CHAPTER 14

# China's Pharmaceutical Sector

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## Introduction

This chapter describes the market opportunities and competitive dynamics in China's pharmaceutical sector. The rewards for pharmaceutical firms – both multinational companies (MNCs) and local players – are high. However, despite robust recent growth, companies are finding it increasingly difficult to compete in the new environment. Winners who wish to separate themselves from losers require a new strategy – one that is radically different from the strategy they have successfully employed before or in other markets. This chapter examines how the pharmaceutical sector evolved historically, its commercial model and current R&D efforts, and the latest policy and industry trends that are reshaping the landscape. The latter part of the chapter analyzes the biologics and vaccine segments, as well as over-the-counter (OTC) drugs, which are unique markets in different stages of development.

### *Measurement Issues*

China's pharmaceutical manufacturers come in a variety of shapes and sizes. This makes it difficult to compare their business mix, market share, and performance on "an apples to apples" basis. For example,

- few companies are publically listed
- companies have a varying degree of active pharmaceutical ingredient (API) business mixed in with formulation business
- many have both a distribution and a manufacturing business
- companies often sell both traditional Chinese medicines (TCM) and western medicines
- some companies have both an OTC and prescription business blended together

Data reliability is another issue. Better data are available for hospital sales of prescription drugs in the top-tier cities and large hospitals. The more diversified the business and/or the greater the company's focus on smaller cities and hospitals, the less reliable the information becomes. With this heterogeneity in mind, the next section compiles a picture of the sector using estimates from different sources.

## Overview of the Pharmaceutical Sector

### *Sector Fragmentation and Market Concentration*

China's pharmaceutical sector is fragmented and subscale. Researchers and analysts estimate there are anywhere between 5,300 and 7,000 local manufacturers, each with a small share of the market. Most firms have a small revenue base (e.g., less than $16 million) and produce only a handful of products. The top 100 companies account for roughly 45 percent of the total revenue, with a minimum revenue among these top firms of 800 million RMB (approximately $130 million) in 2011. More recent data (2014) from IMS suggests the top 5 players account for only 9.2 percent of revenues, while the top 20 contribute 25 percent of revenues. According to the Commercial and Industry Bureau, company self-reported data suggest an average net profit margin of 10 percent among the 1,000 pharmaceutical manufacturers. The top 136 players generate most (80 percent) of the total profits in this group. Market leaders have higher profitability and can achieve 20–30 percent net margins.

China's pharmaceutical sector is much more fragmented than in the United States and elsewhere in the world.[1] Such fragmentation heightens competition. Moreover, most of the products are generics, and many firms make the same products; both of these factors further increase rivalry and generate price wars. In the face of such fragmentation, the government has set ambitious goals to consolidate the industry to foster larger and stronger players.



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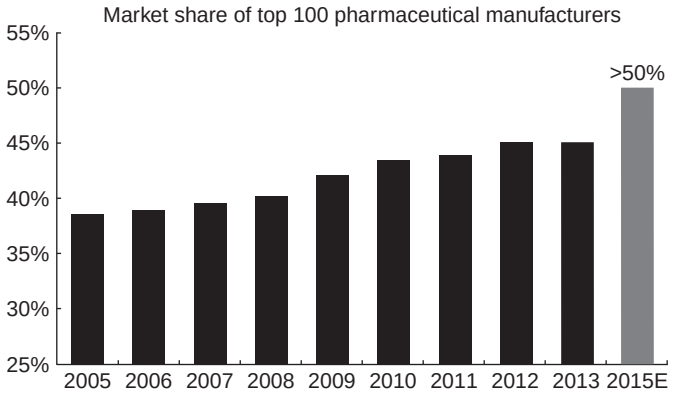


*Figure* 14.1 Growing concentration of pharma sector
Source: Jessica Li and Lillian Wan 2015. *China Healthcare Primer – The Immense Structural Upside*. Bank of America Merrill Lynch (July 9).

Specifically, the Chinese government hopes to achieve the following goals by the end of the 12th Five-Year Plan: (a) the top 100 companies should account for more than 50 percent of sector revenues by 2015, (b) 5+ companies should have revenues of 50 billion RMB, and (c) the top 100 companies should have revenues greater than 10 billion RMB. Admittedly, these goals have also been proposed in previous five-year plans. While they have not been fully met, the government's ambition to implement them has not abated. The sector has been slowly consolidating over time, due to the government's urging and a recent acceleration in company mergers from less than 5 in 2010 to roughly 60 by 2014 (see Figure 14.1).

## *Multinational Companies and Local Players*

China's pharmaceutical sector includes both local domestic players and multinational corporations (MNCs). The MNCs include US, European, and Japanese firms such as Pfizer, AstraZeneca, and Sanofi-Aventis. They have typically been market leaders in terms of sales, with shares in the hospital market of 2–4 percent each (2013 data). As of 2014, there are 35 MNCs registered in China that belong to Research-Based Pharmaceutical Association (RDPAC). Leading local players include Qilu, Sino Biopharm, Hengrui, Fosun, and Shanghai Pharmaceuticals – which have smaller shares of the hospital market (1–3 percent each). The top ten players have captured only 27 percent of the hospital market; the top 50 players have just slightly over half of the market (see Table 14.1).

Collectively, however, the local players control roughly three-quarters of pharmaceutical sales to large hospitals – a share that has been stable over the past five years (Figure 14.2). Since hospitals comprise roughly 70 percent of the Chinese pharmaceutical market, this suggests that local firms control more than half of all pharmaceutical sales in the country.

## *A Leading Pharmaceutical Market in the Making*

The Chinese market grew from just $5 billion in 2000, when it was the 11th largest market in the world, to $55 billion in 2010, making it the number three market.[2] Between 2010 and 2014, the market grew at a compound annual growth rate (CAGR) of 16 percent and reached $108 billion in 2014. For the 2015–2019 period, analysts expect growth to continue but at a lower 9 percent CAGR, reaching an estimated $170 billion by 2019 (see Figure 14.3). Such growth will make China the number two market after the United States. China will also continue to contribute to roughly one-quarter of global growth in pharmaceutical sales.

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**Table 14.1 MNCs versus local players: hospital data**

| Rank ('13 sales) | Pharmaceutical Companies | | Market Share 2013 | 2012 | 1H14 |
|---|---|---|---|---|---|
| 1 | Pfizer | 辉瑞 | 3.98% | 3.03% | 4.09% |
| 2 | Novartis | 诺华 | 3.68% | 2.39% | 3.90% |
| 3 | AstraZeneca | 阿斯利康 | 3.36% | 2.91% | 3.56% |
| 4 | Sanofi-Aventis | 赛诺菲 | 2.90% | 2.41% | 2.66% |
| 5 | Roche | 罗氏 | 2.63% | 2.36% | 2.58% |
| 6 | Merck/MSD | 默沙东 | 2.40% | 1.91% | 2.35% |
| 7 | Qilu Pharma | 齐鲁制药 | 2.31% | 1.63% | 2.25% |
| 8 | Sino Biopharm | 中国生物制药 | 2.29% | 1.96% | 2.21% |
| 9 | Bayer | 拜耳 | 1.95% | 1.82% | 1.95% |
| 10 | Hengrui | 恒瑞 | 1.65% | 1.14% | 1.74% |
| 11 | Yangtze River Pharma | 扬子江药业 | 1.51% | 0.87% | 1.63% |
| 12 | Fosun Pharma | 复星医药 | 1.41% | 1.03% | 1.47% |
| 13 | GSK | 葛兰素史克 | 1.41% | 1.22% | 1.20% |
| 14 | China Resources Pharma | 华润医药 | 1.36% | 1.13% | 1.05% |
| 15 | Shanghai Pharma | 上海医药 | 1.26% | 0.77% | 1.20% |
| 16 | Bristol-Myers Squibb | 百时美施贵宝 | 1.08% | 0.91% | 1.12% |
| 17 | Eli Lilly | 礼来 | 1.06% | 0.79% | 1.11% |
| 18 | Baxter | 百特 | 1.01% | 0.78% | 0.87% |
| 19 | Beijing SL Pharma | 北京双鹭药业 | 1.00% | 0.96% | 1.02% |
| 20 | Fresenius | 费森尤斯 | 0.98% | 0.85% | 0.87% |
| 21 | Boehringer Ingelheim | 勃林格殷格翰 | 0.93% | 0.68% | 0.91% |
| 22 | Aosaikang | 奥赛康药业 | 0.91% | 0.72% | 0.95% |
| 23 | North China Pharma | 中国北方医药集团 | 0.90% | 0.70% | 0.90% |
| 24 | Kelun Pharma | 科伦药业 | 0.89% | 0.51% | 0.90% |
| 25 | Sihuan Pharma | 四环医药 | 0.89% | 0.81% | 0.72% |
| ***Market share of Top 10:*** | | | ***27.2%*** | ***25.0%*** | ***27.3%*** |
| ***Market share of Top 20:*** | | | ***39.2%*** | ***37.5%*** | ***38.9%*** |
| ***Market share of Top 50:*** | | | ***58.8%*** | ***56.2%*** | ***57.7%*** |

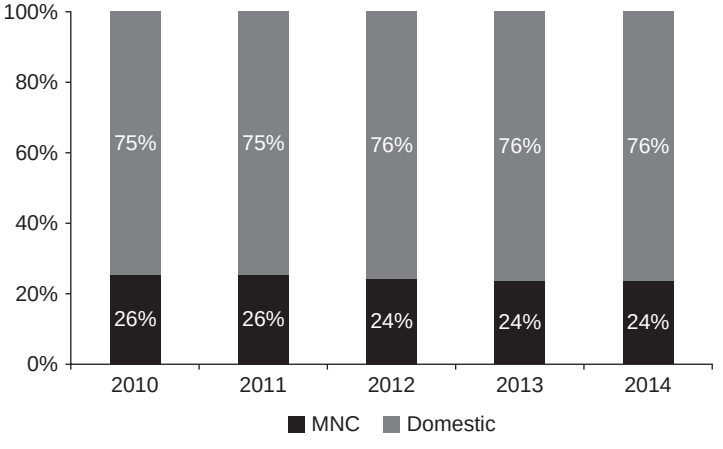


*Figure* 14.2 Domestic players versus MNCs in large hospital market
Source: Jessica Li & Lillian Wan 2015. *China Healthcare Primer – The Immense Structural Upside*. Bank of America Merrill Lynch (July 9).

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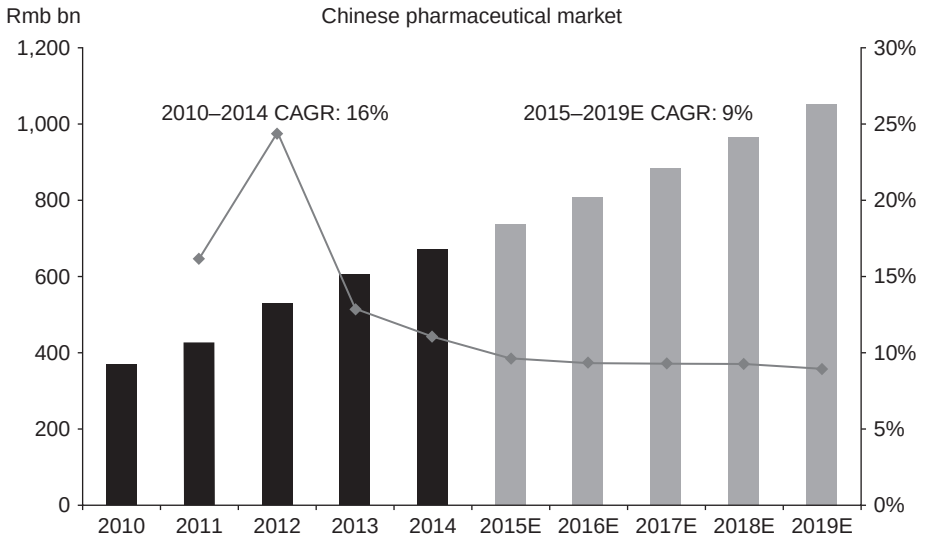


*Figure* 14.3 China's pharmaceutical market growth
Source: Jessica Li & Lillian Wan 2015. *China Healthcare Primer – The Immense Structural Upside*. Bank of America Merrill Lynch (July 9).

