Sinopharm announced it will acquire Zhejiang Wenling Drug Materials, based in Taizhou, Zhejiang province; First China Pharmaceutical Group signed a letter of intent to acquire Shenzhen Ming He Tang Pharmaceutical Company, based in Shenzhen, Guangdong province. Mergers and acquisitions are presented more comprehensively in the second part of this report (M&A highlights).

2.5 China has become one of the top options for global pharmaceutical companies to conduct R&D activities

China's heretofore poor IP protection has been a countervailing factor in pharmaceutical companies' collective drive to carry out R&D in the country. In addition, China's patent law is soon due to be revised, which should foster greater innovation and deter copycat drug makers. In recent years, a growing number of companies have become increasingly attracted to the idea of having an R&D center in China, as in-country research offers a general low cost base, a large patient pool, increasing scientific capabilities, the local industry's knowledge in the field of generic drugs, and insight into the country's growing drug markets. Moreover, manufacturers can only receive regulatory authorisation for products based on clinical trials that have been carried out in China. (Domestic clinical trials are required for all drugs to be sold in China.)

Observers familiar with the phased development process mandated by the U.S. Food and Drug Administration (USFDA) and other foreign regulators will be aware that China has ambitions to be a primary market for contract research organisations (CROs), who serve a key function in this process. China has for years been regarded as a favourable location for research due to the enormous pool of qualified research subjects, and the general lack of regulatory and cultural impediments often found in alternative countries. While cost is always a factor, other key factors in whether, where, and to whom to outsource research are not strictly related to labour cost arbitrage, but to flexibility and transfer of risk, which to some degree distinguishes CROs from other outsourcing industries. Hiring a CRO in a target market also offers the prospect of gaining an inside look at that market before jumping in with both feet, and in China this is an especially attractive proposition.

WuXi Pharmatech, one of the world's largest CROs, with operations in China and the U.S., announced a partnership arrangement with pharmaceutical giant Bristol-Myers Squibb earlier in 2011; and in the second quarter, opened a new API/drug product stability testing facility dedicated to the latter. Whether WuXi Pharmatech is a pathfinder or an outlier depends on to what extent China's pharmaceuticals industry can continue to develop the country's own native research capabilities. In order to expand those resources, expert Chinese nationals with research experienced nurtured at top Western pharmaceuticals companies are being lured home to staff CROs in China.

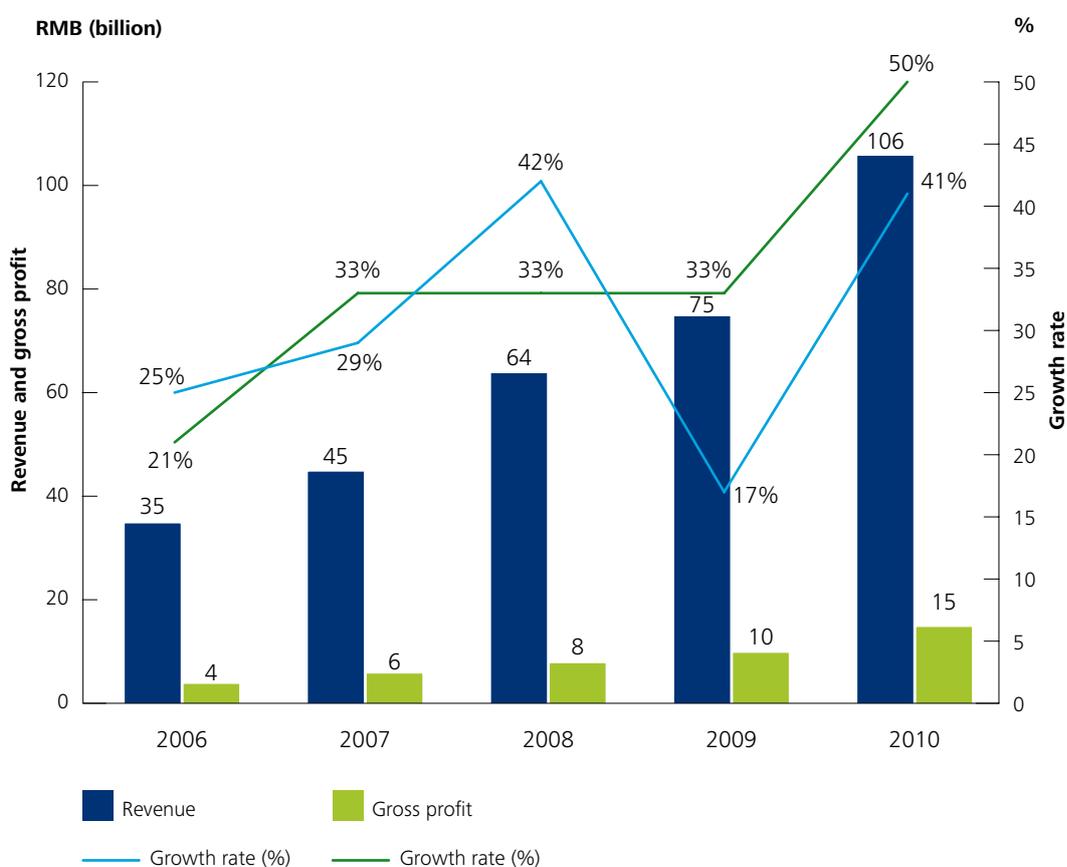
Most of the top 20 multinational pharmaceutical companies have been expanding their footprint and are setting up more R&D facilities through various enterprise structures. For example, in November 2010, it was reported that Novo Nordisk planned to invest US\$100.0 million to expand its R&D center in Beijing. In March 2011, Pfizer announced that it will close its R&D facility in Groton, Connecticut and move its anti-bacterial research operations to Shanghai. GlaxoSmithKline is setting up one of its largest research centers in Shanghai, and has charted plans to recruit between 50 and 100 top international scientists and employ more than 1,000 researchers at the new facility by 2017.

Moreover, global pharmaceutical companies are starting to conduct R&D activity specifically related to Asian markets. Due to environmental, cultural and genetic factors, liver disease, certain cancers, and some communicable diseases are more common in Asian countries, such as China and Thailand. In the past, global pharmaceutical companies tended to bypass this special disease spectrum in the region, but now the situation is changing. Over the past year, Pfizer has begun to develop a treatment for liver disease anti-inflammatory drugs in China. Meanwhile, U.S. healthcare giant Johnson & Johnson recently announced a partnership with Tsinghua University to study a number of infectious diseases in Asia. The U.S. pharmaceutical company Bristol-Myers Squibb entered an agreement with Simcere Pharmaceutical Group, a local pharmaceutical company headquartered in Nanjing, to jointly develop a treatment against cancer.

2.6 The biotech sector has been targeted as a key development sector by the government

There are certain subsectors that will benefit specifically from provisions relating to the Five-Year Plan. Although biologics and biosimilars together only account for 10 percent of the total pharmaceuticals market in China, their recent annual growth rate of 32.2 percent has been quite impressive. Genetic drugs and diagnostic reagents are the main applications for biotechnology in the life sciences industry, accounting for 65 percent of the market share of biologics and biosimilars in 2010 (Figures 14 and 15).

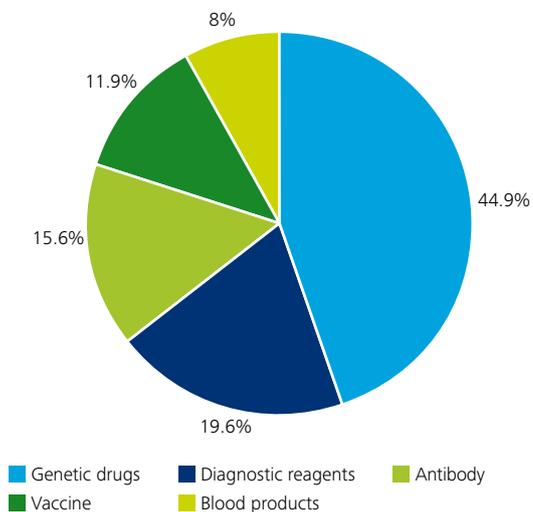
Figure 14: Biologics and biosimilars in China, 2006–2010



Remark: Data in December is excluded.

Source: NSBC

Figure 15: Biologics and biosimilars in China, market shares by sales, 2010



Source: NSBC

Scientists at the Chinese Academy of Sciences say the sector has the potential to become a pillar of the pharmaceuticals industry, with a market size of around RMB600–800 billion. As a result, the government has determined that biotechnology will be one of the key sectors in the 12th Five-Year Plan.

The Five-Year Plan provisions specifically related to biotechnology applications in the life sciences industry are expected to take effect shortly. It has been reported that China's government will invest RMB10 billion to support major new drug innovation, with RMB5–10 million in funding for each project on average from 2011 through 2015. Genetic drugs, protein drugs, monoclonal antibody clone drugs, therapeutic vaccines, and small molecule drugs are the main development focus. Furthermore, 20 biotech zones have been set up nationwide, including zones at Beijing, Shanghai, Tianjin, Guangzhou, and Shenzhen, to improve independent innovation capability.

In addition, biological medicines have begun to gain presence in the market as research focuses on targeting the root causes of disease, to cure patients while minimising side effects. In fact, more than one Western biosimilar manufacturer has already found the Chinese market to be very competitive with strong domestic pharmaceutical capacity. Consequently, there have been quite a few strategic investments by global pharmaceutical giants within the past few years.

In November 2009, Novartis announced that it was planning a US\$1 billion investment over the next five years to expand its R&D activities in China, including further investment in the Novartis Institute of BioMedical Research (CNIBR) in Shanghai. In October 2010, Pfizer announced that its R&D center in Wuhan had opened, with a particular focus on radiation biology and clinical trials. In the first half of 2011, Merck Millipore opened its US\$2 million Biopharmaceutical Technical and Training Centre in Zhangjiang Hi-Tech Park, Shanghai.

3. Regulatory regime and policy development

3.1 National authority & legislation

The China State Food and Drug Administration (SFDA) is the national supervising authority for the pharmaceutical sector in China. It became operational in 1998 as the State Drug Administration (SDA) and was renamed in 2004. The SFDA has a number of departments to execute its different responsibilities, and the most industrial-related are the following three—the Department for Drug Registration, the Department of Drug Safety & Inspection, and the Department of Drug market Compliance.

Pharmaceutical regulation in China is based around the Drug Administration Law (DAL), first implemented in 1984, with the last major amendments taking place in 2001, and coming into force in September 2002.

