

8 China's Pharmaceutical Market: Business Environment and Market Dynamics

Michael Brueckner and Marc P. Philipp: Accenture GmbH, Kronberg, Germany;
Joachim E. A. Luithle: Bayer AG, Leverkusen, Germany

8.1 Introduction

Since the transition from a planned to a market economy started in 1978, China's economy has grown more than 8 percent per annum to a gross domestic product (GDP) of US\$ 1 trillion in 2003 – roughly the size of the United Kingdom's GDP (Beckmann 2004).

A closer look at China unveils a country faced with great complexities, driven by an enormous heterogeneity of customers, suppliers, competitors, regions, and government entities. Approximately 60 percent of the economy is represented by the country's east coast provinces; however, only 30 percent of the population lives there.

Not surprisingly, China's market attractiveness for multinationals varies greatly by sector. Whereas for some sectors China is the dominant force in driving global demand, other areas are still locked out from global trade due to regulatory issues or consumer preferences. With regard to the pharmaceutical industry, several multinational companies have already made significant commitments to shaping the Chinese industry – with some players starting as early as 20 years ago (Prahalad/Lieberthal 1998).

Despite limited short-term returns, major pharmaceutical players are pursuing aggressive growth strategies and trying to benefit from the Chinese market in the longer term. These efforts cover the entire value chain, including sourcing of active ingredients, research and development, and the production and selling of generic and proprietary drugs. In this, administrative hurdles, low healthcare spending, the lack of intellectual property protection and the poor distribution network infrastructure remain the biggest challenges (Trinh 2004).

This article outlines and analyzes the overall business environment, the healthcare system as well as market characteristics and dynamics for pharmaceutical multinational companies in China.

8.2 Business Environment for the Pharmaceutical Industry in China

8.2.1 Sociodemographic Business Environment

China’s trend towards a more developed and affluent society has already initiated a significant shift in its demographic profile. The Chinese population is beginning to age – foremost in the urban areas (see *Fig. 8.1*).

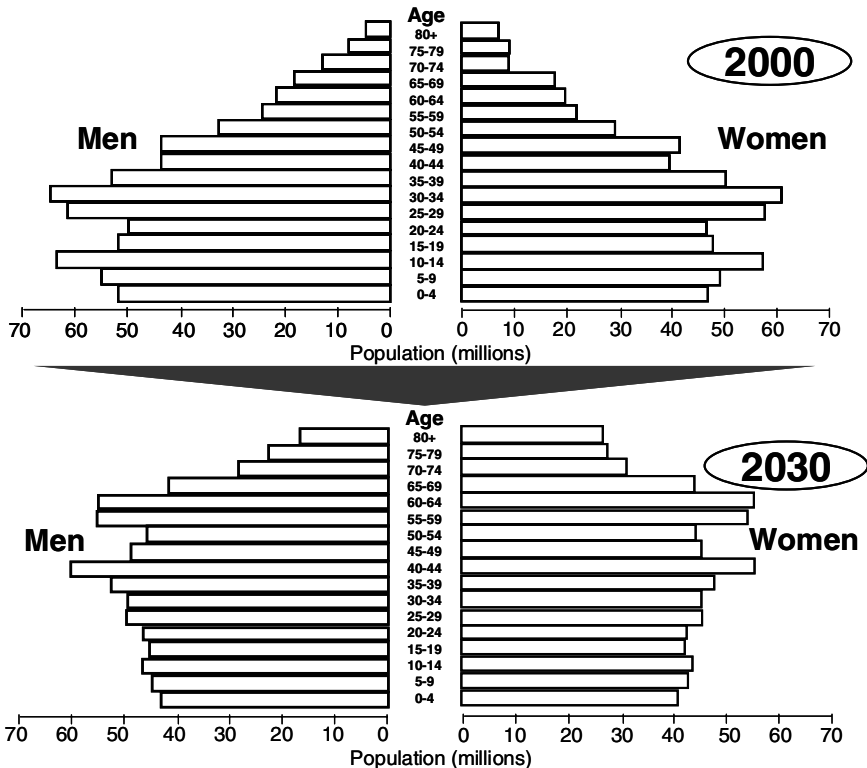


Fig. 8.1. Development of age distribution from 2000 to 2030 in the PR China (Source: U.S. Bureau of Census)

In urban China, the population aged 20 to 39, which accounts for most of the consumer spending, is expected to fall from 34 percent in 2002 to 30 percent in 2012. At the same time, it is expected that the proportion of the total population aged 65 and above will increase to 8 percent by 2008 and to 13 percent by 2025, a proportion that is even higher in major urban areas (*Liu/MacKellar 2001*).

These shifts, as well as the value which the Chinese place on good health, are likely to fuel demand for certain drug categories perceived to have preventive

qualities, such as certain OTC pharmaceuticals, but also substitutes such as nutraceuticals or traditional Chinese medicine (TCM).

China's future disease profile is expected to remain more in line with developing countries than with the Western world, with cancer and heart disease accounting for relatively few cases compared with infectious diseases for the population as a whole. Statistics for the main diseases suffered by hospital inpatients reveal the divide between the urban and rural populations.