## *Growth Drivers*

A number of factors drive expanding demand for pharmaceuticals in the country. As noted in Chapter 6, China is on an accelerated path as an aging society. Over the next 40 years, the population cohort 50+ years old will double from 22 percent to 44 percent of the total population. This process takes 100 years or more in many other countries. At the same time, changing lifestyles are contributing to a rise in chronic illness, which is also associated with older age. China already has the world's largest diabetic population of 92 million people. By 2020, one in three Chinese adults will have hypertension and one in ten will have type II diabetes. These changes in health status are accompanied by the rising wealth of the population: by 2020, the "middle and affluent population" will triple from 142 million to 401 million.[3] All of these trends create a strong underlying demand for pharmaceuticals. The 2009 healthcare reform extended access to public insurance coverage to the entire population, which in turn will result in realized demand. Previously uninsured or underinsured urban residents (retirees, students, children, etc.) and the rural population will increasingly present themselves to the healthcare system to seek care and treatment.

The Chinese government's 12th Five-Year Plan (2011–2015) set three overarching goals that suggest ambitious plans for the country's life sciences sectors. These include accelerating structural changes in the pharmaceutical sector, meeting the rising demand for healthcare services, and developing the biotechnology sector as one of the seven emerging strategic industries. Structural changes include targets for innovative products, technological capabilities, and manufacturing quality. With regard to product innovation, the goal is to have 30 innovative small molecule drugs for severe and highly prevalent diseases; 15 new biologic drugs to treat cardiovascular, central nervous system, gastrointestinal, AIDS, and immunological diseases; and 50+ new TCM drugs. With regard to technological capabilities, the goal for small molecule drugs is to improve active pharmaceutical ingredients (API), fermentation, and formulation. For biologics, the goal is to develop capabilities in antibodies, vaccines, cell culture technologies, and protein expression technologies. With regard to

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manufacturing, one goal is that all manufacturers meet the new good manufacturing practice (GMP) standards. To meet this goal, the pharmaceutical sector needs to consolidate into fewer but larger and stronger companies.

## Market Segments: Diverse and Dispersed

### *Sales Channels*

In contrast to the United States, China's pharmaceutical market relies heavily on the institutional channel (hospitals and clinics). The majority of total drug spending flows through hospital pharmacies; the remainder is sold in retail pharmacies across the country (see Figures 14.4 and 14.5). Figure 14.6 illustrates the market segments among the healthcare institution and retail channels. The six types of customer segments vary significantly in terms of drug purchase levels, patient profiles, and growth drivers. These segments are covered in detail below.

#### City Hospitals

City hospitals, particularly the large Class III institutions (cf. Chapter 8), are the most well-equipped facilities with highly trained doctors and more sophisticated treatment practices. On average, the 11,300 city hospitals spend about 30 million RMB on drugs annually. Moreover, most patients in these hospitals have either Urban Employee Basic Medical Insurance (UEBMI) coverage or higher levels of disposable income, which in turn make drugs and hospital services more affordable. Growth drivers in this population segment of hospital customers are primarily attributed to the rising prevalence of chronic illness stemming from economic development (noted above).

#### Community Health Centers and Stations

Urban-based community health centers (CHCs) and community health stations (CHSs) have on average only 3.8 million RMB in annual drug spending. Moreover, they are required to use only drugs on

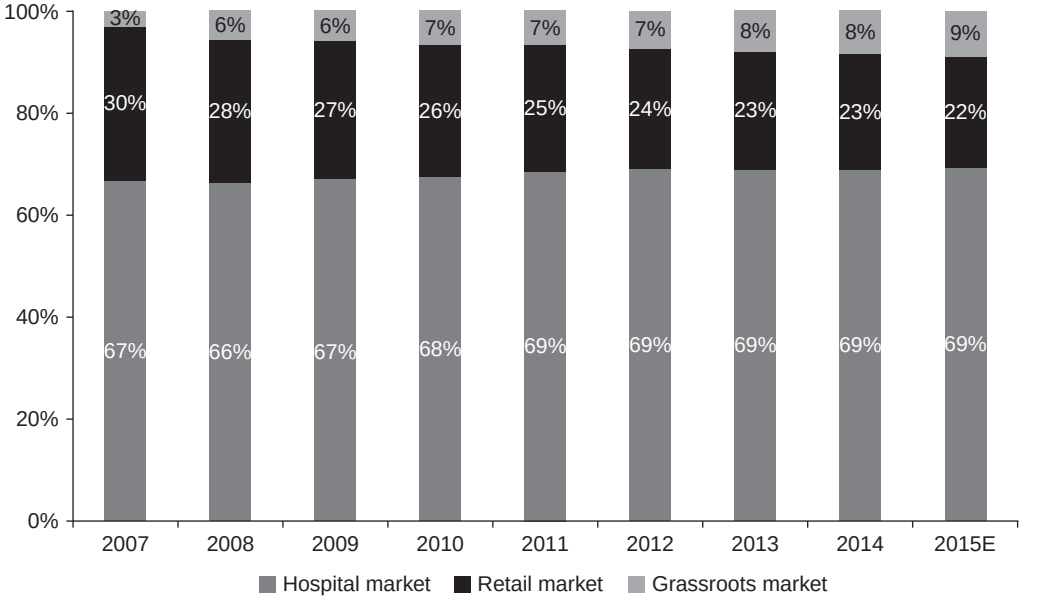


*Figure* 14.4 Shares of hospital, retail, and grassroots markets
Source: Jessica Li & Lillian Wan 2015. *China Healthcare Primer – The Immense Structural Upside*. Bank of America Merrill Lynch (July 9).

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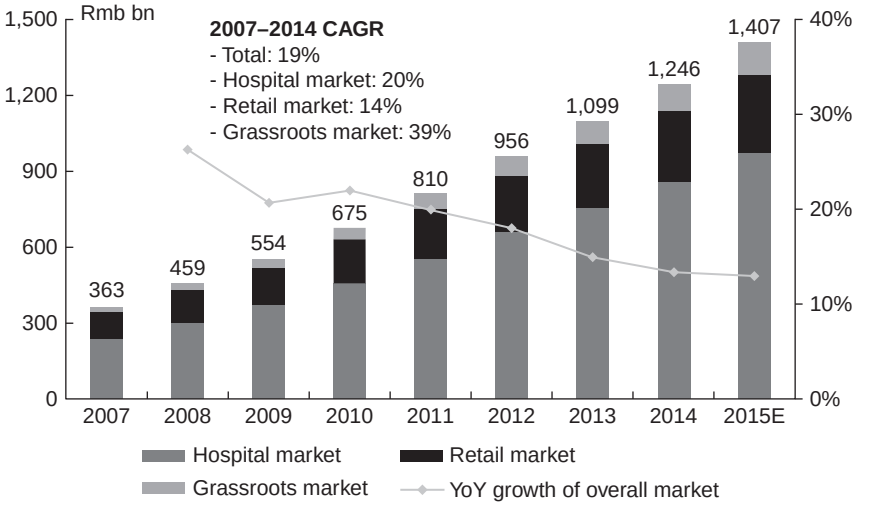


*Figure* 14.5 Sales and growth of end market
Source: Jessica Li & Lillian Wan 2015. *China Healthcare Primer – The Immense Structural Upside*. Bank of America Merrill Lynch (July 9).

the Essential Drugs List (EDL) (see Chapter 5 and below discussion). These care sites include 7,800 CHCs and their satellite CHSs that number about 25,000. The 2009 reform converted Class I hospitals and some Class II hospitals to CHCs/CHSs in order to serve as the country's new primary care system. The goal is to have this primary care system divert patient flow away from the crowded tertiary care settings (Class II and III hospitals) to less intensive and lower-cost sites with lower utilization. Patients who seek care in these community sites are typically elderly patients with chronic illnesses or patients with Urban Resident Basic Medical Insurance (URBMI) coverage.

Since the reform, however, these community sites have seen only a slow uptake in their patient volume. Despite free registration fees, low cost medications and services, and more convenient locations, patients are reluctant to seek care in the CHCs/CHSs. They are instead willing to wait in long lines to see doctors in the Class II and III hospitals. Nevertheless, there are some signs of change in the role these centers play. Instead of only refilling prescriptions initially written in the large hospitals, CHC doctors are now more confident to conduct the initial diagnosis, to write the scripts themselves, and to undertake disease management for chronic illnesses. The growth of this market segment is driven by the government's mandate to use these facilities in order to obtain insurance reimbursement. Any fundamental changes to patient uptake will need to come from further upgrades in the quality of the centers' personnel and facilities.

## County Hospitals

County hospitals serve as tertiary care centers for the rural population. Compared to the other rural care sites, county hospitals are larger, better equipped, and have more highly trained physicians. They are also the biggest beneficiaries of the 2009 healthcare reform. As part of the reform, the government spent $9 billion to upgrade their personnel (via training) and facilities in order to attract rural residents to seek quality tertiary care locally rather than travel to the city hospitals. Among the total of 10,300 county hospitals, 500 are slated to become Class III facilities by 2020.

County hospitals account for 17 percent of the pharmaceutical market today. Due to the reform, they are expected to grow at a faster rate than other segments and account for roughly 30 percent of the total market by 2020. These rural tertiary care hospitals have large spending power. The county

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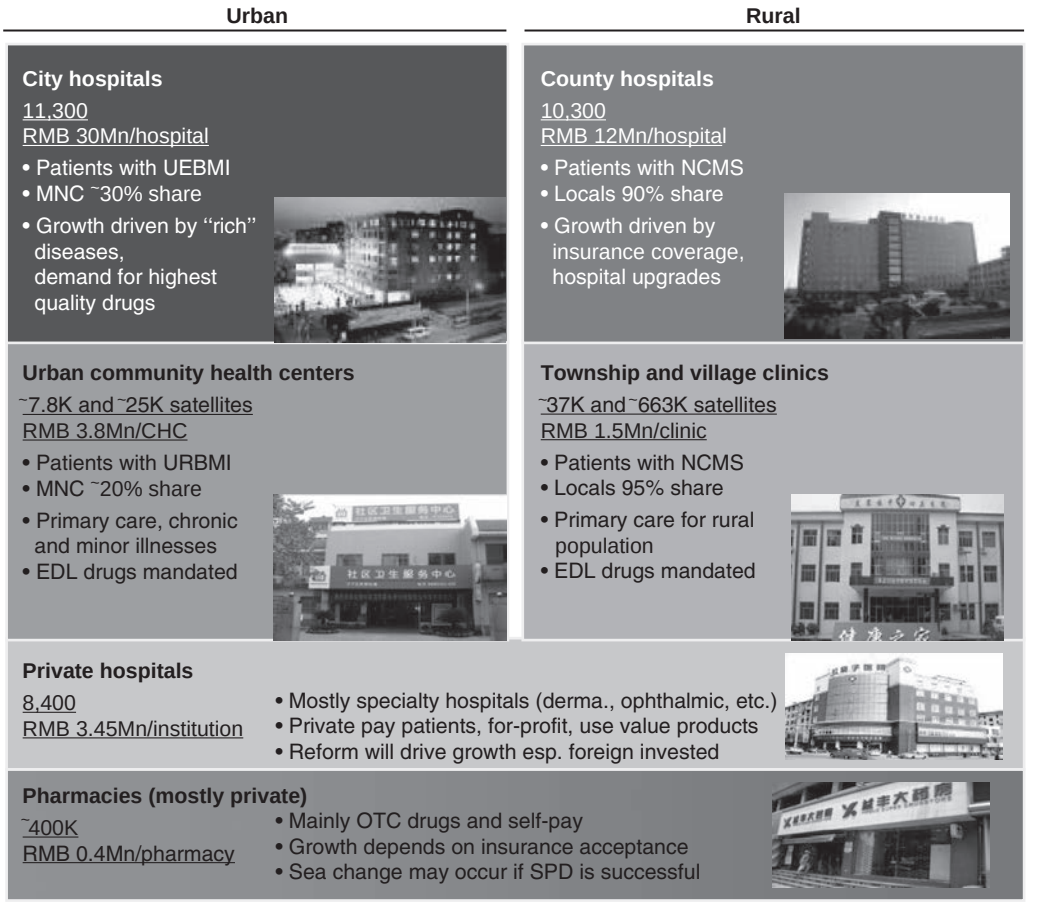