3.2 Drug registration, approval, and manufacturing

Drug registration in China is a complicated and time-consuming process, involving a number of regulatory bodies at various levels of government, and at various regional levels. Drug approval applications could be sent directly to the central SFDA prior to 2002, but the applications are now initially reviewed by provincial and municipal authorities, and then passed to the SFDA for approval. The entire approval procedure generally takes between 18 and 26 months.¹² Domestic clinical trials are mandatory for all drugs which are new to the Chinese market required by the Good Clinical Practice (GCP) guidelines. If a drug has not been approved in China or anywhere else, permission for the trial must be granted by the SFDA and the MOH, and it normally takes 12 months for the trial process.¹²

Once the clinical trials have been completed, the product must undergo a quality test. The manufacturer should provide enough product samples to conduct three complete tests. Manufacturers should be prepared for unexpected questions and test results; a large number of Chinese test laboratories are not rigorously controlled. The quality test should take around three months.¹²

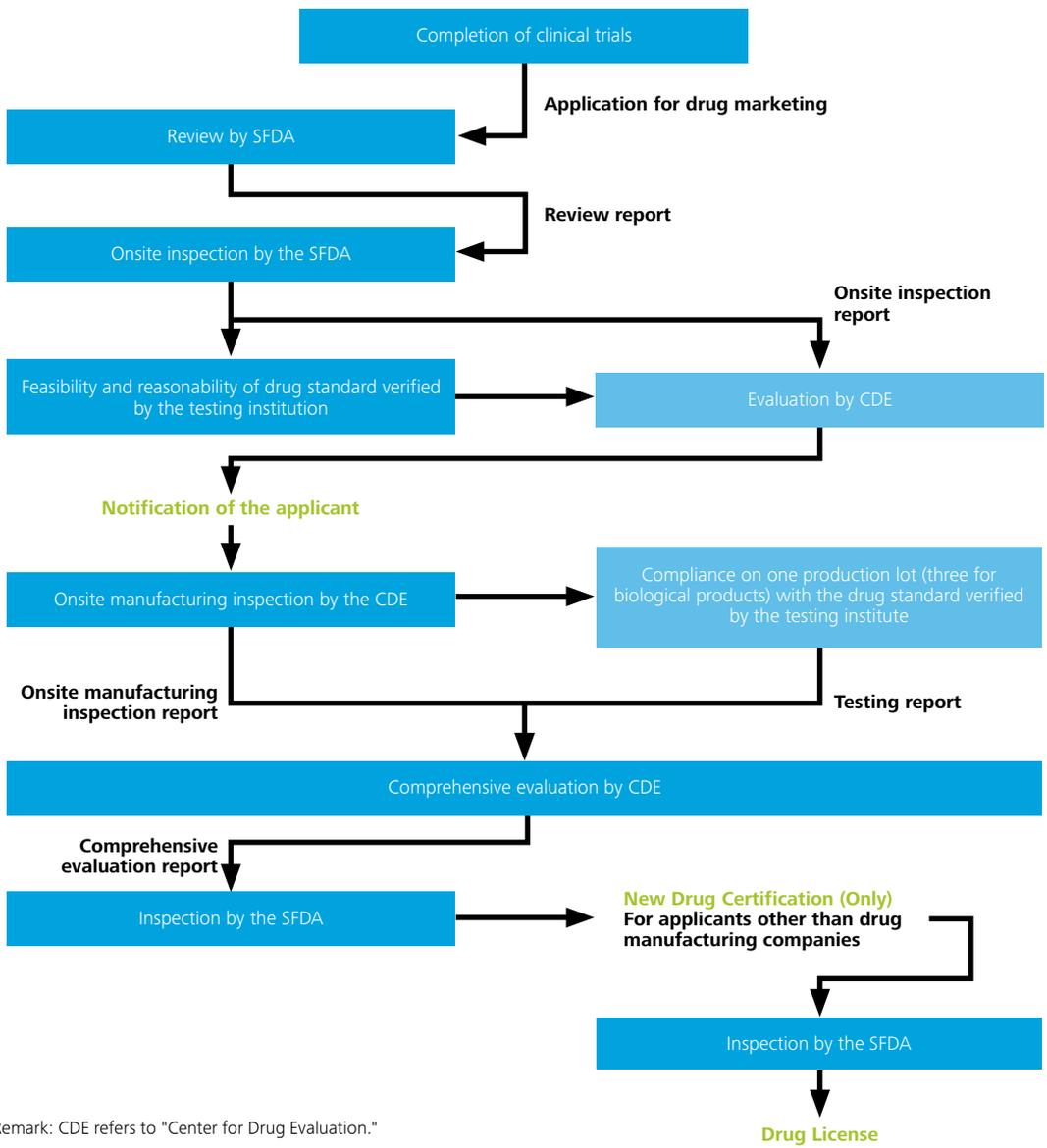
Overseas manufacturers may apply direct to the SFDA, although using a Chinese firm may make the process easier. For imported products, documents must first be submitted to the appropriate customs authorities. The customs inspection authorities will evaluate the application and then pass it to the central SFDA office.¹³

Note that all drugs, including traditional Chinese medicines (TCM), must be approved by the SFDA, although TCMs are exempt from the normal licensing procedure. Testing institutions are set up by the SFDA and the provincial or equivalent Food and Drug Administrations (PFDA) to test drugs, which are evaluated both in terms of quality and conformance to standards. Importantly, only drug companies registered in the PRC are allowed to apply for a New Drug Certificate and Drug License. R&D companies can only apply for the New Drug Certificate, which they may later transfer to a qualified drug manufacturer, who may then apply to the SFDA for a Drug License (Figure 16).

¹² Espicom Business Intelligence, *World Pharmaceutical Market—China, Q2 2011*.

¹³ Ibid

Figure 16: Diagram of China's approval procedures for new drugs



Remark: CDE refers to "Center for Drug Evaluation."

Source: CMS, *Life sciences: a legal guide to China*.

This system demands that foreign drug manufacturers partner with or acquire Chinese companies that are qualified for a Drug License. This is just one of a number of regulatory hurdles that foreign companies will encounter en route to a China market entry.

On 25 April 2011, the SFDA issued final notice on mandatory Good Manufacturing Practice (GMP) inspections for all pharmaceutical companies doing business in China, whether with manufacturing operations in China or abroad.¹⁴ The SFDA and the PFDA will administer the rules. Manufacturing costs will rise somewhat, pushing out some smaller manufacturers. Foreign pharmaceutical companies must comply, and see to it that their China-based subsidiaries, JVs, and potential M&A targets are also in compliance.

3.3 Advertising

The Department of Drug Market Compliance of the SFDA is in charge of the central regulation of pharmaceutical advertising. Pharmaceutical advertisements must be approved by this department, as well as by the local authorities in the provinces or municipalities where they are to be broadcast or published.

According to the research by AC Nielsen, the pharmaceuticals industry is one of the highest spenders on advertising in China. However China is cracking down on pharmaceutical advertising after a string of complaints from the public. In addition, pharmaceutical advertising is now the subject of more concerted efforts to raise standards.

Under the rules, guarantees of efficacy and the use of patients and medical professionals to promote treatments are prohibited. Actors portraying medical experts or disease sufferers in radio and television promotions are also banned.

3.4 Pricing

Overall control of drug prices is the responsibility of the NDRC, whose pricing policy is based on the control of profit levels and sales discounts within the industry. Prices of drugs on the EDL are set by the government, while most other drug prices are set after negotiations between the government and manufacturers.

The NDRC's purpose is to diminish the reliance of hospitals on drug prescriptions as a source of income by implementing the EDL. Some 300 drugs have been identified as critical for common illnesses and diseases, and should be made available to all patients. For drugs on the list, prices are fixed and no commission is paid for their prescription. Prices for these drugs have come down by 30 percent to 50 percent, which has reduced the cost of inpatient and outpatient care.

The MOH will also focus on streamlining the centralised procurement and distribution of essential drugs (i.e., through separation of prescription and dispensing of drugs, or "SPD"), to bring down drug prices at the supply end and thus lower drug prices for patients.

3.5 Reimbursement

Drugs must be included on provincial reimbursement lists in order to qualify for reimbursement of products prescribed at public hospitals at the provincial level or lower. With reference to the national basic insurance scheme and the national EDL, local governments have all created reimbursement lists of their own, which differ in scope and the levels of reimbursement offered.

¹⁴ *SFDA Notice and Proposed Regulation.*

Under the basic insurance scheme, Category A and Category B medicines receive full and partial reimbursement, respectively. Category A comprises basic, lower-priced drugs (including many essential generics), while Category B is made up of a core group of higher-priced, less frequently used drugs, and up to 15 percent of its content can be modified by local governments according to need. The 2009 edition of the China National Basic Medical Insurance included a total of 2,151 medicines, of which 1,140 were Western medicines including 349 Category A medicines and 791 Category B medicines.

The EDL was last updated in August 2009, which at the time included 307 essential medicines in their generic names; 205 were Western medicines and 102 were traditional Chinese medicines. The list will be reviewed every three years.

In addition, the government has instructed provincial governments to organise public bidding for medicines (conducted online), to achieve the lowest possible purchase prices for medicine used to treat the most frequent and prevalent medical conditions. This will result in contracts given to specific suppliers and distributors that can best compete on price, and smaller are likely to be pushed out of the market by larger ones. Imported drugs are often excluded unless the manufacturer agrees to large price cuts; according to Espicom, discrimination in favour of locally produced drugs is an accepted practice.¹⁵

4. Summary

The key takeaway from China's healthcare reform and health-related economic data is that broader access to healthcare nationwide and elevated protection for pharmaceutical brands will combine to raise the visibility and prescription of patented drugs. This phase is beginning now, as both domestic and international manufacturers seek partnerships and M&A investment, lining up the resources they need to maximise their opportunities.



¹⁵ Espicom Business Intelligence, *World Pharmaceutical Market—China, Q2 2011*.

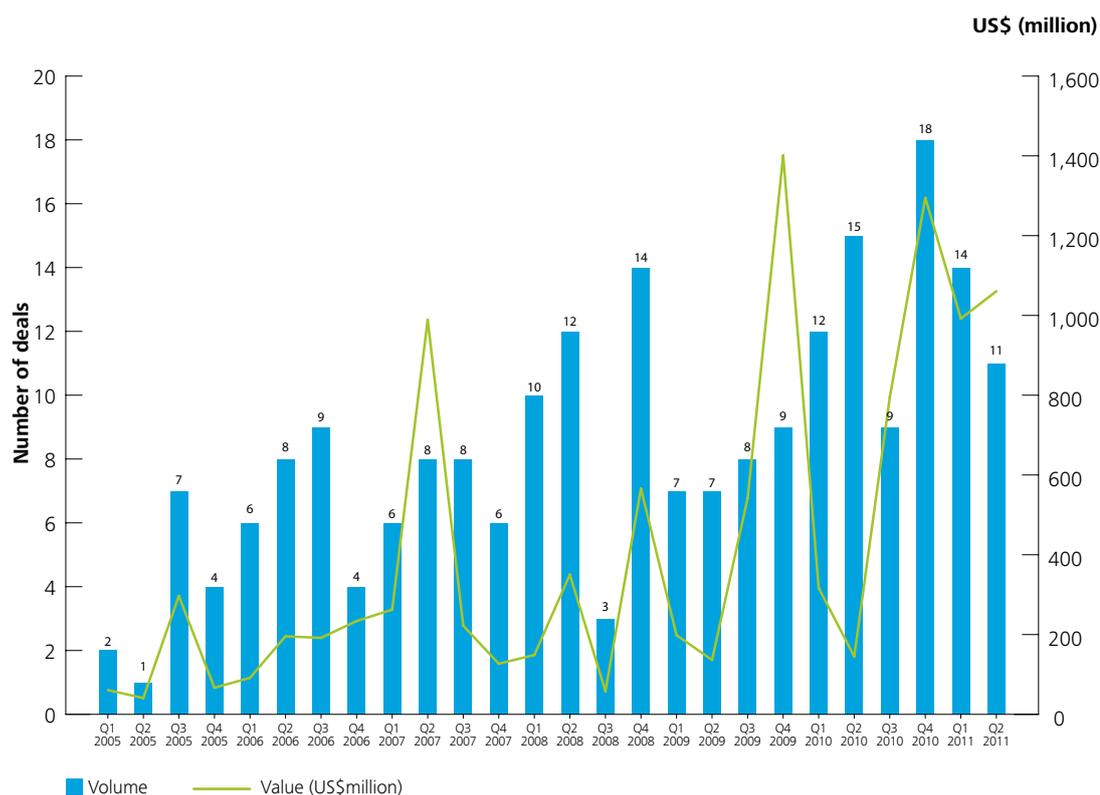
M&A highlights

M&A highlights

Top-down pressures are fueling acquisitions in LSHC subsectors, in particular pharmaceuticals and pharmaceutical distribution, biotechnology, and medical devices. The Chinese government's planned investments of some US\$130 billion pursuant to the healthcare reform from 2009 through 2011, as well as increasing regulatory pressures to consolidate fragmented LSHC sectors, are major factors encouraging domestic players and MNCs to engage in M&A. Moreover, a focus on pharmaceuticals and biotechnology in the 12th Five-Year Plan as one of the seven national "strategic emerging industries" will encourage public and private investment in these sectors to boost innovation and growth.