One of the major disease issues facing China in the future will be the increasing HIV epidemic. Some 840,000 official cases of HIV infection were reported in 2003. Nevertheless, one must assume underreporting especially in rural areas, understating the true extent of the problem. The projections of the National Intelligence Council (NIC) foresee as many as 10 to 15 million HIV/AIDS cases in 2010. However, these individuals will remain diffused among very large populations. The economic effect will be limited – at least until 2010. China has started to counter this problem with its 'China Plan of Action to Contain, Prevent and Control HIV/AIDS (2001-2005)' program.

Diabetes is another disease that might reach unknown dimensions in China. Diabetes being a multi-factorial disease, in which the genes not only interact with each other but also with environmental factors, genetically predisposed individuals will not necessarily develop Type 2 diabetes unless they are also exposed to environmental factors. Considering the effects of the demographic shift and of increasing affluence, the number of diabetes patients in China alone might exceed 150 million in 2025. The economic burden of the diabetes epidemic could be tremendous, if direct healthcare costs are considered along with indirect costs related to co-morbidity, mortality and loss of productivity. Hypertension is one of the most common co-morbidities linked to diabetes.

8.2.2 Economic Business Environment

Although China is one of the largest sources of overseas profit for many multinationals across all industries, they are beginning to feel competitive pressure from local market players. Chinese companies have significantly improved their capabilities and are increasingly able to pull together great market offerings. One reason is that domestic firms benefit from an enormous pool of workers, flexible working conditions, and an average hourly pay of approximately US\$ 0.50 – even lower than Mexico's US\$ 2.30 and India's US\$ 0.80. Also, raw and processed materials are often cheaper in China and frequently match global quality standards; overall procurement costs generally run at 20 to 40 percent below the costs of comparable goods in established markets (*Joseph/Schaefer 2004; China Economic Information Network 2003*).

Despite great sourcing advantages, multinational drug makers' aversion to risk has resulted in imports being one of the driving forces, making up 40 percent of the Chinese pharmaceutical market in the mid 1990s (*Easton 2003; IMS Health 2004*). However, Chinese political leaders soon realized the importance of having their own champion league players in the pharmaceutical sector. Today, although

import quotas and licenses are not applied to medical products, biotech-based equipment, instruments and consumables and imported medical products are subject to import tariffs of 4.2 percent plus an additional 17 percent value-added tax.

Moreover, by introducing non-tariff barriers, such as a central reimbursement list or financial promotion of the TCM industry, policy makers have been actively fighting against extensive spending on imported drugs. Consequently, as the market has developed, the market share of drug imports has plunged to as low as 10 percent in recent years.

In addition to China's expected disease progression, a large portion of the country's future market attractiveness depends on how consumer spending develops. Although 10 percent of the total population still lives below the poverty line and the "middle class" with an annual household income of more than US\$ 20,000 makes up only 4 percent of the population, the growth trend will provide these 52 million people with the additional, necessary purchasing power to spend on healthcare, Western drugs and medical equipment.

8.2.3 Political and Regulatory Business Environment

It is expected that the political focus of the new Secretary General of the China Communist Party (CCP), Mr. Hu Jintao, will settle on two major issues in the coming years: advancing China's integration in the global trade community and improving China's social security system and infrastructure (*Hein 2004*).

With respect to the first issue, China's accession to the WTO in December 2001 has initiated the next round in opening up the country. However, the magnitude of change to be expected varies by industry sector, with the greatest impact in financial services and retailing. The pharmaceuticals market was already quite competitive before the country gained WTO membership.

Intellectual property (IP) rights – perhaps the most important issue for foreign R&D-based drug makers in China – are often expected to benefit significantly from WTO membership. Unfortunately, China's amendable IP climate is not the result of an inadequate legal framework, since the country's IP law conforms to most international IP standards such as the Trade-Related Aspects of Intellectual Property Rights (TRIPS) agreement granting 20-year patent terms and six years of data exclusivity from the date of marketing approval. Rather, the problem lies in poor enforcement, resulting in an estimated annual loss in sales of US\$ 800 million due to trademark infractions and patent infringements. Of particular concern is the increase in counterfeiting, which costs multinationals approximately 10 to 25 percent of annual sales. Nevertheless, China's WTO commitment has influenced the drug distribution system. The retail pharmaceutical sector was opened at the end of 2004, a particularly important step not only for OTC product manufacturers.

Despite the general trend toward opening the country to world trade and generating economic prosperity, a strong government relations program remains an important factor in success in China. As in other emerging markets, the state utilizes

its influence on market access and business rights to shape the involvement of foreign companies.

With respect to the second issue, the country's ill-preparedness for dealing with the SARS crisis and the particular problems faced by rural populations have moved disease prevention to a high position on the government's agenda. In 2003 and 2004, close to US\$ 1.4 billion were spent on improving the healthcare system and develop new centers and hospitals for infectious diseases. The aim is to have a system in place within three years which is able to effectively respond to emergencies. In this, a major role will be played by the State Food and Drug Administration (SFDA), which was founded in 2003 to replace the State Drug Administration (SDA) and consolidate some responsibilities of the State Administration for Industry and Commerce and the Ministry of Health.

In addition, the government has established the 'National High-Tech R&D Program', giving biotechnology the highest priority among its seven categories with funding estimated at US\$ 850 million from 2001 through 2005.