*Figure* 14.6 Pharmaceutical market customer segments

hospital segment is dominated by local Chinese companies, which command a 90 percent share of the generics market. As the gatekeeper for 600 million rural patients, these hospitals will be the next battleground for pharmaceutical manufacturers. However, affordability constraints, regional differences, and the large geographic dispersion of these facilities pose challenges to the traditional go-to-market approach. Cost-effective sales and marketing will be key competitive capabilities.

## Rural Clinics and Township Centers

Village clinics and township health centers (THCs) represent the primary and secondary care sites for the rural population. There are an estimated 37,000 THCs with another 663,000 clinics that serve as village satellites. Collectively, these sites each account for an average of 1.5 million RMB spending on drugs. As in the county hospitals, prescribing drugs on the EDL is mandatory.

## Private Hospitals

Private hospitals have historically played a minor role in China's healthcare system. While there are roughly 8,400 private hospitals today, they are typically small in size and command only 10 percent market share in patient utilization. Collectively, their drug spends account for an even smaller percentage (4 percent) of the total pharmaceutical market. Nevertheless, the government has encouraged

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the private sector to expand capacity, meet rising demand for healthcare services (in part driven by increased insurance coverage), and foster competition with the public hospital sector. This segment is expected to grow at more than 20 percent annually as a result – a rate faster than the public hospital segment.

### Retail Pharmacies

The non-institutional (retail pharmacy) channel has long played a supplemental role in the dispensing of drugs in China. Only 20 percent of drug spending flows through non-hospital pharmacies. The major issue in this channel is that government insurance does not reimburse retail prescription drugs. Patients nevertheless seek drugs in this channel for purposes of convenience and/or privacy concerns (e.g., drugs to treat erectile dysfunction or hepatitis). In recent years, some pharmacy chains have collaborated on coverage with the public insurance bureau to obtain reimbursement on selected drugs. Going forward, volume growth in this segment will depend on broader public insurance coverage. The real upside potential for this channel lies in current efforts to separate the dispensing and prescribing of drugs in public hospitals (see Chapter 8). This long-discussed initiative has been difficult to implement due to hospital reliance on drug sales to subsidize their operations.

## *Therapeutic Categories*

Another way to segment China's pharmaceutical sector is by therapeutic category. Table 14.2 lists the top 20 therapeutic categories in China's pharmaceutical sector for 2013. Not surprisingly, based on analyses in prior chapters, antibiotics are the leading category. Figure 14.7 displays

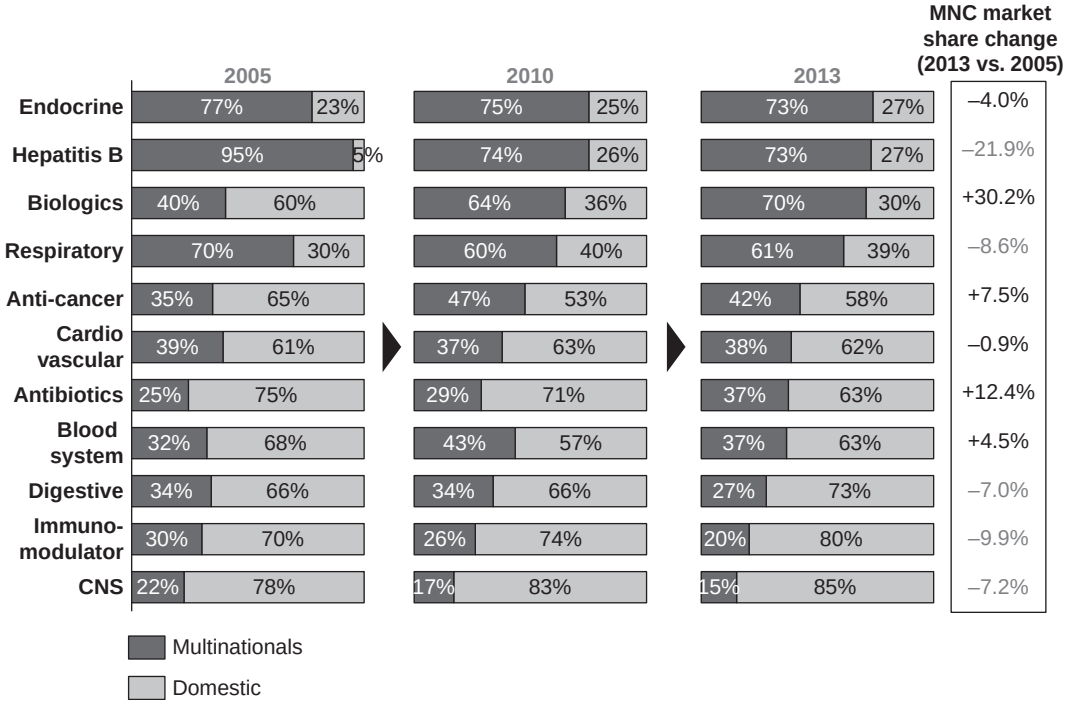


*Figure* 14.7 MNCs versus local players by therapeutic category
Source: Richard Yeh, Ziyi Chen, & Sean Lo. 2014. *Chinese Healthcare Sector Handbook 2015*. CitiResearch (December 9).

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**Table 14.2 Top 20 therapeutic categories**

| 治疗小类 | Therapeutic Class | 2013 Market Share | '10-'13 CAGR | '13 yoy | 1H14 yoy |
|---|---|---|---|---|---|
| 抗感染药 | Antibiotics | 15.8% | 0% | 4% | 11% |
| 心血管系统用药 | Cardiovascular | 13.5% | 16% | 12% | 10% |
| 血液系统用药 | Blood system | 11.2% | 15% | 9% | 11% |
| 抗肿瘤药 | Anti-cancer | 9.7% | 17% | 11% | 16% |
| 消化系统用药 | Digestive system | 8.5% | 17% | 14% | 15% |
| 神经系统用药 | Central nervous system | 8.4% | 25% | 16% | 16% |
| 免疫调节剂 | Immunomodulators | 7.5% | 17% | 13% | 12% |
| 内分泌用药 | Endocrine | 5.8% | 15% | 13% | 15% |
| 生物技术药物 | Biologics | 3.0% | 23% | 18% | 12% |
| 呼吸系统药品 | Respiratory system | 2.9% | 20% | 13% | 14% |
| 骨骼与肌肉用药 | Bone and muscular | 2.5% | 16% | 8% | 11% |
| 精神障碍用药 | Mental disorders | 1.8% | 20% | 15% | 14% |
| 麻醉药 | Anesthetics | 1.7% | 16% | 12% | 15% |
| 生殖系统用药 | Reproductive system | 0.8% | 17% | 10% | 18% |
| 感觉器官用药 | Sensory organ | 0.7% | 17% | 9% | 15% |
| 皮肤科用药 | Dermatology | 0.6% | 14% | 11% | 4% |
| 泌尿系统用药 | Urinary system | 0.5% | 11% | 3% | 3% |

Source: Richard Yeh, Ziyi Chen, & Sean Lo. 2014. *Chinese Healthcare Sector Handbook 2015*. CitiResearch (December 9).

the market shares of MNCs versus local firms in selected categories.

## A Land of Generics, but Slowly Changing

Until MNCs entered China with their branded innovative drugs, China's own pharmaceutical sector manufactured and sold generic products. Even today, 75 percent of the pharmaceutical market is still comprised of generics (15 percent unbranded, 60 percent branded); only 5 percent of the market value derives from sales of patented drugs, while another 20 percent derives from MNCs' sales of off-patent drugs. These percentages are expected to change to a slightly higher share for patented drugs as local firms increase their production of innovative products (see Figure 14.8). One interesting quirk is that only 15 percent of the generics market consists of unbranded products. This is due to legacy regulations whereby approved new drugs receive a brand unless the molecule is already in the pharmacopeia (see Figure 14.9 for the classification of new drugs).

The dominance of generics and the lack of patent protection heighten price competition, price wars, and susceptibility to government price-cutting to control rising healthcare costs. All of these factors suggest that the growth of China's pharmaceutical sector depends more on volume than on price. Over the period 2003–2013, volume growth doubled price growth (14 percent vs. 7 percent CAGR); in 2013, pharmaceutical prices actually declined for the first time (see Figures 14.10 and 14.11). While China enjoys a favorable global position in terms of its large population and volume potential, it is also distinguished by a low level of drug spending per capita (Figure 14.12).

Moving forward, the composition of the market will gradually shift (see Figure 14.13). Patented drugs will grow the fastest and are expected to double their presence. The driving forces behind this shift are twofold. First, MNCs are expediting global launches of new products in China, while local companies are endeavoring to generate domestic patented drugs. Second, improved insurance coverage and the general rise in drug affordability due to economic development will support the consumption of patented drugs.

The share of originator off-patent drugs will shrink, as the government actively reduces the premiums on these drugs marketed by MNCs. Rising volume may partially offset the price erosion due to growing affordability of drugs, trust in MNCs' brand quality, and perceived higher value. The market share currently enjoyed by off-patent brands can potentially shrink from 20 percent today to roughly 15 percent over the next decade.

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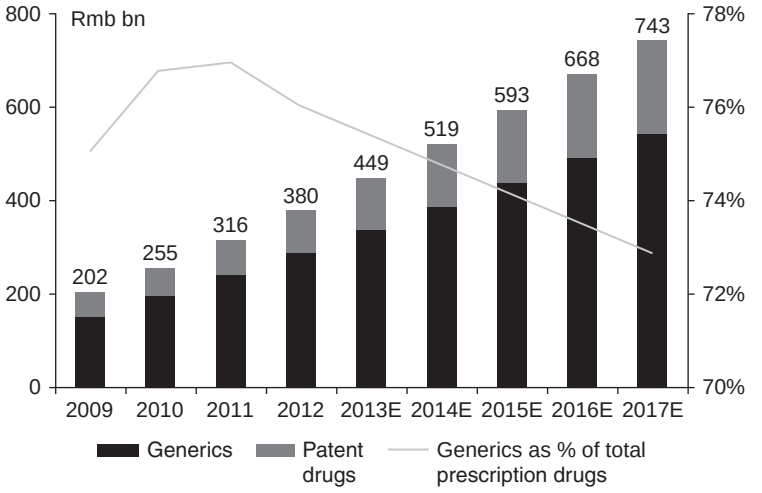


*Figure* 14.8 Sales of patent/off-patent originators versus generics
Source: Jessica Li & Lillian Wan 2015. *China Healthcare Primer – The Immense Structural Upside*. Bank of America Merrill Lynch (July 9).