Deal volumes have been growing steadily over the past six-and-a-half years, with just 14 domestic and inbound transactions conducted in 2005, compared with 54 in 2010, and an additional 25 in the first two quarters of 2011. Average quarterly deal volumes have swelled from 3.5 in 2005 to 13.5 in 2010, and 12.5 in 2011 to date. Overall spending on domestic and inbound M&A in life sciences and healthcare sectors over 2005 to mid-2011 has likewise risen dramatically, demonstrating a CAGR of more than 50 percent over that period. A total of US\$352 million spent in 2005 can be compared with a much more substantial US\$2.55 billion spent in 2010, and the US\$2.08 million already invested in H1 2011 (Figure 17).

Figure 17: China Life Sciences & Healthcare M&A activity, domestic and inbound, 2005–H1 2011

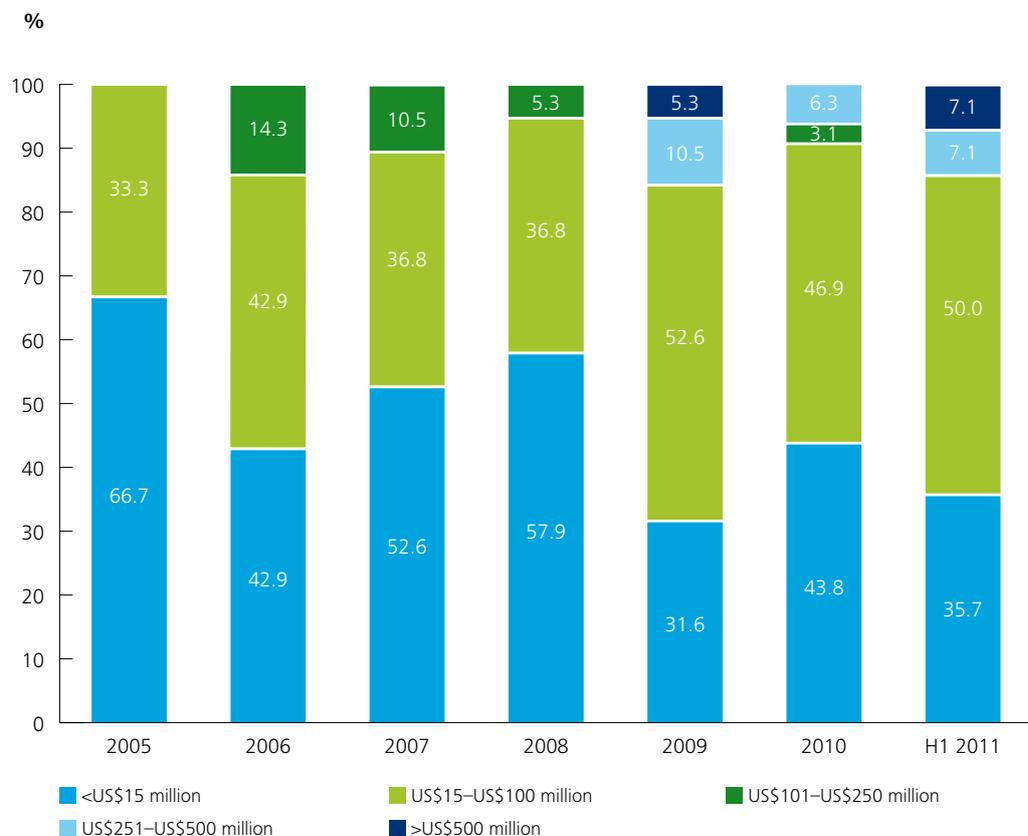


Source: mergermarket

Rising cumulative deal values do not only show that more players are making acquisitions. In fact, the average value of LSHC transactions has grown steadily in recent years, indicating that the acquisitions themselves are changing in nature. For one thing, acquirers have matured and grown more serious. Many are ready to invest more heavily in order to take advantage of China's favourable environment for phased drug trials; or to obtain assets such as distribution chains that are unavailable to greenfield foreign investors. Additionally, increasing consolidation in the marketplace is leaving fewer small targets available for acquisition, so deals are trending larger as the remaining big players compete for scarce resources. Moreover, as a result of overall sector growth and increasing market consolidation, we are seeing a general rise in valuations of attractive targets, further driving deal values up.

Average values in 2005 stood at US\$25 million, with a majority of deals (66.7 percent) valued at less than US\$15 million, and no deals above US\$100 million. It was not until 2006 that the market saw its first set of deals above US\$100 million, and it would not be until two years later, in 2009, that the first transactions valued at more than US\$250 million were closed. This was also the year in which truly large-cap M&A deals (value above US\$500 million) began to emerge, representing over 5 percent of deals in 2009. While there were no large-cap LSHC deals in Greater China in 2010, such transactions have accounted for more than 7 percent of deals by volume in H1 2011. Also by 2011, the average deal value had risen to US\$83 million, with small transactions worth less than US\$15 million comprising only about a third (35.7 percent) of all deals, down from two-thirds five years prior. Conversely, almost 15 percent of transactions deals were valued at US\$250 million and up, compared with 0 percent in 2005 (Figure 18).

Figure 18: China LSHC domestic and inbound M&A by disclosed deal value (%) , 2005–H1 2011

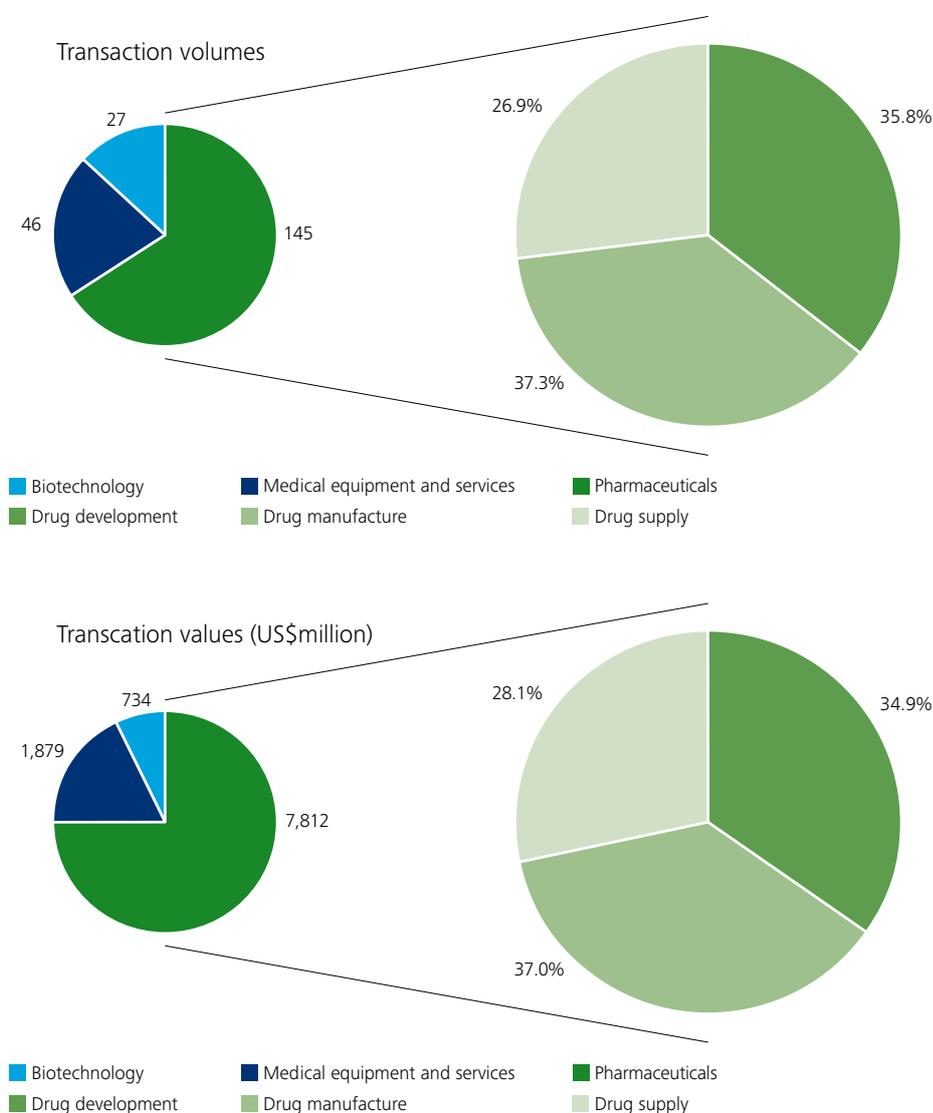


Remarks: Annual percentages represent the proportion of overall deals in each deal value range. Figures may not add due to rounding

Source: mergermarket

In the context of a burgeoning transaction environment and regulatory pressures, the pharmaceuticals sector has been a clear leader in terms of both M&A volumes and values over the past six-and-a-half years, making up 66.4 percent of all transactions by volume (a total of 145 deals) and 74.6 percent by value (US\$7.9 billion). Deals in medical equipment and services, meanwhile, amounted to 21.2 percent by volume (46 deals) and 18.3 percent by value (US\$1.9 billion), while deals in the biotech sector comprised just 12.4 percent (27 deals) and 7.1 percent (US\$734 million), respectively. Within the pharmaceuticals sector, subsector purchases of companies in drug development, drug manufacture, and drug supply have been roughly equal by both volumes and values (Figure 19).