8.3 Market Characteristics and Dynamics of China's Pharmaceutical Industry

8.3.1 China's Healthcare Environment

Healthcare and Drug Expenditure

With a compound annual growth rate (CAGR) of more than 13 percent, China's total spending on healthcare has increased dramatically, faster than the country's general GDP levels.

Total healthcare expenditure accounted for 5.4 percent of GDP in 2002, up from 4.1 percent a decade earlier. However, OECD countries still spend significantly more – on average over 8 percent of their GDP – on healthcare. Furthermore, China's per capita spending is still 98 percent lower than the OECD average (see *Fig. 8.2*).

With respect to geographical differences, healthcare spending is very much concentrated on the more affluent provinces. Urban residents account for approximately 80 percent of total healthcare spending. The cities of Beijing, Shanghai, Jiangsu and Zhejiang, home to more than ten percent of China's population, already account for 25 percent of total spending. In comparison to per capita annual spending on healthcare in the United States (US\$ 300), China's expenditure is still 30 times lower (US\$ 10) (*Liu/Rao/Hsiao 2003*).

The geographical concentration of healthcare spending is also found with respect to drug expenditure. Consumption generally varies widely, with Beijing and Shanghai accounting for three times higher drug expenditure per capita than Tianjin (*Forney 2003*).

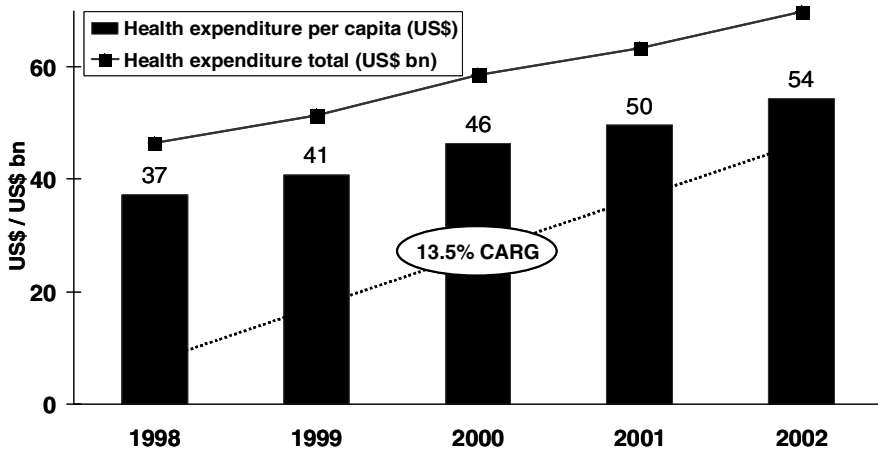


Fig. 8.2. Development of healthcare spending in the PR China (Source: Ministry of Health; Accenture Analysis)

Payers and Health Insurance System

Over the last decade, China's healthcare system has undergone various reforms as a result of cost explosions (since it provided basic healthcare services free of charge and thus established no incentives for cost effectiveness). In December 1998, the Chinese State Council agreed to establish a basic health insurance system for employees in the urban areas as part of the "Golden Social Insurance Scheme". For pragmatic reasons, the Ministry of Labor and Social Security (MOLSS) delegated the responsibilities for implementing the insurance scheme to regional level administrations. Consequently, only the major cities (again Shanghai is the leading force) have taken a professional approach to this initiative. Unfortunately, uncoordinated rudimentary systems still exist in many of China's provinces (Lampton 2003).

The "Shanghai model", currently China's most advanced health insurance system, consists of a welfare fund as well as individual and coordinated insurance accounts (see Fig. 8.3). However, as organizing the welfare funds is the responsibility of the city, provincial and regional administrations, a generalized view of the system is not practical.

Switching from a free healthcare system to one with a high level of individual financial contribution became unaffordable for the rural population, resulting in further aggravation. In 1998, 37 percent of the rural population could not afford a hospital stay; two thirds did not even have access to a nearby hospital. Currently, over 70 percent of the rural population pays for the major share of medical services entirely out-of-pocket.

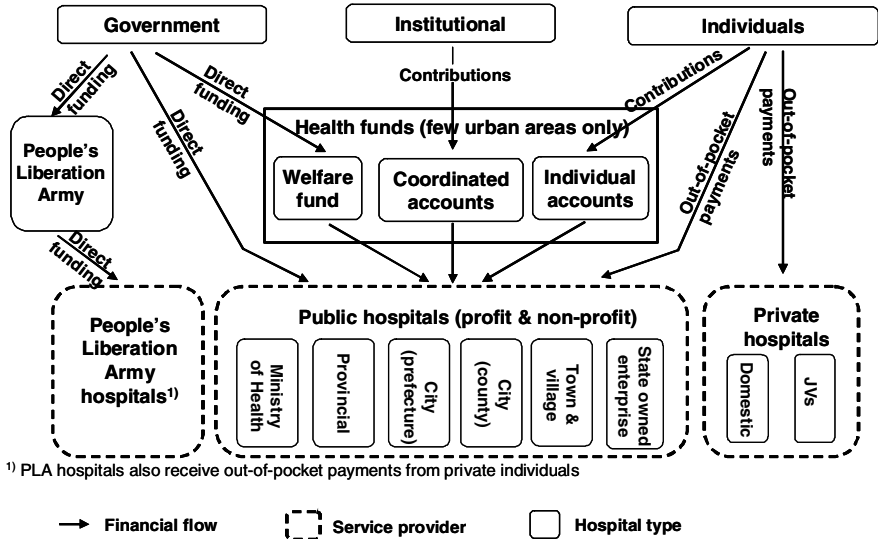


Fig. 8.3. Payers and providers in China's healthcare system (Source: Accenture Research & Analysis)

A program is currently underway to establish a healthcare funding scheme for the rural community. The ambitious goal is to cover all of China's 900 million farmers by 2010. The scheme will be funded by central and local governments, as well as by individuals, with subsidies promised for farmers living in the poorer central and western regions. The eastern province of Zhejiang is among the first to implement the new system and aims to have it fully operational by 2006.