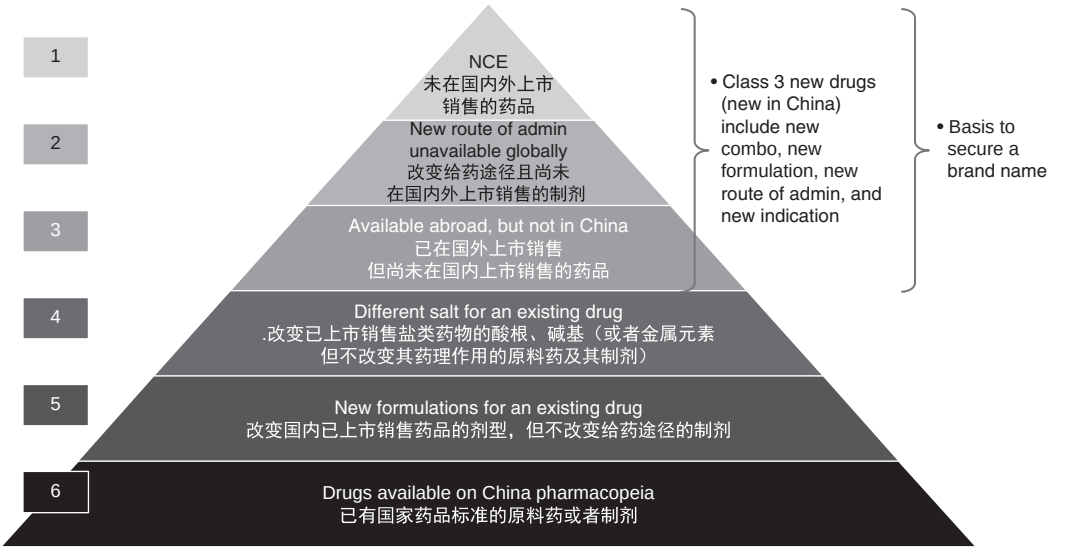


*Figure* 14.9 Classification of prescription drugs in China

What will happen to the 60 percent of the market controlled by branded generics? A portion of branded products will become unbranded: the China State Food and Drug Administration (CFDA) tightened the rules in 2006 to allow only Class I through III new drugs to be entitled to a brand. Another portion of branded generics will become differentiated generics as local companies strive for incremental innovation and quality for a price premium. This segment is likely to represent another 15 percent of the total market in ten years' time.

Another way to segment the market is by the product's reimbursement status. There will be products on the Essential Drugs List (EDL) and

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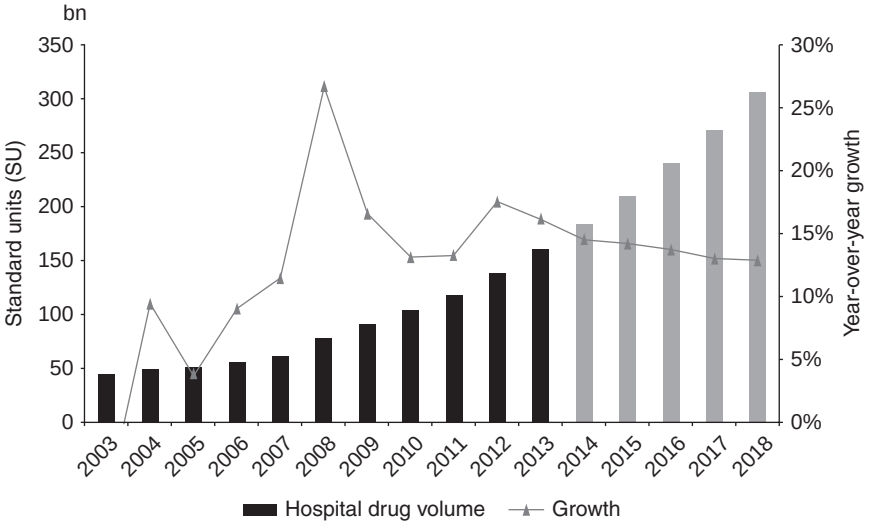


*Figure* 14.10 Sector growth: hospital volume
Source: Jessica Li & Lillian Wan 2015. *China Healthcare Primer – The Immense Structural Upside*. Bank of America Merrill Lynch (July 9).

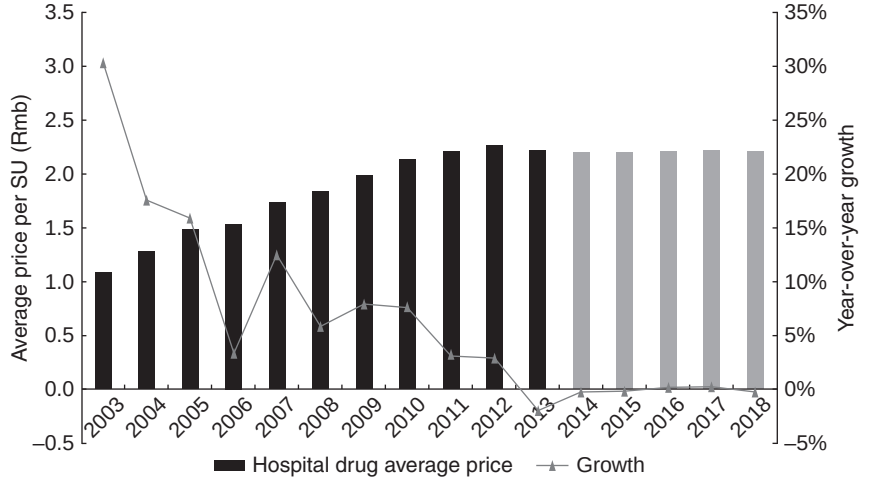


*Figure* 14.11 Trend in average drug price
Source: Jessica Li & Lillian Wan 2015. *China Healthcare Primer – The Immense Structural Upside*. Bank of America Merrill Lynch (July 9).

products on the RDL (Reimbursement Drug List). EDL drugs will experience strong growth as the government continues to expand the list and mandate their usage – not only in basic healthcare institutions but also increasingly in tertiary care settings. This segment may account for one-third of the total market by 2020.

## Complex Market Access Hurdles

Market access is a long and complicated process in China (see Figure 14.14). Success demands long-term investment in resources and careful navigation of the following steps: registration and approval of new drugs, pricing and bidding,

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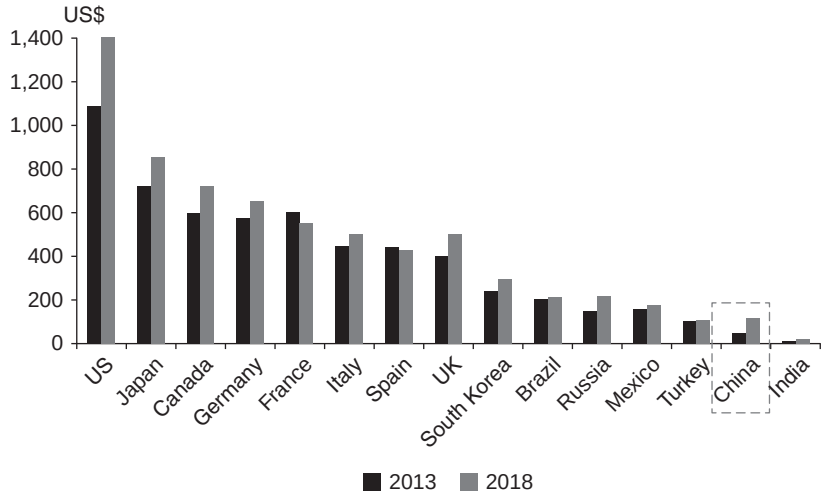
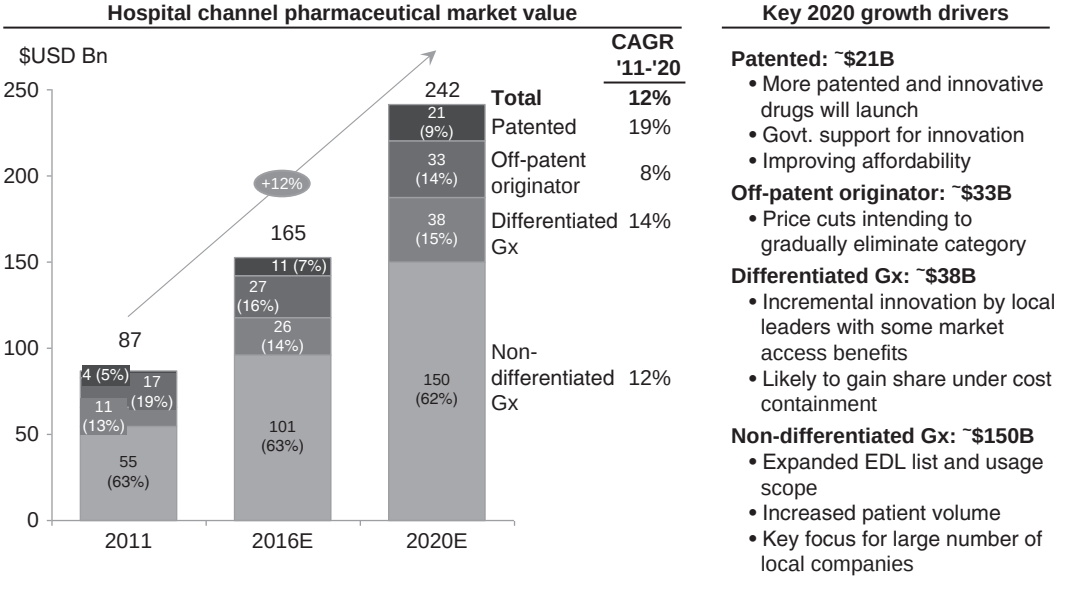



*Figure* 14.12 Per capita drug spend
Source: Jessica Li & Lillian Wan 2015. *China Healthcare Primer – The Immense Structural Upside*. Bank of America Merrill Lynch (July 9).