Figure 19: China LSHC domestic and inbound M&A by subsector (%), 2005–H1 2011



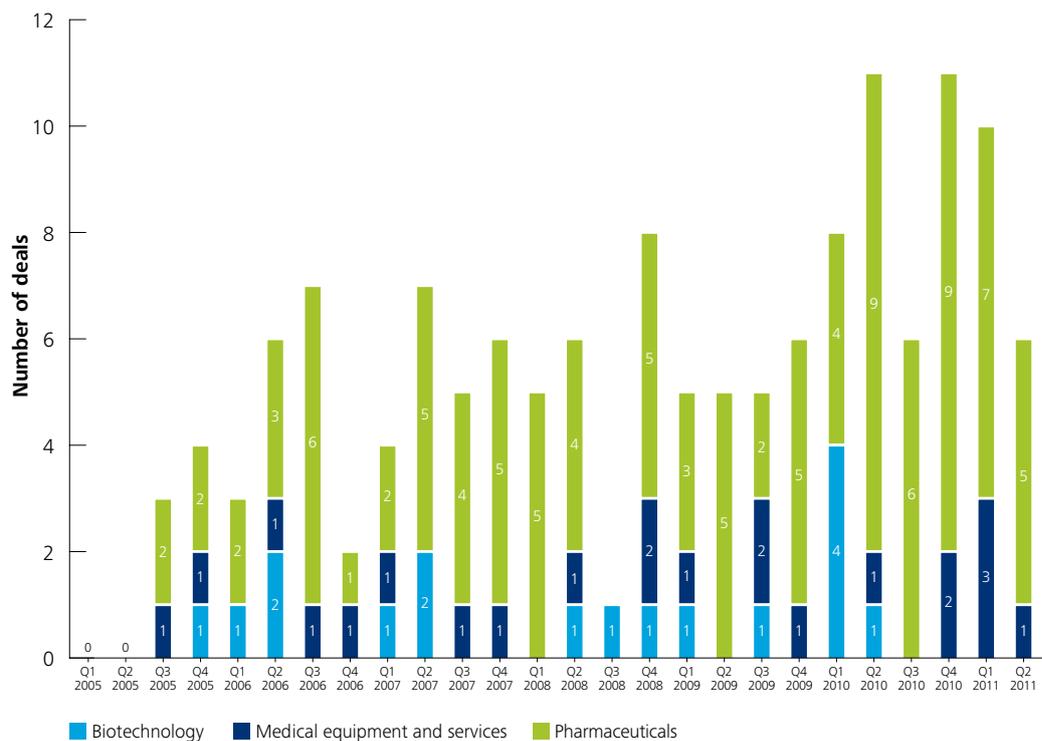
Source: mergermarket

1. Domestic M&A surges as pharmaceutical players lead a new wave of consolidation

Domestic deal-making has a clear mandate to focus on a fragmented pharmaceuticals sector, especially in an environment where over 75 percent of drugs are generics, and an additional 11 percent are TCMs. It seems that strong market leaders have yet to emerge that have the resources, the experience, and the incentives to innovate in the sector, thus just a small minority (less than 15 percent) of drugs are patented products. One clear government priority is the diversification of the pharmaceuticals sector away from the manufacture of generics towards a more robust model, with companies turning out modern, patented products to rival the best on international markets.

Before innovation is a possibility on a wide scale, however, the marketplace needs to see significant reshuffling. The national government's policy is to promote a few "national champions," providing them with the resources to innovate and to compete internationally. Consolidation via M&A will intensify concentration and limit competition in the sector.

Figure 20: China domestic LSHC M&A activity 2005–H1 2011, by volume



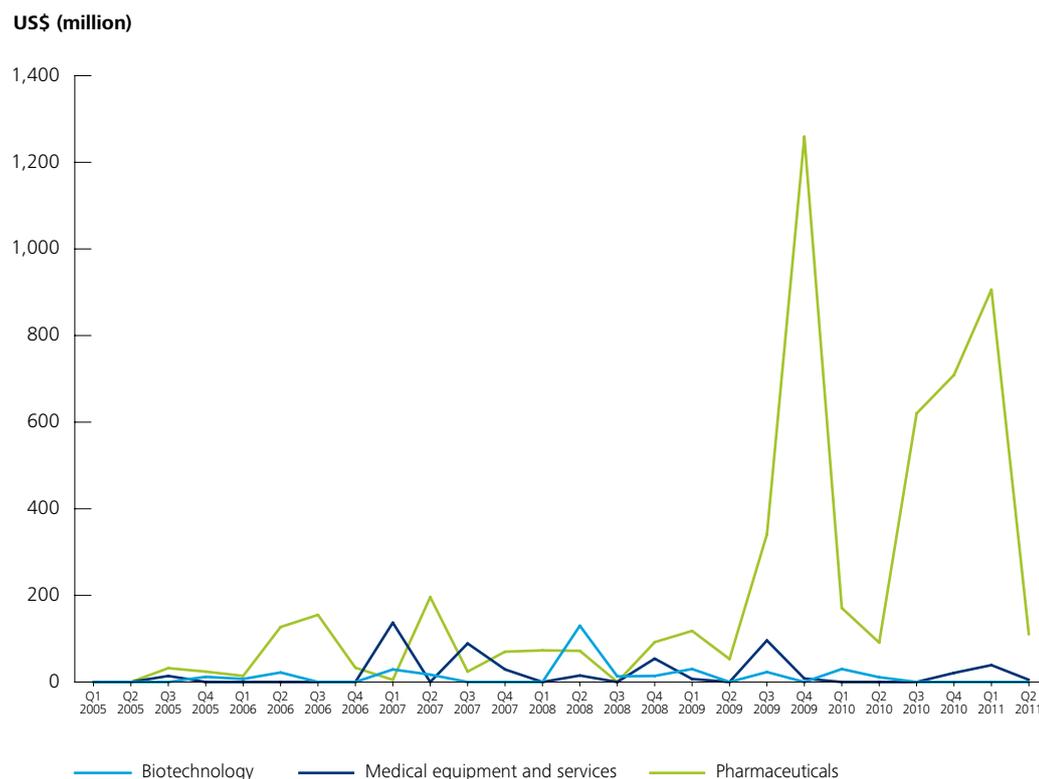
Source: mergermarket

The data (Figure 20) reveal a strong trend of consolidation in the LSHC marketplace as a whole, beginning in 2005 H2, in which seven deals valued at US\$82 million were closed (after no activity in the first half of that year), and building at a steady pace through 2008 H2, which saw nine deals worth US\$173 million. The year 2009 saw 21 transactions (five each quarter Q1–Q3, and six in Q4). It was in 2010 that domestic deal-making crossed the threshold into the next phase, with a total of 36 transactions, a 71 percent year-on-year increase over 2009. In the year 2011 this strong trend of consolidation-oriented transaction seems set to continue, with 16 deals in H1, just slightly below the 19 seen in H1 of the previous year.

The pharmaceuticals sector in particular, accounting for two-thirds of all LSHC transactions by volume, is seeing a gradual de-fragmenting. However, with more than 5,600 players still in the pharmaceutical manufacturing marketplace as of the end of H1 2011 (70 percent of which are small companies), as well as more than 16,000 pharmaceutical distributors and chain retailers nationwide, it is clear that there is still a long way to go.

Activity in the pharmaceuticals sector has dominated the LSHC M&A scene as a whole since mid-2009, with a strong surge in Q3 and Q4 of that year (a total of US\$1.6 billion spent, up 1,600 percent year-over-year), followed by a robust 2010 (US\$1.65 billion) and a seemingly healthy H1 2011 (US\$1.06 billion). Average deal values are up from US\$14m in 2005 to nearly US\$85 million in H1 2011 (after dropping from an all-time high of US\$118 million in 2009) (Figure 21).

Figure 21: China domestic LSHC M&A activity 2005–H1 2011, by value



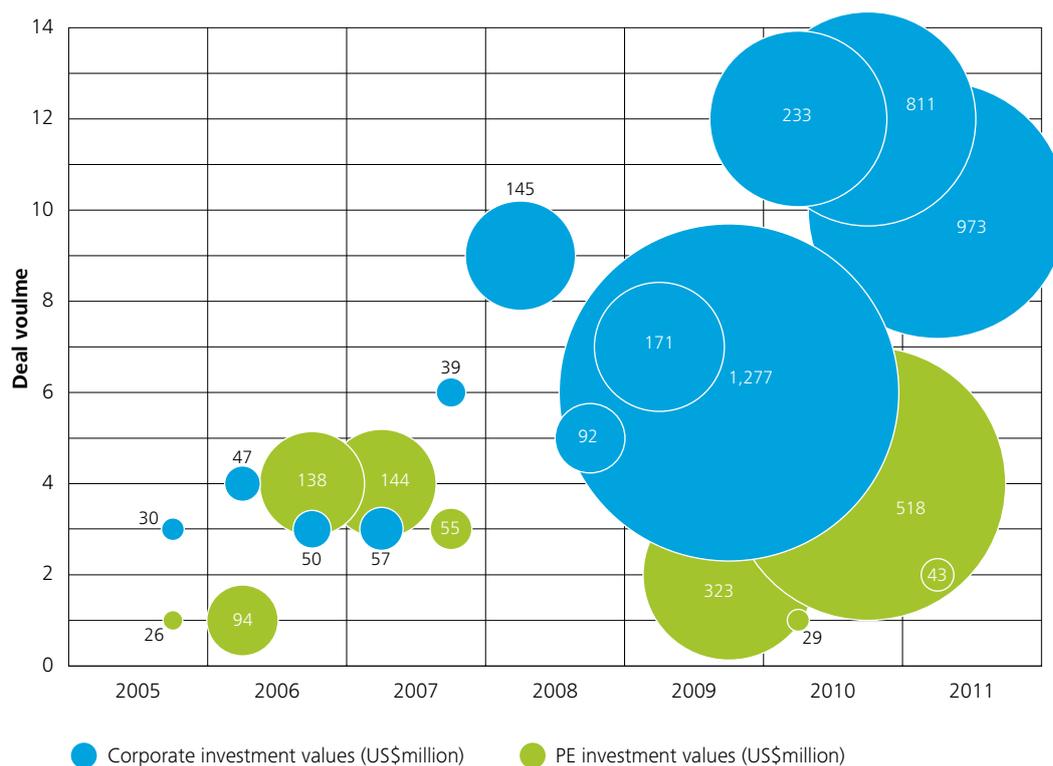
Source: mergermarket

Driving these dramatic surges in investment are a few companies that seem poised to take up the "national champion" mantle, and that are snapping up smaller targets left and right. These include Shanghai Pharmaceuticals, Sinopharm, and Harbin Pharmaceutical Group, among others. Shanghai Pharmaceuticals, the China-based listed pharmaceuticals producer and seller, for instance, was virtually single-handedly responsible for 2009's sudden and steep investment surge: the Group spent US\$1.2 billion of the cumulative US\$1.6 billion spent in H2 of that year. First, it spent US\$828 million to acquire Shanghai Industrial Pharmaceutical Investment Co., followed by an additional US\$386 million to acquire Shanghai ZhongXi Pharmaceutical Co. These acquisitions, among others, have helped the group to centralise its procurement of bulk drugs, as well as reduce its operating and selling expenses and further optimise its corporate structure, allowing it to maintain high margins despite increasing costs of raw materials.

Optimisation of distribution channels is another major concern and driver of acquisitions. For example, Sinopharm, the listed China-based distributor of medicines and pharmaceutical products and operator of pharmaceutical chain stores, announced in March 2011 its acquisition of Zhejiang Wenling Medicine & Medicinal Materials Company, a pharmaceuticals distributor, for an undisclosed sum. Not only do such acquisitions reduce distribution costs, but also allow major players bent on expansion a chance to break into new regional marketplaces and capture fresh market share, as was the case with Shanghai Pharmaceuticals' 2011 takeover of China Health System Ltd., Beijing's third-largest drug distributor. This acquisition marked an important avenue for the company to expand its market to Northern China from its Shanghai base. In conjunction with its January 2011 acquisition of Aixin Weiyi Medical for US\$34 million, this purchase may allow Shanghai Pharmaceuticals' market share in Beijing's drug distribution sector to surpass that of Sinopharm (currently second-largest).