Even the urban systems are still far from being perfect. In Shanghai more than 30 percent of the total population is still uninsured. As a consequence of the system transformation, individual contributions to healthcare expenses have nearly doubled (see Fig. 8.4). This trend toward private spending is likely to continue.

Nevertheless, by the end of 2003 more than 100 million citizens had joined the health insurance scheme. This has led to increasing demand for medical services; in 2002 China recorded over 2 billion hospital visits and almost 60 million in-patients.

The speed of improvement in the healthcare system is one of the key levers for providing a larger potential patient pool for reimbursed pharmaceutical products. However, increased consumer price consciousness due to out-of-pocket contributions has driven up the demand for generic products instead of expensive brands. Furthermore, the new health insurance system drives the dynamics of the hospital sector, which will have even wider implications on drug usage.

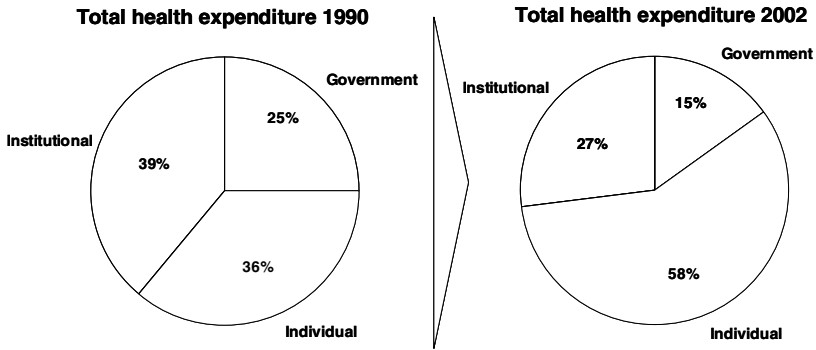


Fig. 8.4. Composition of health expenditure in PR China, 1990 and 2002 (Source: Ministry of Health)

Healthcare Providers and Facilities

The vast majority of medical benefits in China are provided through hospitals and other healthcare facilities. The total number declined by 7.4 percent in 2002, bringing it to as low as 310,000 facilities and reversing the growth trend. Contributing to the decline was a consolidation of health centers and outpatient clinics. Nevertheless, there was strong growth in the number of hospitals, which increased by more than 10 percent in 2002 to a total of almost 18,000 (see Fig. 8.5).

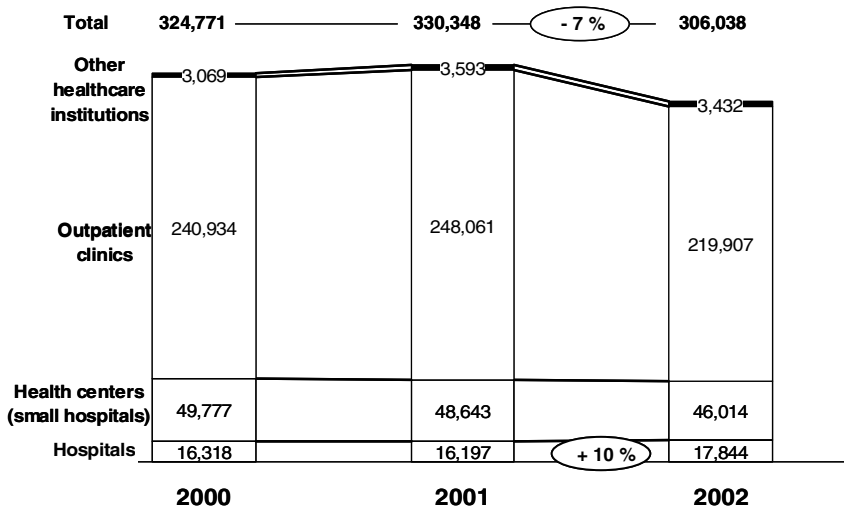


Fig. 8.5. Development in the number of healthcare facilities in the PR China (Source: Ministry of Health, IMS Health)

While almost half of healthcare facilities in China today are operated on a for-profit basis, the majority of hospitals (88 percent) remain non-profit institutions. There are currently very few private hospitals in the country, most of which charge fees comparable to U.S. facilities and thus primarily cater to expatriates. Selling drugs to these private providers requires a strong local presence, normally in the form of an agent or distributor.

The public hospital sector can be segmented into three tiers according to size and available equipment. Since the level of a patient's co-payments to the new insurance scheme differs according to the type of hospital, there is a trend towards polarization. Whereas patients with serious diseases prefer to go to tier III hospitals to receive the highest quality care, those with less serious conditions favor community hospitals (tier I).