Notes: Sales are based on hospital purchase price and do not include retail pharmacies or TCM. Exchange rate 1USD = 6.2RMB

*Figure* 14.13 China's pharmaceutical market by product segment

reimbursement listing at the local and national level, and finally hospital listing. The process typically takes about four to six years for companies who are registering patented or differentiated generics. Provincial bidding takes place every two years or so; national reimbursement listing is every four to five years; the hospital listing process can take another two years' time. As a result, new

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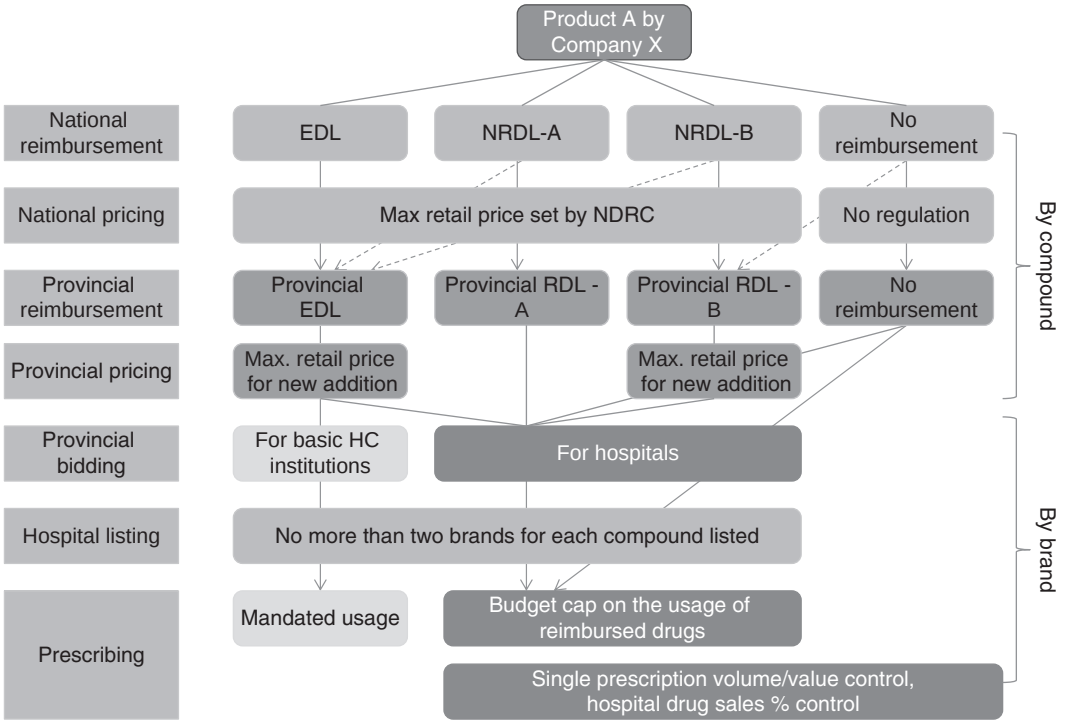


*Figure* 14.14 Market access in China

drug launches in China may wait an average of seven years for drug approval, launch, and listing in the target hospitals. Only upon completion of this process can companies commence sales activity in full force.

Depending on where the launch date falls during the five-year interval of national reimbursement listing, the company may wait another two to five years to see significant volume uptake from higher affordability. On the other hand, off-patent products have enjoyed higher premiums and do not see precipitous drop in revenue following the entry of generics. The volume and share largely depend on hospital economics – e.g., where higher-priced imported drugs are key to higher hospital profits. As a result, a product's life cycle in China looks dramatically different. Instead of a bell-shaped curve as in developed markets, it has a much slower ramp-up but maintains high growth for a long time. The total product life cycle can thus be as long as 20–30 years (see Figure 14.15).

### *Pricing*

As with all other products in China, drug prices are regulated by the government's pricing bureau. The National Development and Reform Commission (NDRC) sets the maximum retail prices for drugs. GMP price is determined by surveying representative companies to obtain the average production price for a given molecule. Then a reasonable profit over the cost of production and business operations is added to reach the maximum retail price. For close to a decade, a second pricing mechanism existed whereby companies could apply for independent pricing for products they deemed as having original innovation or quality and technical differentiation. In this case, the price was determined through direct negotiation between the manufacturer and the NDRC. Historically MNCs were able to obtain independent pricing status for all of their drugs (globally patented or already off-patent); a few local companies managed to obtain

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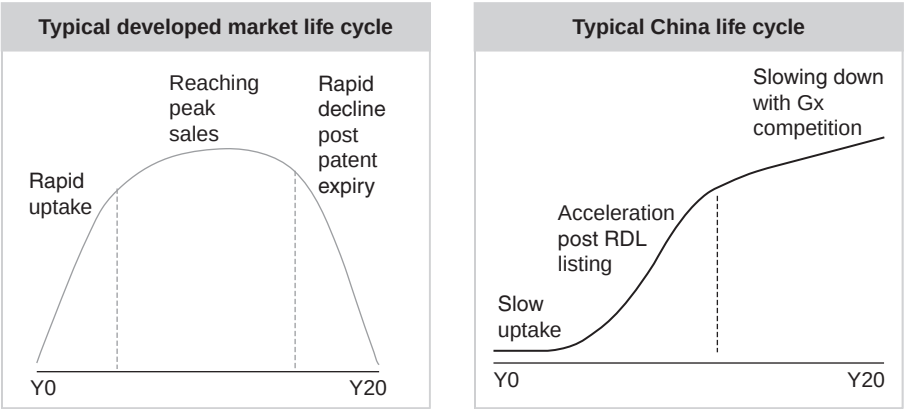


*Figure* 14.15 Product life cycle comparison

independent pricing status as well for selected drugs. The independently priced drugs often enjoyed a premium over the GMP price to 2–3x in the case of primary care treatments, 5–6x for drugs used in oncology and specialty care.

The rules have repeatedly changed in recent years, however. In 2007, the NDRC stopped granting independent prices to any drugs while they contemplated how to improve and enhance the overall drug pricing policy. The government revised its policy and put in place a five-step process for price-setting: regulators would visit the manufacturer to assess product cost and evaluate the proposed price, an expert group then evaluated the price, a public hearing gathered comments on the price, group discussions were convened, and a final price was determined. New drug imports generally obtained prices near the free-market price; imported generics obtained lower prices but higher than that enjoyed by local generic manufacturers. In 2010, the NDRC imposed price ceilings on the retail prices of selected drugs, rather than allow manufacturers to independently set prices. Most of the products that were targeted were made by MNCs and their joint ventures with local firms.

The new policy formulated conveyed a sense of balance between encouraging innovation (even if it is incremental innovation) and discouraging unnecessary generic duplication. More transparent and stringent criteria were applied when granting premiums over GMP prices. Under this new policy, maximum retail prices for patented drugs were based on a combination of manufacturer costs and reference pricing using domestic and international prices of similar drugs. The first-to-market generic product would be priced at 90 percent of the originator's drug; prices for the first three generics to reach the market would be set at 90 percent of the predecessor's product. If a generic was not among the first three to market but presents evidence of differentiation, it could obtain up to 30 percent premium over the GMP price. The criteria needed to qualify for differentiation are still relatively vague but appear to be more stringent than before (e.g., those that have won a national technology award or those with higher quality).

In June 2015, the NDRC and six other government agencies issued a circular that removed many of its prior constraints on drug prices (e.g., price ceilings such as maximum retail prices or MRPs, or specific prices). The new policy extended to nearly 2,700 drugs included for reimbursement on public insurance schemes and included on the Reimbursement Drug List (see below); the number represents about 23 percent of all drugs sold in China. Now, with the exception of narcotics and certain psychotropic products (which would remain subject to MRPs), various market mechanisms would set drug prices; the government would also rely on a "pricing bureau" inside the NDRC to scrutinize illegal pricing behavior. These market mechanisms include (a)

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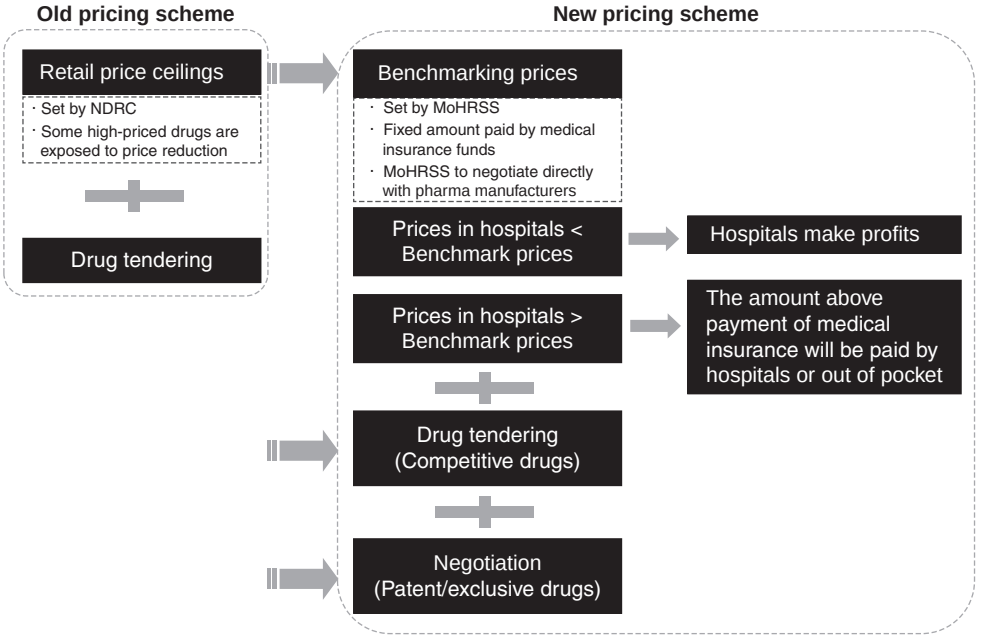


*Figure* 14.16 2015 change in drug pricing
Source: Jessica Li & Lillian Wan 2015. *China Healthcare Primer – The Immense Structural Upside*. Bank of America Merrill Lynch (July 9).

transparent negotiations involving hospitals, provincial governments, and insurance schemes for the purchase of patented drugs or TCM products made exclusively by one manufacturer; (b) negotiations between hospitals and public insurance schemes, which can set benchmark prices (rather than price ceilings) for products listed on the NRDL; (c) bidding processes or procurement negotiations for blood products outside of the NRDL; and (d) free pricing for other drugs, provided that prices accurately reflect cost and conditions of supply and demand (see Figure 14.16).[4]

## *Reimbursement*

The Reimbursement Drug List (RDL) originated from the drug formulary for UEBMI enrollees. The national RDL (NRDL) is managed by the Ministry of Human Resources and Social Security (MoHRSS) and issued/updated every five years. The most recent NRDL was issued in 2009 and includes 987 TCM products and 1,164 western products. Criteria for listing on the NRDL include clinical need and utilization, safety and efficacy, reasonable pricing, average total cost, number of years on the market, and cost-effectiveness.

There have been four rounds to date, the latest in 2014. The formulary is divided into two lists (A and B) and goes by molecules rather than brands. The RDL-A list contains the most basic treatments and older generation drugs, supplied by multiple manufacturers, typically at fairly low prices. The RDL-B list contains more advanced treatments that carry higher prices and lower reimbursement. For example, for the oral treatment of diabetes, Metformin IR (regular release) is on the A list, while Metformin XR (extended release), Arcabose, and Pioglitizone are on the B list. The A list includes 349 western drugs; the B list includes 791 western drugs (the remaining drugs are for occupational injuries and contraception). An updated NRDL was anticipated in 2014 but was still delayed as of April of the following year.

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The RDL-A list is national in nature; the RDL-B list can be modified locally by the Provincial Bureau of Human Resources and Social Security (BOHRSS). This results in a provincial reimbursement drug list, or PRDL. The government allows up to 15 percent variation in the number of molecules to accommodate variations across provinces in their economic development and fiscal strength.

RDL-A list drugs enjoy 100 percent reimbursement; reimbursement levels for RDL-B list drugs vary across provinces and typically range from 50 percent to 80 percent. Drugs on RDL-B list are categorized by active ingredient, not by brand name. This means there is one reimbursement for each active ingredient, regardless of brand name or price. This policy renders western medications more affordable to Chinese consumers, because the imported product and locally made generic receive the same level of reimbursement. Consumers also end up choosing the imported version due to preference for branded and western products.

The Essential Drugs List was created by the Ministry of Health (MOH) in 2009 as part of the healthcare reform initiative. The goal is to provide quality, low-cost medications to the entire population; the list reflects treatments for roughly two-thirds of the most common conditions in the country. The EDL list nearly overlaps the RDL-A list. However, the administration of EDL falls under the Pharmaceutical Policy Division (药政司) of the MOH, in collaboration with MOHRSS and several other related ministries. This is due to the fact that, historically, the MOH's Rural Administrative Division handled the provision as well as the financing for healthcare for the rural population. The national EDL expanded from 307 molecules in the 2009 version (including 5 western medicines) to 520 molecules in the 2012 version (with 317 western medicines). The latter version includes some of the most popular and best-selling MNC off-patent drugs (e.g., Pfizer's Norvasc and Diflucan, Novo Nordisk's Novolin, Bayer's Glucobay). If the MNC and its molecule participate on the EDL, the MNC originator premium will likely be eliminated and prices for the MNC brands will be 50–80 percent lower.