In such a clearly competitive environment, it would be easy to assume that cutthroat corporates are doing nearly all of the acquiring in an effort to grab pieces of the pie before it's all gone. However, is this really the case? What role do PE funds and private investors play in pharmaceuticals M&A activity?

Figure 22: China domestic pharmaceuticals acquirers by type, 2005–H1 2011



Remark: Bubble size is indicative of cumulative half-year deal values by investor type.

Source: mergermarket

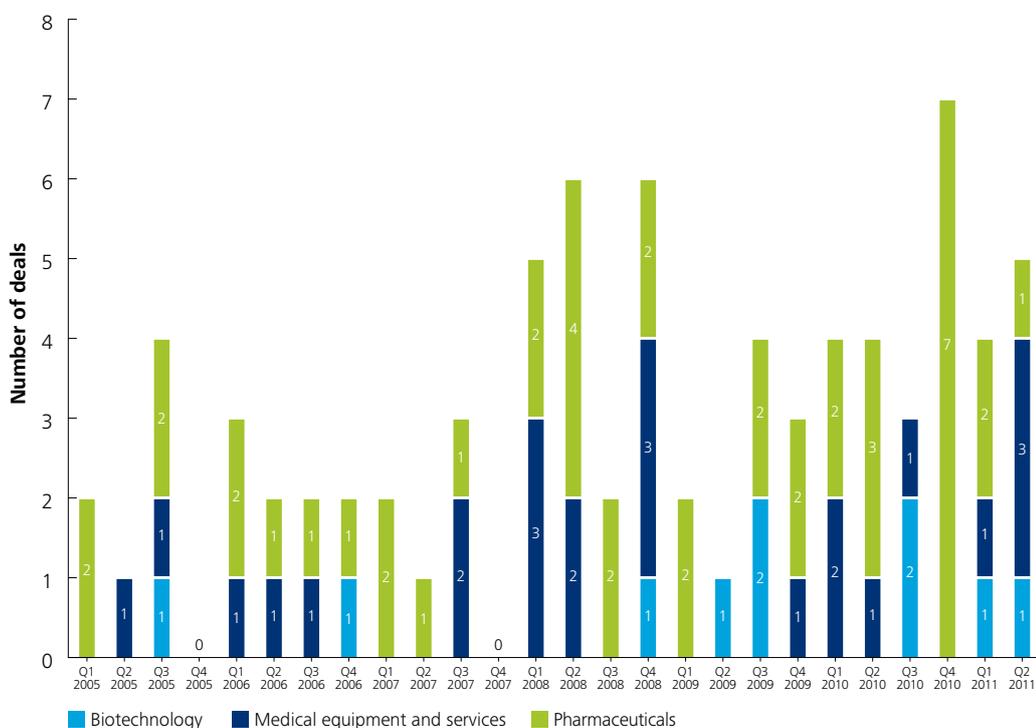
The data (Figure 22) clearly indicate that in the early years of M&A activity in this sector (2005–2008), both PE and corporate players showed equally dynamic movements, investing roughly the same amounts if not by deal volumes (33 corporate deals versus 13 deals by PE investors), then at least by values (US\$460 million spent by corporate, versus US\$457 spent by PE funds). However, in the year 2009, a sea change occurred, and PE investors truly began to play second fiddle to their more ambitious, deep-pocketed corporate counterparts. Over the period 2009 to H1 2011, corporate invested US\$3.5 billion via M&A, while PE investors spent a mere US\$913 million in nine deals, a handful in comparison. This is further evidence that the regulatory emphasis on consolidation may be accelerating corporate deal-making, while PE firms investing on more near-term horizons lack the same incentives to ramp up their acquisitions.

2. Inbound M&A activity making a gradual recovery

The inbound LSHC data (Figure 23) demonstrate a marked uptick in transactions beginning in the first quarter of 2008 (quarterly deal volumes averaged 4.75 in that year, versus 1.75 over the previous three years). After a predictable slump in 2009 due to the global recession, deal volumes rose slightly in the first half of 2010 (averaging 4 per quarter), and have showed an even more distinct increase in the past three quarters (Q4 2010–Q2 2011), back up to 4.75 per quarter.

Unlike in the domestic M&A arena, the pharmaceutical sector is not so clearly dominant in inbound transactions. However, it did make up a majority (56 percent) of all LSHC deals over the period from 2005 through H1 2011, versus 31 percent in medical sectors and just 13 percent in biotech. These proportions remain almost exactly the same for the most recent six quarters (2010 and the first half of 2011): 55.6 percent pharma, 29.6 percent medical, and 14.8 percent biotech (Figure 23).

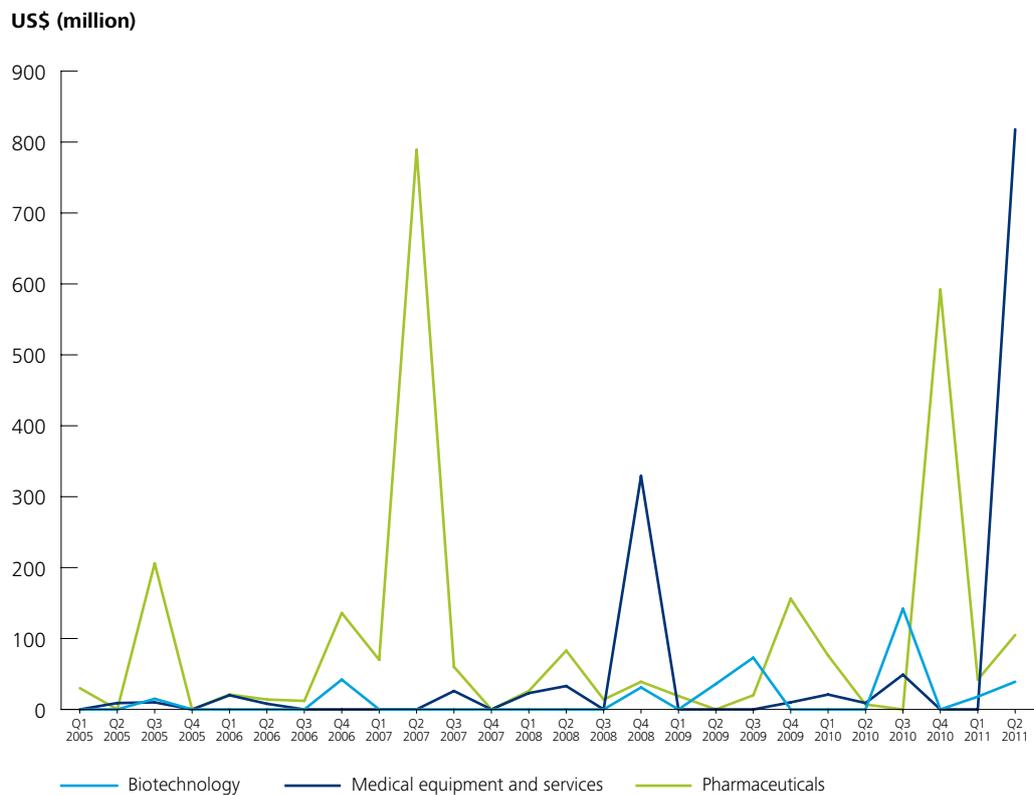
Figure 23: China inbound LSHC M&A activity 2005–H1 2011, by volume



Source: mergermarket

Deal values exhibit similar tendencies. Pharmaceuticals accounted for 57.5 percent of all LSHC transactions by value, compared with 33 percent and 9.5 percent for medical sectors and biotech, respectively, from 2005 through H1 2011. Pharmaceutical companies have consistently attracted the most cumulative inbound investment on an annual basis, and interest continues to rise. Average deal values in 2005 stood at US\$38.6 million, and have risen since then to US\$113.6 million in H1 2011. (Although average values did hit US\$157 million in 2007, this was due almost entirely to one massive acquisition—valued at US\$789 million—of Chinese pharmaceutical company Sanjiu Enterprise Group by China Resources Holdings, the state-owned Hong Kong-based conglomerate. As such, it is not specifically representative of a larger trend). These robust deal values mentioned above can be compared with smaller averages for domestic deals (US\$14 million in 2005 and US\$85 million in H1 2011), indicating that foreign players continue to have more economic clout and more clarified expansionist ambitions, allowing them to make the really big plays over the more fragmented local Chinese firms (Figure 24).

Figure 24: China inbound LSHC M&A activity 2005–H1 2011, by value



Source: mergermarket

Certainly overall market movement towards consolidation is affecting foreign players just as it does domestic players. Today's thousands of drug manufacturers, suppliers, and distributors, will someday soon be funneled down to a few hundred, with an eventual few dozen emerging as the true market leaders. The time to act is now, and multinationals know it. Major market leaders and smaller MNCs alike are acting fast, as demonstrated by the 2011 acquisition of NovaMed Pharmaceuticals Inc, the China-based company engaged in distribution and marketing of pharmaceutical products, by SciClone Pharmaceuticals, a U.S.-based biopharmaceutical company for US\$104.8 million. The deal, announced and executed in very short order, was designed to advance SciClone's position in the China market—top of mind as everyone scrambles for positioning.

Besides consolidation, though, there are other forces at work. Many multinationals have already invested significant resources in the China market, mostly to build market share by manufacturing and/or distributing domestically; and to conduct R&D, either more cost-effectively than in developed markets (due to decreasing willingness of developed world patients to participate in clinical trials), or to take advantage of China's regulatory and financial incentives to conducting R&D in-country.

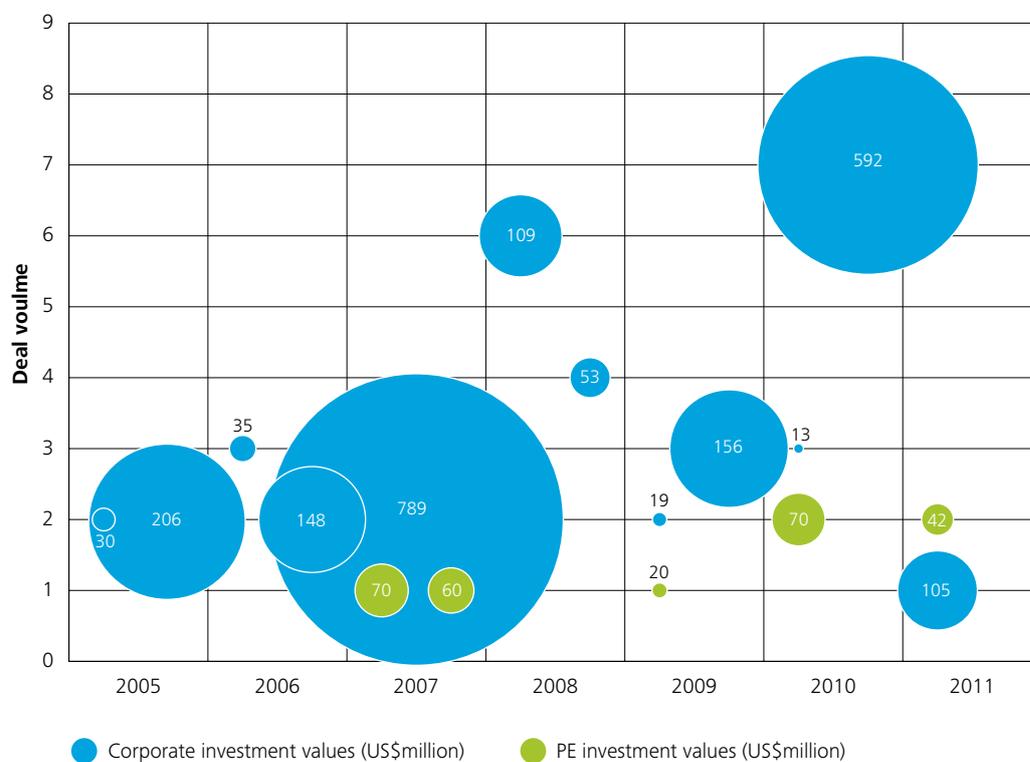
Most large multinational pharmaceutical players have R&D facilities in-country, including AstraZeneca and GlaxoSmithKline (of the U.K.), Eli Lilly (of the US), Roche (of Switzerland), and Bayer (of Germany). U.S.-based Pfizer has one of the largest presences, having invested over US\$500 million into the country and employing over 4,000 staff. Likewise, Swiss giant Novartis is in the process of investing some US\$1.3 billion into China after having chosen it as one of its three global research hubs.