Consequently, successful market penetration by pharmaceutical corporations will require further differentiation of sales channels for different product classes and target price levels. China's ongoing medical reform could result in stronger drug consumption. However, it will take several years for the reform to benefit foreign drug manufacturers.

Drug Distribution and Market Access Regulations

For the most part, drug manufacturers are not allowed to sell directly to hospitals and pharmacies but must go through state-owned wholesalers. Moreover, hospitals purchase most of their drugs through a tendering system.

Originally implemented to improve cost awareness, tendering has driven the general focus on price competition to such an extent that the drugs purchased through this system are often of very poor quality. The price discounts for hospitals achieved through tendering are often not passed through to the patient, but simply increase hospitals' profit margin. Furthermore, local manufacturers are still favored in tender processes since their investment in the local economy is regarded positively. Thus, bids are also evaluated according to the manufacturer's annual turnover and number of employees in the PR China.

Although it seems unlikely that the tendering system will be improved to deliver tangible benefits for patients in the short to medium term, the failure will support China's retail pharmacy sector (e.g. there is progress with the pilot scheme to separate hospital pharmacies from the hospitals).

In addition to the wholesale and tendering hurdle, hospitals carefully consider whether or not a patient can be reimbursed for his drug through the insurance scheme in their purchasing decision.

The patient is only refunded if a drug is listed on the insurance scheme's reimbursement list. This is based on the National Essential Drug List (managed by the SFDA), to which access is given only after a drug has been on the Chinese market for two years and has proven to be cost-effective.

To gain reimbursement status for their products, pharmaceutical companies should first focus their efforts on achieving provincial listing as this is regarded as an important factor in gaining national listing. Cost-containment measures will, however, include restrictions on the use of certain reimbursed drugs. Whereas two

thirds of all reimbursed drugs are regulated with respect to their profit margin (mainly Rx products), one third are commonly used drugs (mostly generics) whose retail prices are regulated.

Governmental plans are now in place to establish a separate supplementary scheme to cover occupational medical expenses, which will include more expensive drugs than those on the standard reimbursement list. This may be a chance, especially for Rx drug makers, to make a deeper footprint in the Chinese market.

8.3.2 China's Pharmaceutical Industry Structure

The Chinese pharmaceutical market has demonstrated impressive growth since the mid-1980s, at a rate far exceeding annual GDP growth. Pharmaceutical sales in 2003 grew to US\$ 6.2 billion, representing an increase of 20 percent over 2002 (see *Fig. 8.6*; *IMS Health 2004*). However, this expansive growth also reflects abnormal operating conditions driven by the SARS outbreak in 2003. Although China already holds a leading position for ethical pharmaceuticals in the region (exceeded only by Japan), the Chinese market is still comparatively small given the country's population. With an estimated average annual growth rate of 13 percent, the Chinese pharmaceutical market will achieve sales of over US\$ 11.5 billion in 2008.

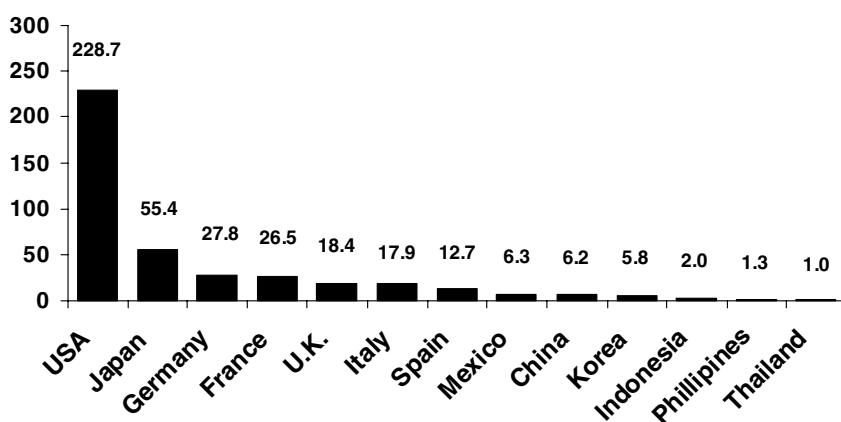


Fig. 8.6. Size and growth of key pharmaceutical markets in 2003 (US\$ billion) – audited hospital market for ethical drugs (Source: IMS Global Market Report)

Market Structure and Segmentation

Chemical products account for around 70 percent of the pharmaceutical market in China. TCM (accounting for 24 percent) posts above-market growth and are particularly strong in rural areas (*Schmidt 2002*). Biopharmaceuticals make up 7 percent (see *Fig. 8.7*).