Provinces have latitude to modify the list to fit their fiscal conditions and local healthcare needs. The 2009 National EDL contained an average of an additional 188 molecules than were on the provincial EDLs. When these molecules listed on the EDL, 45 percent of them had their maximum retail price reduced by 12 percent on average; 49 percent maintained their previous maximum retail price while on the RDL. EDL usage is mandated in the basic healthcare system (small public clinics and health centers); such clinics and centers are required to purchase only EDL products. There is also an effort to increase the EDL's usage in city hospitals (e.g., using a ratio of essential to non-essential pharmaceutical revenues: 45 percent of Class II hospital revenues, 25 percent of Class III hospital revenues); by 2020, all state-owned facilities are expected to be fully stocked by EDL products. Because EDL drugs are fully reimbursed, there is strong pressure to ensure that EDL drug prices are kept low.

## *Bidding*

The practice of provincial level bidding began in 1995 and assumed its current format with the 2009 healthcare reform. The early impetus behind regional government bidding was the rising cost of drugs that resulted from distribution markups. China's drug distribution network gained notoriety for the multiplicity of small distributors and multiple points in the supply chain. In prior years, bidding rules varied significantly; some provinces even started municipal level bidding. Savings from bidding were passed onto hospitals, but not to patients. In 2009, the MOH and five other ministries issued guidance on public hospital purchasing practices. The provincial bidding is to benefit all Class II and III hospitals in the city. Once the results are finalized, prices to these hospitals in the province cannot exceed the provincial cap.

Drugs are separated into two groups: (a) non-differentiated or common generics and (b) differentiated generics (previously with independent pricing status). In the former (non-differentiated) group, typically two to four drugs of the same molecule with the lowest prices can win the bid. In the latter (differentiated) group, winners include the originator product and one to two differentiated generics.

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Each province has its own sets of rules that balance between cost and quality. Some provinces set up quality tiers and give more weight to quality considerations. Companies are scored on various merits including the product itself, along with the company's standing and history. For example, companies can earn points and increase their score by being more highly ranked by the Ministry of Information and Industry, by having a manufacturing site located in a government planned high-tech zone, or by having a drug with a National Science and Technology award.

Provincial bidding typically opens every two years. However, there are no set dates; each province sets its own dates. There are no unified national timelines for bidding; provinces often change the timelines for various reasons. In the summer of 2013, due to the anti-corruption campaign, many provinces placed bidding on hold. Drugs launched during that summer and fall faced a much slower ramp-up due to a lack of market access. EDL drugs have a separate bidding process. Discussions were undertaken to unify the bidding, with some industry experts advocating for complete removal of provincial level bidding.

It is important to note that, unlike tendering in other markets, these bidding and tendering exercises require no volume purchasing commitment attached to a given bid. They thus serve effectively as ways to obtain lower prices from drug manufacturers. Discussions during the ongoing healthcare reform have considered whether EDL drugs should follow a true tendering process that exchanges volume commitment for price discounts.

### *Hospital Listing/Formulary*

The hospital formulary listing is the last market access hurdle to overcome. Started in 2007, hospitals have implemented the policy whereby only two manufacturers (two brands) are allowed seats in the hospital formulary for any given drug with a specification (一品双规). The actual implementation of the policy varies, but typically a hospital gives one seat to the originator product and another seat to a local generic. It is uncommon to give both seats to two generics. Such a policy has helped to secure hospital access for MNC originator products and made it more difficult for generics to win against each other or displace the incumbent.

### *Drug Cost Control Measures*

Drug costs account for one-third of China's total healthcare expenditure and thus constitute a prime target for cost containment efforts. Cutting drug prices has been the strategy of choice to control drug costs for many years. Between 2000 and 2010, the government initiated 18 rounds of price cuts that yielded over $300 million in cost savings. The magnitude of the price cuts varied; they generally ranged between 10 percent and 15 percent for large spend therapeutic areas such as antibiotics, diabetes, and hypertension drugs. The expansion of health insurance coverage during the 2009 reform increased pressure on the government to further contain healthcare costs and reduce drug spend.

At the same time, however, the government recognized a need to balance cost containment with rewards for innovation. As a result, the NDRC formalized the price cutting policy in 2010 by specifying the frequency and magnitude. Drugs with patent protection or equivalent would face a 6 percent price cut every two to three years, while off-patent drugs would face a 15 percent price cut every two to three years. Under this new policy, the major issue facing the MNCs is the disappearance of the originator premium for their off-patent brands. Because these products often account for 70–80 percent of their total China business, the policy and the loss of premium pricing pose a very large risk. The government has previously indicated that they would like to reduce the originator premium to about 30 percent over the GMP price. Officials have also stated that while this is a goal, policy implementation will vary by drug. It is likely that the MNC originator premium will range between 30 percent and 100 percent by 2015.

Basic healthcare facilities (e.g., urban CHCs and CHSs, rural township hospitals, and village clinics) are required to use 100 percent EDL drugs; Class II and III hospitals have a minimum usage mandate which varies by province. Due to low medical service charges, hospitals have relied heavily on drugs

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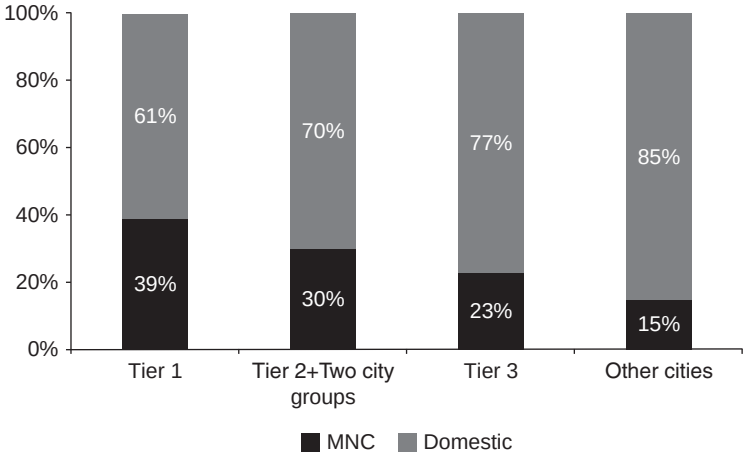


*Figure* 14.17 Domestic players versus MNCs by city tiers
Source: Jessica Li & Lillian Wan 2015. *China Healthcare Primer – The Immense Structural Upside*. Bank of America Merrill Lynch (July 9).

and diagnostic tests to generate revenues. Prescribing higher-priced drugs meant higher hospital profits. In the current reform era, local governments have deployed various cost containment measures to reduce hospital incentives to prescribe these higher-priced medicines. For example, the implementation of global budgeting by Shanghai reduced prescription volume and shifted the mix toward less expensive generic drugs.

## Competitive Capabilities and Performance

As noted earlier, the government is seeking to consolidate the pharmaceutical sector and increase the average size of firms. The government has also pursued policies to support quality improvement and incentives to innovate in the sector. With regard to quality, the 2011 new GMP standard contains more stringent requirements than in previous versions; all manufacturers need to be qualified by 2015. While China has upgraded its GMP standards on a regular basis, the government issued its policy on bioequivalence in 2013 whereby all generic chemical drugs approved before October 1, 2007, need to conduct bioequivalence studies against their reference compounds. Failed drugs will no longer be allowed on the market. The plan is to have all the EDL drugs go through bioequivalence testing by 2020. Both policies are geared toward the minimum quality standards for industry entry. With regard to innovation, the government has initiated a different set of policies using pricing and bidding levers to reward higher quality and more innovative players (discussed below).

Table 14.1 displays the performance of pharmaceutical companies in terms of their hospital market sales; Figure 14.17 shows that MNCs perform better relative to the local firms in the larger Tier 1 cities. The MNCs' average annual compounded growth rates ranged from 20 percent to 28 percent during the past few years. The other top performing group were the local private companies (e.g., Qilu, Sino Biopharm, Hengrui) which achieved a higher average CAGR around 25–35 percent during the same period. Large state-owned enterprises (SOEs) such as Shanghai Pharmaceuticals have come in a distant third with average growth rates hovering around 10 percent.

These three groups of companies have arrived at the top revenue positions by taking different approaches. For example, Shanghai Pharmaceuticals is an SOE with 600 molecules, the largest portfolio in the sector; however, only 12 of these molecules have some form of

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differentiation from other generics. Moreover, the average market size of its top ten western medicine drugs is 220 million RMB; by comparison, the market size of its top TCM drug is slightly better. The company achieved top market position by virtue of large scale and a large number of small products that are not the most competitive in their therapeutic class.

By contrast, the leading privately-owned companies have developed and promoted a handful of individual "blockbusters" that gained independent pricing status. Among the MNCs, success has been built on academic promotion of individual products that have originator premiums. They have also been more heavily engaged in continually educating the market and driving underlying demand.

The Chinese pharmaceutical market has undergone three major periods of development. In each period, different MNCs have out-competed the others using different success drivers. During the 1980s and early 1990s, China's pharmaceutical market was quite immature with loose regulation (e.g., blurry lines between OTC and prescription drugs). OTC drugs enjoyed coverage under the limited public insurance available, which enabled them to leverage both advertising (for patients but also doctors) and hospital reimbursement to drive adoption. Leading MNCs (e.g., Xi'an Janssen, Bristol Myers Squibb, and Tianjin SmithKline) gained first-mover advantage here, relied on *guanxi* (relationships) with government officials, and used heavy advertising to create a strong corporate brand.

During the mid-1990s to mid-2000s period, particularly after China entered the World Trade Organization (WTO) (see Chapter 2), the pharmaceutical sector was the target of increased government regulation and public policies that served to attract foreign investment and technology. The healthcare delivery sector (including demand for drugs) experienced rapidly growing demand in affluent urban areas. MNCs flourished in this period with a simple formula: develop a China-appropriate portfolio of products and heavily invest in a commercial arms race (sales force size and marketing budgets) to gain a share of voice and build the market. Companies that did particularly well in this era were AstraZeneca, Bayer, and Pfizer.

The third period (since 2009) was a turning point: significant issues with access to care triggered the 2009 healthcare reform. The new operating environment for pharmaceutical companies changed. Demand will continue to grow but will be more widely spread geographically. Due to rising utilization of drugs, MNCs will be subjected to pricing pressures. Local players aim to further close the gap with MNCs on additional competitive dimensions of quality and remote R&D. Going forward, the winning formula for MNCs will be more challenging, including portfolio management of all three categories of products, enhanced capability in market access, commercial model innovation, and talent management.

In contrast to the MNCs and their branded products, the global generics companies (e.g., Sandoz, Teva, Dr. Reddy) have had very limited presence in China. Their lack of success reflects time-to-market and cost disadvantages against locals: imported generics lag behind local versions by a couple of years, there are no cost advantages after importation, and it is harder for non-originator non-Chinese brands to obtain listing on hospital formularies. Sandoz started selling in China in 2005 and reached only $80 million in sales after six years; 80 percent of their sales derived from one drug (Sandostatin) that Novartis agreed to transition to them in 2007. Sandostatin is a well-established brand that was built up over many years by Novartis with independent pricing status and limited generic competition.