It would stand to reason that after having devoted such significant resources to date into the country, MNCs would have an appetite for M&A transactions to further solidify their market presence. Indeed, in Q4 2010, GlaxoSmithKline announced plans to acquire Nanjing MeiRui Pharma Co., the China-based pharmaceutical company which manufactures urology and allergy medicines, for a consideration of US\$70 million.

As with motivations for domestic companies, optimisation of distribution channels may also increasingly play a role in driving inbound deals. For instance, in Q4 2010, Cardinal Health, the listed U.S.-based pharmaceutical provider of products and services for healthcare industry, acquired Zuellig Pharma China, the China-based company engaged in distribution of pharmaceuticals, for a total deal value of US\$470 million. This transaction marks the only major acquisition to date in the distribution sector by a foreign buyer and may be indicative of future moves to come.

Inbound investment into the China pharmaceutical market is even more dominated by corporate players than is transaction among domestic companies, with corporates accounting for nearly 84 percent of all deals by volumes (36 deals) over 2005–H1 2011, versus just over 16 percent (7 deals) for PE investors. By value, the trend is even more pronounced: transactions conducted by corporate acquirers accounted for 89 percent of all deal values (US\$2.2 billion), compared with 11 percent of values for deals done by PE players (US\$262 million). Moreover, it does not appear that PEs are either increasing or diminishing in influence in the China pharmaceuticals space—they have neither seen a commanding presence weaken, nor have carved a strong position in the market in recent quarters. Most likely, PE investment is simply overwhelmed by international pharma companies deploying their resources to prepare for China's emerging dominance among their markets. On the other hand, the PE firms' seemingly ambivalent position at present may connote a future opportunity for their investors to take advantage of previously-untapped niches (Figure 25).

Figure 25: China inbound pharmaceuticals acquirers by type, 2005–H1 2011



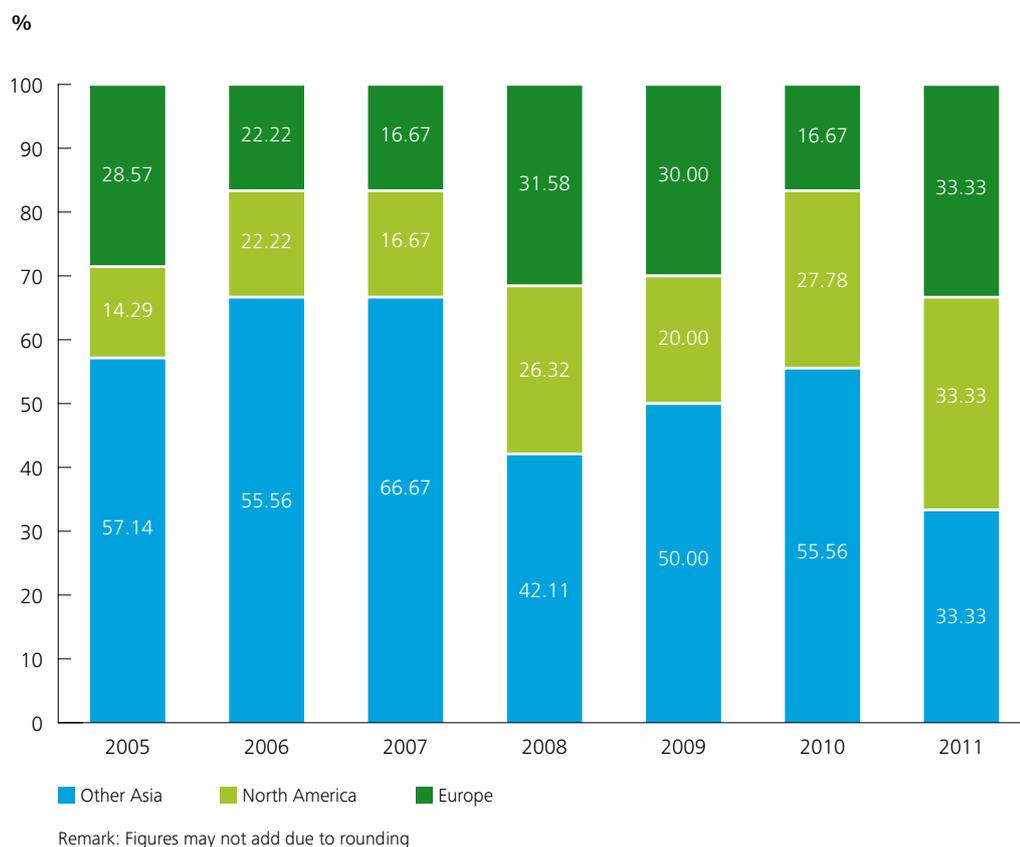
Remark: Bubble size is indicative of cumulative half-year deal values by investor type.

Source: mergermarket

2.1 Inbound acquisitions

By volumes, transactions by bidders in Asian countries (51.5 percent) dominated those by bidders from North America, mostly USA (23 percent), and Europe (25.5 percent) over the period 2005–H1 2011. However, the past three-and-a-half years have seen a significant shift from the 2005–2007 period, when Asian bidders (mostly Hong Kong-based) accounted for around 60 percent of all deals annually. In 2008, this percentage dropped to just above 40 percent, and by 2011, Asian bidders accounted for just 33 percent of transactions into Greater China. In contrast, deals by Europe-and-Americas-based acquirers in H1 2011 made up two-thirds of all transactions by volume (Figure 26).

Figure 26: Regional distribution of China LSHC inbound M&A, by deal volume (%), 2005–H1 2011



Source: mergermarket

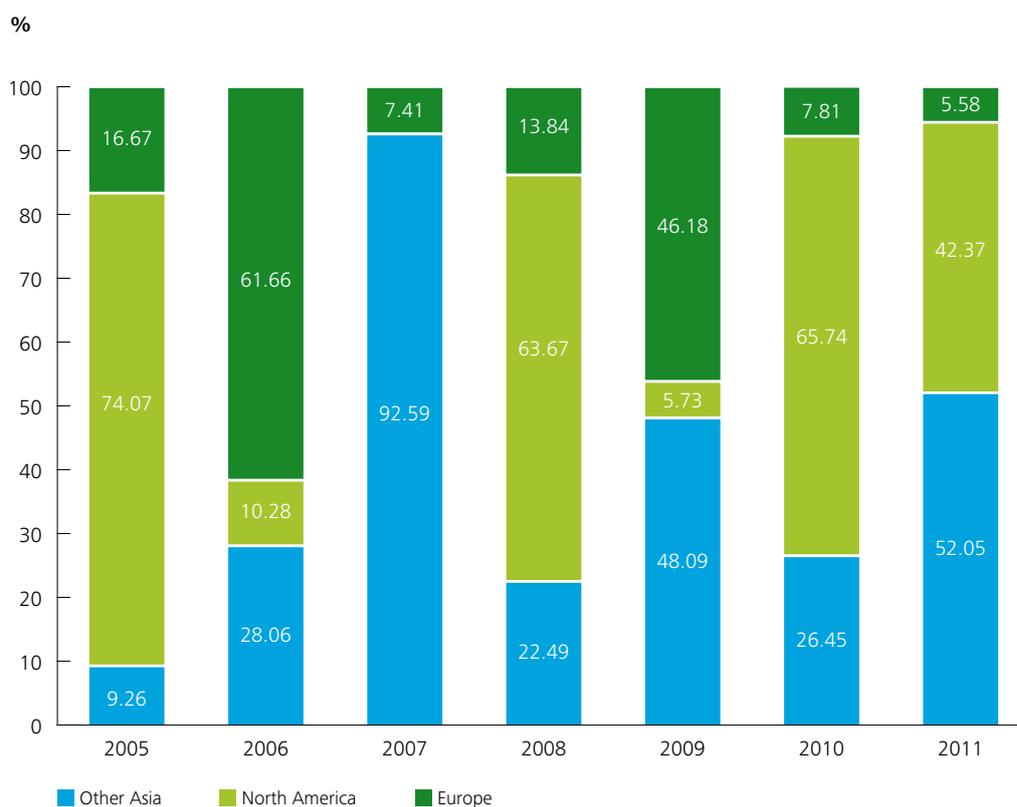
In June 2011, Hologic Inc., the listed U.S.-based manufacturer and supplier of diagnostics, medical imaging systems, and surgical products for women, closed its acquisition of TCT International Co., Ltd., the China-based distributor of medical products, for a cash consideration of US\$300 million. This was the second-largest deal to date in 2011. The largest deal announced in this first half, however, was conducted by an Asian buyer: Singapore-based Biosensors Interventional Technologies Pte. Ltd. agreed to acquire the remaining 50 percent stake in JW Medical Systems Limited, the China-based company engaged in production and sales of heart stents and other medical devices, from Shandong Weigao Group Medical Polymer Company Limited, for US\$508 million. (It had previously acquired the first 50 percent in 2007.)

Despite Biosensors Interventional Technologies' massive acquisition in 2011, however, most of the largest acquisitions (over US\$100 million) in the past six-and-a-half years have not, in fact, been by Asian companies, but rather, as one might expect, by U.S. and European pharmaceutical giants. Of the ten deals valued in excess of US\$100m that took place from 2005–H1 2011, totaling US\$3.09 billion, seven deals valued at US\$1.67 billion (54 percent), were by U.S. and European acquirers. This included a US\$125 million deal by Switzerland-based Novartis to acquire an 85 percent stake in Zhejiang Tianyuan Bio-Pharmaceutical Co. Also included was a US\$136 million deal wherein Bayer Healthcare China Ltd, the China-based consumer care division of Bayer HealthCare AG, acquired the Western over-the-counter (OTC) cold and cough portfolio of Topsun Science and Technology Co., Ltd, the listed Chinese pharmaceutical company. The remaining five of the seven deals were all by U.S. companies: Bausch & Lomb, China Cord Blood Corporation, Cardinal Health, SciClone Pharmaceuticals, and Hologic. Three transactions were in the pharmaceuticals sector (total US\$775 million), while two were medical devices/equipment deals (a cumulative US\$629 million).