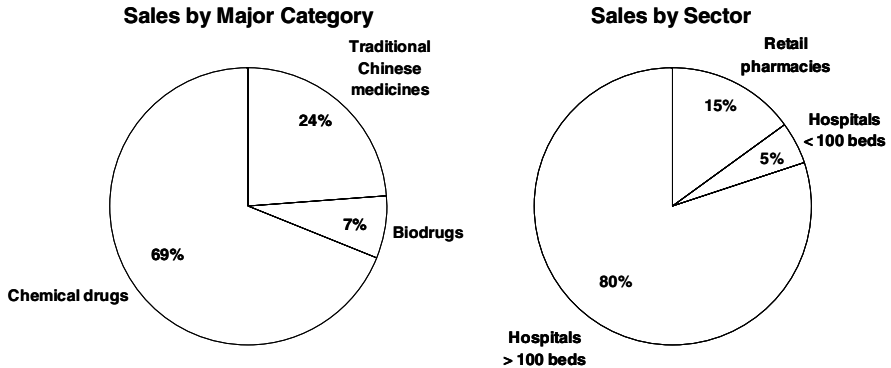


Fig. 8.7. Segmentation of Chinese pharmaceutical market by categories and sectors in 2003 (Source: IMS Health)

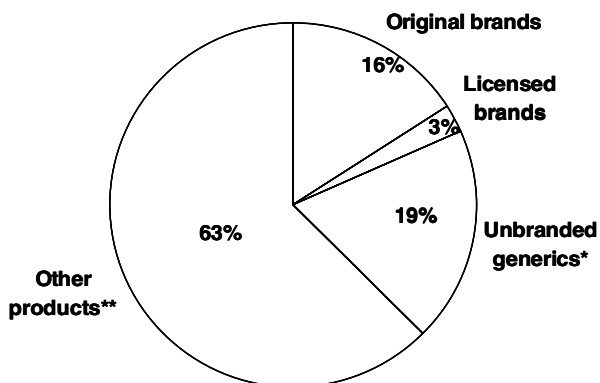
Approximately 85 percent of all products are sold through hospitals, with the majority of sales realized in the larger tier II and tier III hospitals (*Von der Hagen/Gruss/Wolff* 2002). The remainder is sold via retail pharmacies. The retail sector has grown significantly since the beginning of the new century and has currently more than 180,000 outlets and more than 800 pharmacy chains distributed unevenly across the country (e.g. Chongqing Tongjunge Pharmacy with more than 1,200 outlets) (*Schmitt* 2002a). Also, pharmaceutical manufacturers such as Shenzhen 999 or North China Pharmaceuticals have integrated vertically into wholesaling or retailing in order to increase channel power.

The Chinese market is dominated by generic drugs. In 2003 unbranded generics (products marketed under the generic name of their active ingredient) commanded 19 percent of the overall market. Original and licensed brands represented a combined 19 percent (see *Fig. 8.8*). Other products - mainly comprising branded generics, copycat products and products without licensing agreements - account for more than 60 percent of the market.

The local manufacturing sector specializes in the production of off-patent products such as antibiotics or copied drugs. Historically, new drugs in China were quickly copied and their price eroded by "illegal" generics. In the case of Pfizer's Viagra, four local counterfeits were already on the market before the product was actually introduced by its originator. As a consequence, multinationals have found it difficult to justify the investment to introduce innovative new products. It is estimated that another three years will be needed before intellectual property protection is enforceable, giving multinationals a bigger incentive to introduce innovative blockbuster drugs. In this context Pfizer, which is often quoted as an example of successful operations in China (having marketed seven out of ten blockbuster drugs in China), plans to introduce 15 innovative products. This is three times the number of products in the past five years and emphasizes the strategic and economic importance of this market. Furthermore, at the beginning of 2004 Pfizer established a strategic partnership with the SFDA bureau on anti-counterfeiting

training, bringing global experience in this area to Chinese drug officials (*Sharper 2002; IMS Health 2004*).

It is estimated that around 98 percent of the drugs produced by domestic firms are replicas of foreign drugs. Government programs have been initiated (e.g. revised reimbursement lists) to reduce the price differential between off-patent original brands and generics, which may often be anywhere between 30 and 50 percent (*Vaishampayan/Chen 2004*).



* incl. products marketed under the generics name of their active ingredient(s)

** incl. branded generics, copycat products, products where there is no evidence of a licensing agreement, products for which a licensing category has not yet been identified, as well as non-patentable products

Fig. 8.8. Segmentation of Chinese pharmaceutical market by licensing status, 2003 (Source: IMS Health)

Therapeutic Classes and Products in China

In 2003, local products generally posted stronger growth than those of multinationals, e.g. a JS Yangziji anti-infective grew more than 60 percent in the light of the SARS outbreak (see *Table 8.1*). Sales of this product were more than double those of the second largest product - Rocephin from Roche. With approximately 20 percent market share, systemic anti-infectives are the largest therapeutic area followed by cardiovascular, alimentary tract and metabolism (see *Fig. 8.9*).

Table 8.1. Sales of leading therapeutic products in China, 2003 (Source: IMS Health)

Product (manufacturer)	US\$ million ¹⁾	Change (%)
1. Zuo Ke (JS Yangzijiang Fty)	73	60
2. Rocephin (Roche)	35	- 12
3. Da Li Xin (Shenzhen)	34	79
4. Heptodin (GSK)	31	- 4
5. Sulbactam/ Cefoperazone (HLJ Harbin)	29	49
6. Tienam (MSD)	27	- 1
7. Glucobay (Bayer)	26	21
8. Sandostatin (Novartis)	26	16
9. Lu Nan Xin Kang (Shandong Lunan)	26	15
10. Kai Shi (Beijing Taide)	23	38

