China's pharmaceutical market: summary and prospects
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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, 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

<table>
<thead>
<tr>
<th></th>
<th></th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>Set up the basic health system</td>
<td>Strengthen basic health system</td>
<td>Minor adjustments to the health system based on circumstances</td>
</tr>
<tr>
<td><strong>Basic Medical Insurance System</strong></td>
<td><strong>National Essential Drug List</strong></td>
<td><strong>Fundamental Health Service System</strong></td>
</tr>
<tr>
<td>• Allocate RMB850 billion to Chinese healthcare industry</td>
<td>• Issue the essential drug list</td>
<td>• Fund 986 county hospitals, 3,549 township health centres, 1,154 community health clinics and other types of fundamental healthcare organisations</td>
</tr>
<tr>
<td>• Increase basic medical insurance coverage to more than 90% of the Chinese population</td>
<td>• Promote public bidding and purchasing of essential medicines</td>
<td>• Setting up a two way referral system between community centers and the high level hospitals</td>
</tr>
<tr>
<td>• Restructure the drug distribution mechanism</td>
<td>• Restructure the drug distribution mechanism</td>
<td></td>
</tr>
</tbody>
</table>

The next phase: Opportunities in China’s pharmaceuticals market
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. 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.

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. 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$ (billion)

<table>
<thead>
<tr>
<th>Year</th>
<th>Pharmaceutical sales</th>
</tr>
</thead>
<tbody>
<tr>
<td>2007</td>
<td>26.2</td>
</tr>
<tr>
<td>2008</td>
<td>33.1</td>
</tr>
<tr>
<td>2009</td>
<td>42.1</td>
</tr>
<tr>
<td>2010</td>
<td>52.2</td>
</tr>
<tr>
<td>2011f</td>
<td>63.5</td>
</tr>
<tr>
<td>2012f</td>
<td>74.8</td>
</tr>
<tr>
<td>2013f</td>
<td>85.1</td>
</tr>
<tr>
<td>2014f</td>
<td>96.0</td>
</tr>
<tr>
<td>2015f</td>
<td>107.1</td>
</tr>
</tbody>
</table>

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

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

The next phase: Opportunities in China’s pharmaceuticals market
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. 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

1 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

![Figure 8: Rising net income and healthcare spending of rural households](image)

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, and 96 percent in 2011 according to the latest news release by the MOH. 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**

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

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)**

<table>
<thead>
<tr>
<th></th>
<th>Urban area</th>
<th>Rural area</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>2009</td>
<td>Change 08-09</td>
</tr>
<tr>
<td>Malignant Tumour</td>
<td>167.6</td>
<td>0.6</td>
</tr>
<tr>
<td>Heart Disease</td>
<td>128.8</td>
<td>7.8</td>
</tr>
<tr>
<td>Cerebrovascular Disease</td>
<td>126.3</td>
<td>5.5</td>
</tr>
<tr>
<td>Diseases of the Respiratory System</td>
<td>65.4</td>
<td>-7.8</td>
</tr>
<tr>
<td>Trauma and Toxicosis</td>
<td>33.5</td>
<td>-2.2</td>
</tr>
<tr>
<td>Endocrines, Nutritional &amp; Metabolic Diseases</td>
<td>20.3</td>
<td>-0.8</td>
</tr>
<tr>
<td>Diseases of the Digestive System</td>
<td>16.6</td>
<td>-1.0</td>
</tr>
<tr>
<td>Diseases of the Genitourinary System</td>
<td>7.3</td>
<td>0.4</td>
</tr>
<tr>
<td>Diseases of the Nervous System</td>
<td>6.9</td>
<td>0.6</td>
</tr>
<tr>
<td>Infectious Disease (not including Respiratory Tuberculosis)</td>
<td>4.4</td>
<td>-0.3</td>
</tr>
</tbody>
</table>

Source: NSBC

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6 NSBC
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

![Generic drug sales chart]

Source: SMEI, AESGP, BMI
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

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.\(^\text{10}\) 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).\(^\text{11}\)

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
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.

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

<table>
<thead>
<tr>
<th>Category</th>
<th>Market Share</th>
</tr>
</thead>
<tbody>
<tr>
<td>Genetic drugs</td>
<td>44.9%</td>
</tr>
<tr>
<td>Diagnostic reagents</td>
<td>11.9%</td>
</tr>
<tr>
<td>Antibody</td>
<td>15.6%</td>
</tr>
<tr>
<td>Vaccine</td>
<td>19.6%</td>
</tr>
<tr>
<td>Blood products</td>
<td>8%</td>
</tr>
</tbody>
</table>

Source: NSBC
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

- Completion of clinical trials
- Application for drug marketing
- Review by SFDA
- Onsite inspection by the SFDA
- Feasibility and reasonability of drug standard verified by the testing institution
- Comprehensive evaluation by CDE
- Onsite manufacturing inspection by the CDE
- Onsite manufacturing inspection report
- Onsite inspection report
- Onsite inspection report
- Compliance on one production lot (three for biological products) with the drug standard verified by the testing institute
- Testing report
- Compliance on one production lot (three for biological products) with the drug standard verified by the testing institute
- Testing report
- Comprehensive evaluation report
- Inspection by the SFDA
- New Drug Certification (Only) For applicants other than drug manufacturing companies
- Drug License
- Notification of the applicant
- Examination and approval by SFDA
- Onsite manufacturing inspection report
- Comprehensive evaluation report
- Inspection by the SFDA

Remark: CDE refers to “Center for Drug Evaluation.”

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.\(^\text{14}\) The SFDA and the PFDAs 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.

\(^\text{14}\) 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.
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
PFDAs—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

For the full report, please refer to the website of www.deloitte.com.