Indeed, in 2010 and 2011, North American players accounted for 65.7 percent and 42.4 percent, respectively, of all LSHC inbound deals by value, compared with 26.5 percent and 52 percent by Asian players and a mere 7.8 percent in 2010 and 5.6 percent in 2011 by Europe-based companies. The relatively larger proportion of deals volumes for Asian companies, but lower shares of values, suggest that a host of smaller Greater China and Asia players are involved in a wide array of small-cap acquisitions, leaving the big ticket items mostly to the MNCs (Figure 27).

This proposition is borne out by an analysis of average deal values. Excluding two very large deals by Asian players (Hong Kong-based China Resource Holdings US\$789 million acquisition of Sanjiu Enterprise Group in 2007, and the 2011 US\$508 million purchase by Singapore's Biosensors Interventional Technologies discussed above), clearly exceptions to the rule, the average deal size for Asian bidders over 2005–H1 2011 stood at just US\$20 million. This is in comparison to an average of US\$86 million for transactions by North American companies. European companies, somewhat surprisingly, averaged just US\$25.6 million per transaction, broadly in line with the sums paid by their Asian peers, perhaps making it clear how the priorities (and cash flows) of U.S. acquirers differ markedly from the priorities of other players worldwide

Figure 27: Regional distribution of China LSHC inbound M&A, by deal value (%), 2005–H1 2011



Remark: Figures may not add due to rounding

Source: mergermarket

2.2 The due diligence challenge

In addition to the distinctive features of China's overall pharmaceuticals market, foreign pharmaceuticals companies planning to enter China will find certain shared characteristics among the domestic Chinese companies with whom they may seek to partner, or whom they may seek to acquire.

Any acquirer, foreign or domestic, will be looking for certain attributes in targets shortlisted for acquisition. The same prospective acquirer should also undertake due diligence on their likely target to find potential deal roadblocks and circumvent them if possible. Pharmaceutical transactions in China will encounter a range of familiar due diligence issues: quality of information; revenue recognition; misstatement of revenue due to unrecorded rebates; recording of intangible assets such as in-licensing agreements; and sales incentives, to name a few. These and other issues will affect the buyer's decision of what to pay, and ultimately whether to go forward with the deal.

Other challenges in choosing Chinese pharmaceutical companies for partnership or investment are cataloguing the products and capabilities of a company, including compounds in their drug development pipeline, as well as correctly understanding their strategic relationships and costs of doing business. In respect of the former, it is important to note what kinds of products are being manufactured and by what means the relevant intellectual property is obtained, whether by in-house development, by in-licensing, or by other means.

Most companies in China's pharmaceutical market may be categorised in four different ways:

- Western foreign-invested enterprises (FIEs) for a range of purposes, from opening a window on the Chinese market, to enabling access for distribution
- Chinese manufacturers of "Western" chemical and biological pharmaceuticals, especially APIs and generic finished drugs
- Manufacturers of "traditional Chinese medicines" (TCM), generally medicinal and botanical treatments
- Contract research organisations (CROs) and other research companies.

Except for the Western FIEs, which often indicate the Western parent's name, the legal name of a Chinese LSHC company is not a strong indicator of to which category it belongs. Many manufacturers of medicinal and botanical TCM bear the word "pharmaceutical" in their English name. Moreover, many companies do not fit neatly into one type or another, as companies that manufacture generics or pharmaceutical preparations of various kinds often also produce TCM treatments. The SFDA certifies TCM remedies through a separate path of drug certification apart from Western-styled chemical and biological pharmaceuticals.

Furthermore, as with many Chinese state-owned enterprises, some companies branded as pharmaceutical companies and listed as such on stock exchanges are engaged in a range of non-pharmaceutical businesses, from heavy industry to property speculation. Superficial analysis of stock listings, official names, and stated business lines does not therefore necessarily convey a complete, straightforward picture of how a "Chinese pharmaceutical company" earns money for its owners.

3. Outbound M&A

While inbound and domestic LSHC M&A activity has continued to move from strength to strength over the past six-and-a-half years, acquisitions of foreign targets by Chinese-based LSHC players are a relative rarity, with just seven transactions, worth a total of US\$726 million, having been closed from 2005 through H1 2011.

These outbound acquisitions can be broadly divided into two categories—those which were announced before the onset of the global financial crisis and those which came after. The former were generally characterised by acquisitions of controlling interests in target firms, with players such as Mindray Medical and WuXi PharmaTech both conducting deals valued in the hundreds of millions of dollars as they looked to expand their presence abroad, as well as introduce new technological processes and best-practice techniques into their core operations.

3.1 Outbound M&A of China's LSHC industry: historical activity

The smaller of these two pre-crisis deals mentioned above was the US\$163 million acquisition of AppTec Laboratory Services, the U.S. provider of testing, contract R&D, and cGMP manufacturing services, by WuXi PharmaTech Inc., the China-based and U.S.-listed CRO, in Q1 2008.

The larger of the two deals was also announced in Q1 2008 and saw Mindray Medical International, the Chinese developer, manufacturer and marketer of medical devices, acquire the patient monitoring business of Datascope Corp., the U.S. diversified medical device company, from Datascope Corporation, the listed U.S. medical products maker, for US\$240 million. Datascope sold the division to Mindray as it looked to trim annual costs by roughly US\$17 million. For its part, Mindray acquired the business looking to create a global monitoring company, and went on to undertake a domestic acquisition in China in the first quarter of 2011.

With the Global Financial Crisis focusing LSHC corporates' attentions elsewhere, no outbound acquisitions were undertaken in 2009; and when acquirers did return to the market in 2010, they brought a markedly different mindset from what had gone before. Indeed, over 2010, a duo of Chinese-based private equity firms made their mark on the outbound M&A scene, acquiring a Singaporean biotech business and a U.S. medical devices manufacturer. The first of these saw Hony Capital acquire a 29.47 percent stake in Biosensors Interventional Technologies, the medical technology licensing and device manufacturer, for a total of US\$217 million. The deal came about as Biosensors had recently developed the world's first stent to be coated with biodegradable polymers, and they required additional funding to effectively market the product.

The second such deal saw Legend Capital, the Chinese private equity firm, team up with OrbiMed Advisors, a U.S. counterpart, to acquire a 31.25 percent stake in U.S. orthopedic product manufacturer Bonovo Orthopedics Inc. for an undisclosed amount. Legend and OrbiMed's support will allow Bonovo to expand its China operations as it looks to maintain its dominance within China's rapidly booming orthopedic products market.

3.2 Looking forward

While recent outbound LSHC M&A activity emanating from China has been sparse in terms of actual deal volumes and values, the pipeline for deal-making in this particular regard looks suggests otherwise. Looking forward, prospective outbound LSHC M&A activity stemming from China will most likely be driven by large-cap acquisitive pharmaceutical businesses with sizable M&A war chests, private equity interest in medical device manufacturers, as well as CRO tie-ups.

3.2.1 Private equity interest in medical device manufacturers

Notwithstanding Legend Capital's purchase of a minority interest in Bonovo, the fact that following Hony Capital's minority stake acquisition in Biosensors, the corporate subsequently went on to acquire certain assets belonging to U.S. firm Devax, which manufactures another popular type of stent, indicates that locally-based private equity firms are increasingly looking to undertake overseas acquisitions of medical device manufacturers. Indeed, investors such as Hony and AIF Capital Partners, are increasingly looking to support buyouts of businesses with exposure to interventional cardiology and critical care procedures (for example, stents are used on patients suffering from heart conditions in order to keep blood vessels from collapsing). Indeed, Hony's chairman John Zhao said as much following the acquisition, noting that the fund "sees tremendous growth potential in this market, particularly in emerging markets like China, where cardiac disease remains the number one cause of death."

Nevertheless, whether or not this interest in foreign medical device manufacturers will also begin emanating from corporate buyers is too early to be seen. Despite the central government's policy to this effect, some market specialists believe that the domestic market is too fragmented for any one national champion to emerge who will have the scale to undertake transformational acquisitions abroad. Furthermore, if such a national champion did emerge, planned healthcare reforms associated with the recent publication of the 12th Five-Year Plan are focusing medical device manufacturers' attentions on providing more comprehensive and cheaper medical and healthcare services to third- and fourth-tier cities in Central and Western China. Nevertheless, the recent announcement that Dehaier Medical System—a China-based, NASDAQ-listed medical devices company—is reportedly in talks to acquire a U.S. target could open the door for further deal-making opportunities in this regard.

3.2.2 Large-cap pharmaceuticals' expansion abroad

Yet other market practitioners believe that the bulk of potential LSHC deal-making abroad may stem from large-cap, cash-rich Chinese pharmaceuticals such as Sinopharm and Shanghai Pharmaceuticals,

both of which have sizable M&A war-chests following the former's wildly successful IPO on the Hong Kong stock exchange in Q3 2009 and the latter's expected US\$1.89 billion IPO on the same bourse in H2 2011. Shanghai Pharmaceuticals has already made it clear that 30 percent of the proceeds from its proposed IPO are set to go towards domestic and foreign acquisitions, with medium-sized and large European or U.S. targets meeting their needs in terms of acquisitions.

Meanwhile, competitors such as Shanghai Fosun Pharmaceutical, Nanjing Aosaikang Pharmaceutical and state-owned Chongqing Medicines are looking to go public in the foreseeable future, with all the firms having also made it clear that some of the proceeds from their respective listings will be earmarked for further acquisitions.

Nonetheless, such moves abroad will most likely be the preserve of market leaders. China's pharmaceuticals industry is notoriously fragmented, with its top ten players accounting for just 25 percent of the domestic market; in comparison, the world's top ten pharmaceutical companies account for a 50 percent share of the international pharmaceuticals market. As a result, over the short-term at least, second-tier players will continue to focus on domestic consolidation, with a more favourable medium- to long-term outlook, as the current bout of consolidation comes to an end and these newly restructured players also look to move abroad.

3.2.3 Outbound CRO M&A

Industry commentators are also bullish on outbound opportunities in the CRO space, especially since the aforementioned US\$163 million acquisition of AppTec Laboratory Services by WuXi PharmaTech Inc. Indeed, spurred on by supportive government policies, CRO start-ups—many of which are led by members of the Chinese diaspora—are using their overseas connections to grow in size, although many believe that deal values in this particular arena will continue to remain very small—at least for the conceivable future.

4. China and India LSHC M&A: a giant competition or a giant opportunity?

China and India, as two of Asia's largest economies and populations, are on paper perhaps *de facto* competitors. They have many of the same resources at their disposal (cheap, abundant labor; massive market size; large and diverse populations with growing medical demands; booming economies driving healthcare spending; and regulatory incentives for LSHC multinationals to locate there). India has gained a reputation as a global manufacturing powerhouse for generic drugs; but China is fast catching up, certainly in terms of R&D. If, then, they fill the same niche in drug global supply, do synergies exist between these two countries for cross-border M&A?

Although the two countries are the most active M&A players in the region (Greater China accounted for 32 percent of Asia pharmaceuticals M&A activity between 2007 and 2010, and India 31 percent), to date, there have been no cross-border LSHC deals between China and India.¹⁶ This is certainly not to say that opportunities do not exist, but perhaps that domestic maturation in both markets has kept players so occupied that they have as yet had limited chance to search abroad (especially in a similar developing market) for attractive assets. This may be about to change, however, as stronger market leaders in both countries begin to hunt abroad for technologies and brands.