¹⁾ Ex-manufacturer prices MAT Q3 2003

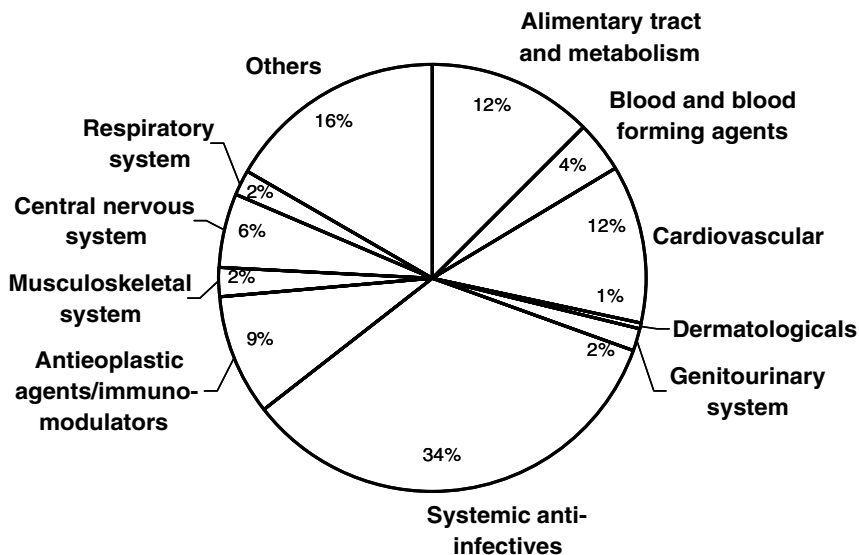


Fig. 8.9. Sales of leading therapeutic areas in China, 2003 (ex-manufacturer prices MAT Q3 2003; Source: IMS Health)

Competitive Environment and Pharmaceutical Manufacturers in China

The first multinational companies from Japan, the United States and Europe entered China to establish manufacturing, sales and marketing branches in the mid-1980s. They formed joint ventures with Chinese companies (Xian-Janssen) or established wholly-owned subsidiaries (Roche) to take advantage of China's low manufacturing costs and to sell into the Chinese market. Most multinational companies are located in the Golden Belt centered on Beijing and Shanghai.

Overall, companies that have established joint ventures or wholly-owned subsidiaries are regarded as performing more successfully than those that only engaged in import.

Nevertheless, domestic firms dominate the market. Today, domestic players hold approximately 65 percent of total sales compared to the foreign companies' share of 35 percent. In terms of volume, local drugs represent 85 percent of unit sales, while joint venture and imported products account for 9 percent and 6 percent, respectively. Recently, none of the leading multinational companies have achieved above-market sales growth. Jiangsu Yangzijiang's anti-infective product helped the leading local company to dominate the hospital market, followed by Pfizer and GlaxoSmithKline (see *Table 8.2*).

Table 8.2. China's leading pharmaceutical corporations, 2003 – audited hospital market at ex-manufacturer prices (Source: IMS Health)

Corporation	US\$ million¹⁾	Market share (%)	Change (%)
JS Yangzijiang Fty	147	2.5	46
Pfizer	113	2.0	11
GlaxoSmithKline	105	1.8	-1
Roche	105	1.8	5
Fresenius	89	1.5	12
AstraZeneca	86	1.5	12
Novartis	83	1.4	15
HLJ Harbin Pharm	74	1.3	26
Merck & Co	72	1.2	6
Johnson & Johnson	72	1.2	-1

¹⁾ Ex-manufacturer prices MAT Q3 2003

In general, the majority of domestic companies are low-tech generic producers that mainly target the local market and compete almost exclusively on price or are bulk manufacturers exporting low-tech intermediates to unregulated markets. Since the late 1990s, some Chinese pharmaceutical companies have started exporting products to developed and unregulated markets to avoid strong pricing competition in their domestic market and to take advantage of marketing opportu-

ities. As a consequence, Chinese companies now play a major role in the global bulk pharmaceutical and drug intermediary markets, thus accelerating pharmaceutical exports in recent years.

The Chinese pharmaceutical industry is seeing rapid consolidation as smaller domestic players exit the market due to their inability to comply with GMP requirements, which became mandatory starting in June 2004. According to information from the SFDA, the number of enterprises has dropped from 7,000 to 3,800. Companies that were not able to satisfy GMP requirements have been closed (*Feng 2002*).

The Chinese domestic industry is keen to work with Western companies in order to gain expertise in management techniques and to increase quality standards, with a view to competing on foreign markets. Among the most progressive is the Sanjui Enterprise Group, which acquired a majority stake in the Japanese company Toa Seiyaku. Even though the market perception is that multinational joint ventures and imported products will see their share of the market erode further, multinationals continue to emphasize their commitment to the Chinese market.

The true challenge for MNCs is not how to become profitable in China, but how to sustain a strong market position. China's growth and competition requires every market leader to continually reinvest its profits to maintain market share. Moreover, although profits can be earned and cash gained, adjusting the risk on those investments may likely change the picture.

Only a few domestic companies have the scale and capability to run effective R&D programs. Currently, domestic firms invest only a small percentage in R&D; commonly 2 percent of sales. However, the increased presence of multinational companies and especially the entry into the WTO have put pressure on the domestic industry to do more than counterfeit proprietary products. As a result, R&D is increasingly being encouraged by the Chinese government at both national and provincial levels. Domestic companies and research institutes increasingly invest in state-of-the-art technologies such as molecular diagnostics, stem cell research and pharmacogenomics. For instance, the Shanghai Institute of Materia Medica and the Beijing Genomics Institute are investigating the SARS virus. The Chinese government has clearly stated that it intends to become a major player in the international biotech industry.