## Commercial Models: Selling, Marketing, and Distribution

### *Sales Representatives*

Commercial investments soared after China's entry into the WTO in 2001. Between 2002 and 2011, seven major MNCs added 16,000 representatives ("reps") in China to reach a combined total of 18,400 reps – nearly an eightfold increase. The increased size of sales forces has been the primary driver of the top MNCs' impressive growth in China (20 percent–35 percent CAGR). Such investments in the commercial arms race made good business sense. Due to the lack of patent cliffs, product life cycles are long in China

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(cf. Figure 14.15): the originators are rewarded with a price premium despite the fact that their products are off-patent. In addition, the market to serve is quite large: there are 700+ county level cities and 21,000 hospitals to cover. Most markets are still in an early stage of development where physicians need education about diseases and their treatment. Placing sales reps in front of doctors is the primary method of communicating such information to them. Furthermore, face time is important, as the Chinese doctors prefer person-to-person interactions. All of these factors require increases in sales reps. Lastly, the prevailing detailing model of single-line, specialized calls requires a large number of reps. AstraZeneca and Sanofi were among the first to adopt this sales force structure. The rationale is that both Chinese doctors and the reps themselves are less sophisticated and cannot handle too many products or complicated messages. The adage "one product, one rep" makes drug detailing more effective. MNCs employ this model for their important brands in major hospitals in the "core market" of large hospitals in large cities.

In the past, when the cost of sales reps was low, adding more sales people was a cheap and easy way to generate sales, compared to extracting higher productivity per rep. However, the resource-intensive sales force is now encountering its own challenges. First, wage rates have been increasing rapidly at more than 10 percent annually over the past decade. The average fully-loaded cost of a sales rep now exceeds $50,000 a year. On the other hand, the average productivity of a sales rep among the top ten companies grew only 4 percent from $250,000 in 2005 to $330,000. As MNCs move beyond the big hospitals in big cities to smaller and more geographically dispersed facilities, the economics make it increasingly difficult to justify the 1:1 sales force detailing model. Per-hospital output is much lower, and scattered hospitals require more time to reach. MNCs may consider hiring cheaper reps in lower-tier cities. However, the economic productivity gain may not be large, while the internal human resources management issues prove challenging.

### *Alternative Models among MNCs*

Some companies have started experimenting with alternative commercial models. Innovations can be summarized along two dimensions: (1) technology-enabled communication channel innovation and (2) customer relationship innovation. On the technology front, the environment is highly conducive. China is on its way to becoming the largest digital country; by 2015, it will have more internet users than the United States and Japan combined. Over 70 percent of Chinese doctors (including those in rural areas) use mobile devices for communication; 86 percent of them spend at least one hour on the phone (mostly checking emails and searching for information on the internet). On the customer relationship innovation front, companies have realized that their relationships with current customers are evolving, and that relationships with new customers need to be changed and segmented. For example, as pharmaceutical firms expand their footprint into smaller cities, they recognize that decision making shifts from the *clinical customer* to the *economic customer*: i.e., from individual doctors and departmental heads in the larger hospitals and cities to the administrators of smaller and local hospitals. Among existing customers, payers and government decision makers have become more sophisticated in their efforts to manage drug spend. There is thus an increasing need to properly market and communicate the right information to them.

Given this market evolution and the internal pressures discussed above, pharmaceutical companies are experimenting with new commercial models. Merck Sharp and Dohme (MSD) is one of the first movers. They have brought the global Univadis marketing platform to China and tailored it to local needs by providing medical education and professional information to Chinese doctors. In the first two years following its 2010 entry, Univadis had registered more than 100,000 users. When MSD entered into smaller cities and county hospitals in China, it heavily leveraged marketing to generate demand and reduce 1:1 detailing effort. The sales reps make the first in-person contact with prescribers to obtain their contact information. MSD established a call center for subsequent

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customer contacts, as well as center check-ins to provide information and help to prescribers.

### Alternative Models among Local Players

Chinese companies have likewise experimented with alternative commercial models. Jointown focuses on broad market distribution and contract sales for manufacturers. It balances customer reach with the economics of commercial investment by deploying different tools for different segments of its commercial activities. The "foot soldiers" provide customer services to hospitals and doctors; telephone reps take orders from providers; and a website provides B2B services for smaller accounts.

A closer examination reveals that the commercial models deployed by Chinese companies are associated with their product portfolios.

> Most local companies outsource commercial activities to either distributors or contract sales organizations (CSOs) to sell non-differentiated generics. Hisun, for example, uses CSOs to conduct bidding, hospital listing, and sales promotion activities. Hisun employs roughly 100 people to manage the CSOs and distributors but has few staff devoted to product marketing.
>
> Other pharmaceutical companies that have a few differentiated products which can obtain independent pricing and price premiums can justify having an in-house sales force that promotes their products directly to doctors. Hengrui, for example, has 2,000 sales reps; three-quarters of them are dedicated to selling products in the firm's oncology portfolio in large cities and hospitals using the single line detailing approach. Hengrui's primary products are Oxaliplatin and Paclitaxel, two popular oncology molecules. Hengrui organizes smaller scale marketing events such as local conferences and departmental seminars to educate physicians about how to treat disease using its products. This approach enables them to gain control of the end-customer relationship.
>
> The third commercial approach uses a mixed model. Simcere, for example, initially leverages CSOs to get its priority products covered and listed on the hospital formulary. Once coverage and market access are reached, Simcere gradually builds its own sales force and takes the bidding and detailing functions back in-house. Marketing of key products is also handled internally. Over time, the company has built up a sales force of 1,000–1,500 reps. For non-differentiated drugs and the majority of its portfolio, Simcere uses a large network of more than 1,300 distributors to penetrate the broader market.

Cost structures differ for each commercial model. Companies that deploy the agency model typically have a cost of goods sold (COGS) around 60 percent and a sales and marketing (S&M) spend of 10 percent of revenue. Companies using a sales force model typically have COGS of 10–15 percent of revenue and an S&M spend of 30–40 percent of revenue.

### Corrupt Practices in Sales and Marketing: GlaxoSmithKline

On June 27, 2013, Chinese investigators raided the Shanghai headquarters of GlaxoSmithKline (GSK) alleging the company had paid bribes to hospital administrators, physicians, and local officials to increase the sales of its drugs. Such bribes could motivate providers to sell more expensive western brand drugs; they also reportedly increased the price of the drugs by one-third.[5] The head of the country's Ministry of Public Security asserted that bribes totaling $450 million were administered through a network of travel agencies and middlemen starting in 2009. Based on allegations of an internal whistle-blower, the company paid physicians between 7 percent and 10 percent of the proceeds from the drugs they ordered as an inducement.

A Chinese court subsequently fined GSK $492 million and sentenced five defendants to prison. GSK responded by terminating the contracts of over 100 employees, and by halting compensation of its sales representatives based on sales targets linked to the number of prescriptions that their physician customers wrote. Some industry observers were surprised that a multinational company was singled out in the country's cross-industry anti-corruption campaign, as this problem in the pharmaceutical industry has been deeply rooted and developing over many years.

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## Competitive Dynamics: Market Convergence

In the past few years, a great convergence has taken place as (a) MNCs move down to the "mid-market" (i.e., tier 3–7 cities and some top-tier counties) with lower-priced branded generics while (b) Chinese firms move up to the core market with more differentiated products. About 60–80 percent of the revenues among seven top MNCs have come from off-patent originator branded generics. The pricing premiums enjoyed by the originators on these off-patent products are declining, exposing their China business to a significant risk. At the same time, the MNCs have been unable to reach the vast majority of the Chinese market with their higher priced products due to lower purchasing power, affordability, and less advanced treatment practices outside the major cities.

Driven by these pressures, Merck, AstraZeneca, and Pfizer made moves to enter the mid-market by 2011–2012. Both Merck and Pfizer sought joint ventures (JVs) with leading local Chinese companies (e.g., Hisun); AstraZeneca pursued an acquisition strategy and formed a broad market business unit dedicated to commercializing branded generics. By contrast, Bayer pursued a complementary strategy by purchasing a generics company with specific products fitting onto the existing commercial platform in a given therapeutic area. The acquisition of Bioton's SciLin filled a portfolio gap in the treatment of diabetes and also provided a more affordable option to the higher-priced products sold by Novo and Lilly.

This wave of mid-market expansion and non-proprietary branded generics play now has a track record of a few years. The Pfizer–Hisun JV is showing early signs of success. According to the parent company's annual report, the JV business nearly doubled to reach 6.3 billion RMB (roughly $690 million) in 2013. A number of factors favor this JV. First and foremost, the portfolio consists of high-selling drugs and category leaders including Pfizer's Medrol and Tazocin and Hisun's Epirubicin. Medrol had 76 percent market share in 2012 in IV steroids, while Epirubicin was the top-selling brand in the antibiotic treatment of various cancers with 56 percent market share. Tazocin was even still on patent. These drugs are expected to be in high demand clinically in the mid-market as well. Second, the relatively large product portfolio (60–80 molecules) enabled sales reps to detail multiple drugs to the same prescribers, lowering the cost of selling and providing selling synergies in the same therapeutic area.

By contrast, the lack of either critical mass in the portfolio or well-chosen molecules may imperil other companies' forays into the mid-market. AstraZeneca dismissed the broad market business unit in 2013, repurposed its $230 million manufacturing investment in Taizhou, and effectively exited its non-proprietary branded generics play in the broad Chinese market. The move partly reflected the company's selection of a new global CEO, who changed focus to innovative rather than generic products. The move also reflects the challenging time AstraZeneca has had with entry into the broad market in China. Due to difficulties in acquiring qualified local companies in China, AstraZeneca only managed to purchase Guangdong BeiKang (a maker of injectable antibiotics) to build up its non-proprietary branded generics portfolio. However, antibiotics suffered dearly in 2012 following the government's crackdown on the overuse of antibiotics in China (see Chapters 7 and 8). The acquisition alone could not enable AstraZeneca to establish a strong foundation. At the same time, the company was unsure how to bring its proprietary branded generics, such as Losec and Betaloc, into the broad market, since both the core business and the broad market business units competed to sell the same drugs. The commercial arrangement highlights the common challenges many MNCs face as they try to manage both the core market and broad market with the same products at the same prices.

JVs have either avoided such cannibalization or made the conflict a healthy competition between firms. This does not suggest that the road in front of Pfizer–Hisun or Merck–Simcere is a smooth one. Several key questions remain to be answered. Success will be highly dependent on careful navigation in the new market that neither JV party has much experience in. On average, top MNCs gain over 80 percent of their revenue from tier 1–2 cities; they have limited presence in mid-level cities or

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county hospitals. On the other hand, a leading local Chinese player often relies heavily on lower-level county hospitals. The mid-market can be quite new to the current players. How to assemble teams serving different markets with divergent capabilities into one integrated team backed by a common culture is a challenge. MNCs are used to resource-intensive selling to cultivate individual brands and physician brand loyalty in the top-tier market. Local companies are good at managing contract sales agents or distributors using relationships in selling. These different capabilities and experiences need to be integrated and well deployed in the mid-market. Further market segmentation is key, with allocation of the right portfolio to the right segment as a first step. Companies then need to design the right commercial model (from market access to marketing) and sell to medical providers in each segment. How to go beyond a strong generics portfolio and generate an ongoing supply of competitive products for the mid-market will be a long-term strategic concern. Companies require a dedicated R&D infrastructure to understand and address the unique needs of the mid-market while factoring in different provider practice patterns and affordability/reimbursement trends.