For example, Sun Pharmaceuticals, the Mumbai-based generic pharmaceutical company, is rumored to be seeking to expand its branded-generic side presence in emerging markets, according to the company. It is specifically looking for small-cap acquisitions in the space, and has recently announced a joint venture with U.S.-based Merck to manufacture generics in emerging markets. In its focus on these jurisdictions, it hopes to build on an already-strong presence in India while simultaneously expanding in countries like China, Mexico, Brazil, and South Africa. Creating local manufacturing capacity in these markets will aid in more rapid market penetration and strengthen global distribution networks. The company also plans to expand sales forces in these target markets to market branded generic products.

With the emphasis in the FYP on strategic emerging industries, of which pharmaceuticals and biotech together comprise one, China can expect to see significant public and private investment in these sectors in the coming years. A major opportunity for Indian investors involves targeted incentives in the "new medical" or "high-tech" zones being developed by many municipalities, such as the Taizhou Medical New & Hi-Tech District in Taizhou, Jiangsu province. Such zones give foreign investors particular tax and financial breaks to set up shop or form JVs, a lower-risk way for foreign investors with eyes on the Chinese marketplace to make a first entry point.

Cross-border LSHC activity between China & India

Only one Chinese acquisition of an Indian LSHC target has been closed over the past six-and-a-half years, with this particular deal actually falling outside the deal criteria specified for this report. The deal in question saw Aurobinda Pharma, the Indian generic pharmaceuticals manufacturer, divest its interest in Aurobindo (Datong) Bio Pharma, a subsidiary of the business, to Sinopharm. The transaction came about as Aurobindo looks to divest its non-core loss-making operations. For its part, Sinopharm has offered to inject sufficient funds into the subsidiary to significantly enhance its capacity, which should ultimately result in better economies of scale.

While not strictly an outbound deal *per se*, this transaction highlights an interesting point regarding cross-border LSHC acquisitions between India and China. In the past, Chinese LSHC players have acquired abroad primarily to access new technological processes or to expand market share overseas. With India being the second-most populous country on the planet, as well as being home to world-class generics manufacturers anticipating the next wave of blockbuster drug patent expirations to come in 2011 and 2012, the prognosis for outbound dealmaking is incredibly healthy.

¹⁶ One exception may be the two acquisitions by Hong Kong-based AIF Capital Asia into India in 2008 (US\$31 million) and 2010 (US\$39 million) but as these are not mainland-originated deals, they are not included for the purpose of this discussion.

Conclusion

The combined effect of China's healthcare reform and growing market has been to offset continuing concerns about regulatory challenges and IP protection, giving confidence to those international pharmaceutical companies that seek to take advantage of the opportunities presented. Those opportunities comprise research, OTC, distribution, and biotech subsector development, as well as the overall growth of China's market, and particularly rural and suburban market growth due to healthcare reform. As has been seen already, foreign companies are making the most of these opportunities by ramping up M&A activity, as China's LSHC industry enters its next and greatest phase of growth yet.



Abbreviations

A

AESGP—Association of the European Self-Medication Society

B

BMI—Basic Medical Insurance

C

CDE—Center for Drug Evaluation

CROs—contract research organisations

D

DAL—Drug Administration Law

E

EDL—Essential Drugs List

EIU—Economist Intelligence Unit

F

FIEs—foreign-invested enterprises

FYP—Five-Year Plan

G

GCP—Good Clinical Practice

GMP—Good Manufacturing Practice

L

LSHC—life sciences and healthcare

M

MOH—Ministry of Health

N

NCMS—New Co-operative Medical Scheme

NDRC—National Development and Reform Commission

NSBC—National Statistics Bureau of China

P

PFDA—provincial Food and Drug Administrations

S

SDA—State Drug Administration

SFDA—State Food and Drug Administration

SMEI—Southern Medicine Economic Institute

T

TCM—traditional Chinese medicine

U

USFDA—U.S. Food and Drug Administration

W

WHO—World Health Organisation

Contacts

For more information, please contact:



Yvonne Wu
Partner, Enterprise Risk Services
National Leader,
Deloitte China Life Sciences and Health Care
Tel: +86 21 6141 1570
Email: yvwu@deloitte.com



Mike Braun
Partner
Financial Advisory Services
Tel: +86 21 6141 1605
Email: mibraun@deloitte.com

Flora Ma
Programme Manager
Deloitte China Life Sciences and Health Care
Tel: +86 21 6141 1500
Email: floma@deloitte.com

For further information, visit our website at www.deloitte.com/cn

Acknowledgements

We wish to thank the following Deloitte people for their contributions to this report.

Lydia Chen
Director
Deloitte China Research and Insight Centre

Jill Qu
Senior Manager
Deloitte China Research and Insight Centre

Vivienne Huang
Assistant Manager
Deloitte China Research and Insight Centre

Douglas Robinson
M&A Research Manager
Financial Advisory Services

William Earl Hillis
Manager
Financial Advisory Services

Chryssa Rask
Senior Associate
Financial Advisory Services

Contact details for Deloitte's China Practice

Beijing

**Deloitte Touche Tohmatsu CPA Ltd.
Beijing Branch**
8/F Deloitte Tower
The Towers, Oriental Plaza
1 East Chang An Avenue
Beijing 100738, PRC
Tel: +86 10 8520 7788
Fax: +86 10 8518 1218

Chongqing

**Deloitte & Touche Financial Advisory
Services (China) Limited**
Room 10-12
13/F International Trade Center
Chongqing
38 Qing Nian Road
Yu Zhong District
Chongqing 400010, PRC
Tel: +86 23 6310 6206
Fax: +86 23 6310 6170

Dalian

**Deloitte Touche Tohmatsu CPA Ltd.
Dalian Branch**
Room 1503 Senmao Building
147 Zhongshan Road
Dalian 116011, PRC
Tel: +86 411 8371 2888
Fax: +86 411 8360 3297

Guangzhou

**Deloitte Touche Tohmatsu CPA Ltd.
Guangzhou Branch**
26/F Teemtower
208 Tianhe Road
Guangzhou 510620, PRC
Tel: +86 20 8396 9228
Fax: +86 20 3888 0119 / 0121

Hangzhou

**Deloitte Business Advisory Services
(Hangzhou) Company Limited**
Room 605, Partition A
EAC Corporate Office
18 Jiaogong Road
Hangzhou 310013, PRC
Tel: +86 571 2811 1900
Fax: +86 571 2811 1904

Harbin

**Deloitte Consulting (Shanghai)
Company Limited
Harbin Branch**
Room 1618
Development Zone Mansion
368 Changjiang Road
Nangang District
Harbin 150090, PRC

Hong Kong SAR

Deloitte Touche Tohmatsu
35/F One Pacific Place
88 Queensway
Hong Kong
Tel: +852 2852 1600
Fax: +852 2541 1911

Jinan

**Deloitte & Touche Financial Advisory
Services Limited
Jinan Liaison Office**
Unit 1018, 10/F, Tower A, Citic Plaza
150 Luo Yuan Street
Jinan 250011, PRC
Tel: +86 531 8518 1058
Fax: +86 531 8518 1068

Macau SAR

Deloitte Touche Tohmatsu
19/F The Macau Square Apartment H-N
43-53A Av. do Infante D. Henrique
Macau
Tel: +853 2871 2998
Fax: +853 2871 3033

Nanjing

**Deloitte Touche Tohmatsu CPA Ltd.
Nanjing Branch**
11/F Golden Eagle Plaza
89 Hanzhong Road
Nanjing 210029, PRC
Tel: +86 25 5790 8880
Fax: +86 25 8691 8776

Shanghai

Deloitte Touche Tohmatsu CPA Ltd.
30/F Bund Center
222 Yan An Road East
Shanghai 200002, PRC
Tel: +86 21 6141 8888
Fax: +86 21 6335 0003

Shenzhen

**Deloitte Touche Tohmatsu CPA Ltd.
Shenzhen Branch**
13/F China Resources Building
5001 Shennan Road East
Shenzhen 518010, PRC
Tel: +86 755 8246 3255
Fax: +86 755 8246 3186

Suzhou

**Deloitte Business Advisory Services
(Shanghai) Limited
Suzhou Branch**
23/F Building 1
Global Wealth Square
88 Su Hui Road, Industrial Park
Suzhou 215021, PRC
Tel: +86 512 6289 1238
Fax: +86 512 6762 3338 / 3318

Tianjin

**Deloitte Touche Tohmatsu CPA Ltd.
Tianjin Branch**
30/F The Exchange North Tower
189 Nanjing Road
Heping District
Tianjin 300051, PRC
Tel: +86 22 2320 6688
Fax: +86 22 2320 6699

Wuhan

**Deloitte & Touche Financial Advisory
Services Limited
Wuhan Liaison Office**
Unit 2, 38/F New World International
Trade Tower
568 Jianshe Avenue
Wuhan 430022, PRC
Tel: +86 27 8526 6618
Fax: +86 27 8526 7032

Xiamen

**Deloitte & Touche Financial Advisory
Services Limited
Xiamen Liaison Office**
Unit E, 26/F International Plaza
8 Lujiang Road, Siming District
Xiamen 361001, PRC
Tel: +86 592 2107 298
Fax: +86 592 2107 259

About Deloitte

Deloitte refers to one or more of Deloitte Touche Tohmatsu Limited, a UK private company limited by guarantee, and its network of member firms, each of which is a legally separate and independent entity. Please see www.deloitte.com/cn/en/about for a detailed description of the legal structure of Deloitte Touche Tohmatsu Limited and its member firms.

Deloitte provides audit, tax, consulting, and financial advisory services to public and private clients spanning multiple industries. With a globally connected network of member firms in more than 150 countries, Deloitte brings world-class capabilities and high-quality service to clients, delivering the insights they need to address their most complex business challenges. Deloitte's approximately 182,000 professionals are committed to becoming the standard of excellence.

About Deloitte China

In China, services are provided by Deloitte Touche Tohmatsu and Deloitte Touche Tohmatsu CPA Limited and their subsidiaries and affiliates. Deloitte Touche Tohmatsu and Deloitte Touche Tohmatsu CPA Limited are, together, a member firm of Deloitte Touche Tohmatsu Limited.

Deloitte China is one of the leading professional services providers in the Chinese Mainland, Hong Kong SAR and Macau SAR. We have nearly 10,000 people in 16 offices in Beijing, Chongqing, Dalian, Guangzhou, Hangzhou, Harbin, Hong Kong, Jinan, Macau, Nanjing, Shanghai, Shenzhen, Suzhou, Tianjin, Wuhan and Xiamen.

As early as 1917, we opened an office in Shanghai. Backed by our global network, we deliver a full range of audit, tax, consulting and financial advisory services to national, multinational and growth enterprise clients in China.

We have considerable experience in China and have been a significant contributor to the development of China's accounting standards, taxation system and local professional accountants. We also provide services to around one-third of all companies listed on the Stock Exchange of Hong Kong.

This publication contains general information only, and none of Deloitte Touche Tohmatsu Limited, its member firms, or their related entities (collectively, the "Deloitte Network") is, by means of this publication, rendering professional advice or services. Before making any decision or taking any action that may affect your finances or your business, you should consult a qualified professional adviser. No entity in the Deloitte Network shall be responsible for any loss whatsoever sustained by any person who relies on this publication.