Up until now, a limited number of multinationals who are represented in China by the R&D Based Pharmaceutical Association (RDPAC) have set up R&D centers (e.g. AstraZeneca, Novo Nordisk, Servier and Pfizer). Other multinationals are expected to follow including Roche, GSK and Lilly, which have set up research laboratories in Zhanjiang Hi-Tech Park – Shanghai's medicine valley (*Chuan 2004; Torreblanca 2004*).

Market for Over-the-Counter Drugs

The Chinese OTC market is evolving. In 2003, nearly 700 products were classified as OTC by the SFDA under the Pharmaceutical Administration Law, which for the first time actually established an official OTC category. Historically, OTC medicines have not been separated from prescription drugs and many still qualify

for reimbursement. However, the government is phasing out reimbursement of these drugs. The official OTC product list includes chemical products as well as TCMs and consists of categories A and B. Category A comprises products that can only be sold in retail drugstores or pharmacies; category B are products that can be widely sold in general retail outlets and drugstores without pharmacy supervision. China's over-the-counter market is currently valued at over US\$ 1.8 billion and is estimated to reach US\$ 6 billion by 2010. Generally, quantification of the OTC market, which is very competitive and dominated by local and joint venture products, is difficult due to its complex distribution system and inaccurate reporting of retail sales (*Espicom Business Intelligence* 2004).

Traditionally, OTC products are sold through hospital pharmacies, with several OTC products included on reimbursement lists. The OTC market is growing well above the overall pharmaceutical market. This is primarily due to an emergence of retail pharmacies, the SARS outbreak, the growing health consciousness of the middle-class and limited access of the rural population to expensive Western medicine. A number of multinational companies such as GlaxoSmithKline, Johnson & Johnson and Novartis have positioned themselves to take advantage of this rapid growth. Bristol-Myers-Squibb's OTC business in China is large but declining against the trend.

Distribution System for Pharmaceutical Drugs

The distribution system for pharmaceutical products in China is highly complex and characterized by regional and local diversity. Drug makers are dependent on a loose network of domestic distributors and sub-distributors who operate on a city or regional level separated by extensive formal and informal trade barriers. Among the biggest obstacles are China's transportation system and storage facilities. Although the government has begun to improve this sector, widespread progress in this area will take years to accomplish. Reform of the distribution sector is gradually advancing towards the government's objective to create at least 40 national and regional distributors which will cover 70 percent of the market and replace mostly state-owned wholesalers operating at the local level (*Schmitt* 2002a).

China is experiencing an accelerated consolidation in the wholesaler sector with at least 4,400 wholesalers exiting in 2002 and more companies going out of business due to non-compliance with GSP. In this context the three leading distributors - CNPG, Shanghai Pharmaceutical Group and Guangzhou Pharmaceutical Group - are building regional networks and selling directly to hospitals and the retail sector.

The first foreign entrant into the distribution sector was Zuellig, which established a joint venture with the China Xinxing Medicine Company in 2004. The joint venture will achieve access to direct distribution (i.e. circumvent the need to sell via wholesalers as in the past). With the full opening of the retail sector to foreign investors at the end of 2004, more companies are expected to enter the market and create national networks, competing head on with the three leading distributors. Foreign distribution companies do not have geographical limitations but

are only allowed to operate in conjunction with a domestic joint venture partner (*Vaishampayan and Chen 2004*).

In the retail sector three distinctive outlets are emerging: chain drugstores, discount pharmacies (estimated at 1,000 and selling mainly low-price generics) and pharmacies designated for reimbursement.

The changing dynamics in the distribution channels are driving pharmaceutical companies to adapt their sales and marketing strategies. Most companies have already established teams to professionalize their tender bidding for hospitals. While the larger tier II and tier III hospitals remain the focus for marketing new premium-priced drugs, Tier I hospitals have to be targeted as well in order to manage the increasing number of patients receiving prescriptions in these community hospitals. Moreover, the growing importance of the retail sector is also encouraging companies to establish a dedicated retail pharmacy sales force, concentrating on the Beijing-Tianjin, Shanghai Delta and Guangdong-Pearl River Delta regions.

8.4 Conclusion and Outlook

The Chinese pharmaceutical market undoubtedly represents one of the most important current and future markets for foreign small and medium-sized companies as well as for multinational enterprises. Many companies such as Bayer, Schering, GSK and Pfizer have already successfully established local operations in this strategic market and are currently expanding their commitment. The opportunities for foreign companies are promising and range from marketing and selling generic and proprietary drugs locally, sourcing of chemical substances, setting up local production facilities and conducting research and development.

However, these positive aspects cannot conceal the fact that, at the beginning of the new millennium, China is still a developing country facing typical challenges such as a high level of bureaucracy and protectionism, a lack of sophisticated infrastructure and underdeveloped healthcare and patent systems. These limitations often make it difficult for foreign companies to justify the huge investments necessary to build market share, local capabilities and footprint in this very competitive market.