While some locals are working with MNCs to tackle the mid-market, others are gathering momentum to compete in the core market. Yangzijiang built the largest pharma business in China over the last several decades mainly through its differentiated selling model: a large in-house sales force that is managed centrally across different subsidiary companies. Realizing the importance of having a competitive portfolio and strong presence in the top-tier cities and large hospitals, Yangzijiang started to (a) build academic detailing capability in 2012, and (b) focus on sales and marketing of a handful of carefully selected differentiated molecules that are first-to-market generics, hard-to-copy generics, or molecules with limited competition. The local companies still have some distance to travel before they take majority share away from originator brands in top-tier cities and large hospitals. Government policy that equalizes the treatment of off-patent drugs will allow leading locals to gain a fair share in the core market.

## The Race to Innovate

China has become an attractive destination for biopharmaceutical research and development (R&D). The government aims to transform China's economy from a manufacturing base to an innovation base. For the pharmaceutical sector, the Ministry of Science and Technology has set the goal to achieve world-leading R&D status by 2020.

The government is increasing funding, building infrastructure, and attracting talent to reach its innovation goals. R&D expenditure as a percentage of GDP will reach 2.2 percent by 2015, a level close to developed nations. Life science technology parks have been built around the country, including Shanghai Zhangjiang, Beijing Zhongguancun, and Suzhou BioBay. Tax exemptions and government subsidies are provided to pharmaceutical companies to incentivize innovation and R&D investment. Government funding of the pharmaceutical sector tripled from 2006 to 2010 to reach $3.5 billion. While this represents an impressive growth in scale, it is still dwarfed by what a global pharmaceutical company spends on R&D. National programs such as the "863 Plan" and the "Torch Plan" award dedicated grants to research projects that are deemed priority and of significant innovation. To stimulate the exchange of talent, the government developed people strategies such as the Thousand Talent plan where top Chinese scientists living overseas are given the recognition and rewards to return to China to conduct biopharma R&D activities. The overall life science talent pool is large and rapidly growing. Universities are turning out more graduates in relevant fields, and the rate of Chinese scientists returning from overseas educations has accelerated. Many of the western-educated and western-trained scientists are coming home with plans to apply their experience in drug discovery and development.

Banking on the dual promise of strategic commitment and burgeoning talent pool, MNCs have increasingly invested in captive R&D centers over the past decade. By 2012, all top ten pharmaceutical companies established some R&D infrastructure in China, with a publically announced investment commitment that exceeded $2.5 billion (see Table 14.3).

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**Table 14.3 MNCs with R&D bases in China**

| Company | Number of R&D Facilities in China |
|---|---|
| **Bayer Healthcare** | 1- Beijing |
| **Sanofi** | 2- R&D facilities in Shanghai<br>Biometrics facility in Beijing and another R&D facility in Chengdu |
| **Novartis** | 3- Shanghai (2) and Changshu |
| **Roche** | 1- Shanghai |
| **Novo Nordisk** | 1- Beijing |
| **Merck & Co** | 2- Beijing (of which one is a R&D headquarter) |
| **Merck Serono** | 1- Beijing |
| **GSK** | Over-the-counter R&D centre in Tianjin<br>Global R&D centre in Shanghai |
| **AstraZeneca** | 2- Shanghai |
| **Pfizer** | R&D facilities in Shanghai and Wuhan |
| **Eli Lilly** | 2- Suzhou and Shanghai |
| **Takeda** | 1- Shanghai |

Source: BMI

Four different China R&D models emerged, although no one company approach is a "pure" model. The most common model is to have the internal team support global development projects with functional expertise such as analogue synthesis and compound generation. Others have internal teams that conduct research on unmet clinical needs in China or (more broadly) Asia, such as the high incidence of liver and gastrointestinal cancers. AstraZeneca and Novartis are two examples. A third model is characterized by highly externalized R&D: minimum internal resources with heavy scouting of external innovation conducted in academic institutions and local biotechnology companies. Sanofi's Asia R&D center used this model to in-license the development of a Phase II cancer compound from Shanghai Institute of Biologics Products. The most aggressive model is an integrated R&D center acting as a global therapeutic area center. A prominent example was the GlaxoSmithKline China R&D center dedicated to neuroscience research – the only dedicated research center in its global network. Pfizer almost decided to put its global anti-infectives research unit in China.

Going forward, global innovative firms need to recognize that their China R&D investment should not be driven by the flurry of activity or peer pressure exerted by the investments made by competitors. Rather, China R&D investment needs to be evaluated and managed by MNCs as rigorously as they would any other R&D project in the world.

In recent years, Chinese companies have been catching up to MNCs on R&D. Spurred by the government's goals for innovation, aggregate R&D spend as a percentage of revenue has grown (see Figure 14.18). Some firms reached as high as 10 percent (e.g., Hengrui's pursuit of category 1 innovation: see Figure 14.9). Perhaps as a result, the number of new drug applications has risen in recent years (Figure 14.19).

The challenge for Chinese companies is to balance long-term innovation goals with short-term returns on their R&D investment. Western management researchers label this the challenge of "ambidexterity." Recognizing the difficult road and significant investment required for novel drug discovery, industry leaders are embarking on a journey toward incremental innovation (仿创结合). Many are looking to develop differentiated generics, which are more difficult to copy than regular generics and are rewarded with price premiums. This means either first-to-market generics or existing molecules with a new formulation or dosage.

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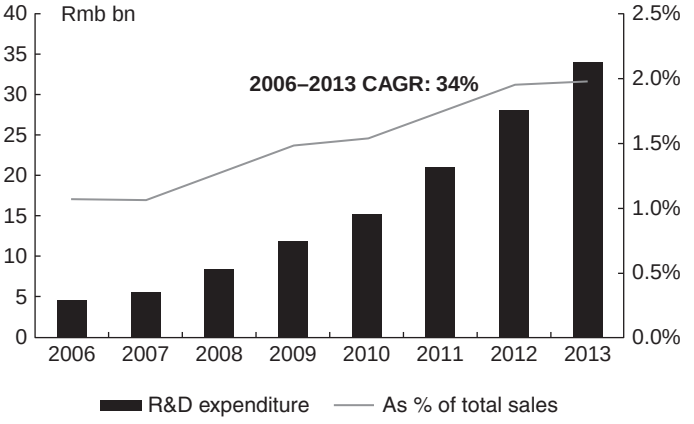


*Figure* 14.18 Trend in R&D spend
Source: Jessica Li & Lillian Wan 2015. *China Healthcare Primer – The Immense Structural Upside*. Bank of America Merrill Lynch (July 9).

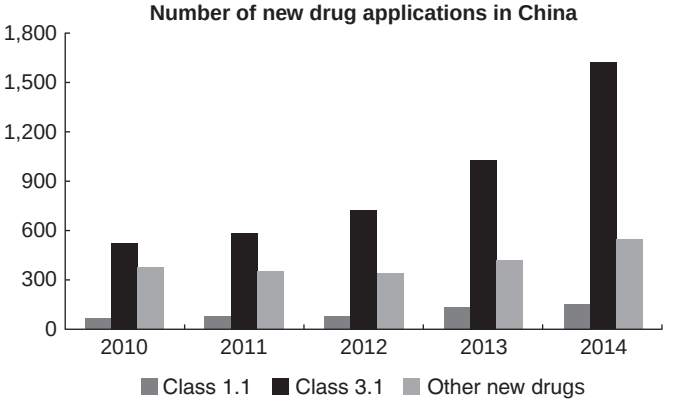


*Figure* 14.19 Innovation among domestic players
Source: Jessica Li & Lillian Wan 2015. *China Healthcare Primer – The Immense Structural Upside*. Bank of America Merrill Lynch (July 9).

Other companies are pursuing a frugal innovation path: i.e., develop a me-too or me-better drug but at a lower cost with faster than usual speed. This usually begins by working on a well-validated target, making sure not to complete all clinical trials alone but waiting for competitors' early study results. This enables them to move further along the drug development process with higher efficiency, which can save a couple of years' time.

The long-term investment can be daunting, but some are destined to succeed. Zhejiang Beta is a success story worth noting. The company spent ten years in R&D to develop an innovative compound (Icotinib, an EGFR-inhibitor) for the treatment of non-small-cell lung cancer. They made a key strategic bet on comparative effectiveness research (CER) by conducting a head-to-head clinical trial of their compound against AstraZeneca's leading drug, Iressa. The favorable CER results were celebrated by the Ministry of Health along with officials from several other ministries who attended the product's launch.

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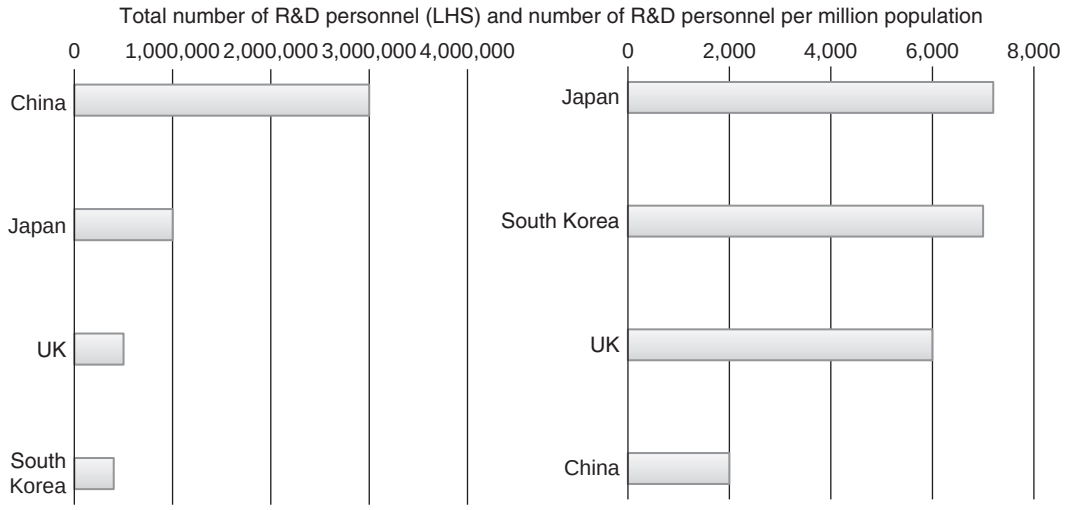


*Figure* 14.20 R&D personnel in China

The path to becoming a major innovation powerhouse will require Chinese companies to address a number of issues. The regulatory process is highly onerous. Companies need to strengthen their intellectual property (IP) rights protection as well as the quality of clinical trials. The investigational new drug (IND) application takes 12–18 months in China, compared to 30 days in the United States and three to six months in other developing countries such as India, Argentina, and Mexico. The CFDA is chronically understaffed, and yet both generics and innovative applications go through the same lengthy process and consume the same resources. As a result, the productivity of per-reviewer application processing is a serious issue.

China has made much progress in upgrading its legal framework for IP protection since the signing of the WTO; however, enforcement still lags behind. The current patent linkage mechanism requires drug registration applicants to provide information regarding any patent and patent ownership rights relating to the subject drug, to submit a certificate of non-infringement of patents, and agree to be liable for any consequences of possible patent infringement. However, the effort to gather the information and the burden of proof borne by the claimant are very high, which discourages innovator companies from pursuing litigation when their patents are infringed. In addition, litigation only makes available a small amount of statutory damages. If various references are unavailable or unreasonable, damage awards can be as small as 5,000–300,000 RMB (and are capped at 500,000 RMB). In most cases, damage awards for lost profits, gained benefits, or royalty payments do not greatly exceed the maximum statutory damage. Another concern is trade secret leakage: it can be difficult to trace the "infringer" or "data leaker" due to the lack of documentation and the challenges in gathering evidence. Finally, on the quality front, despite a vast pool of raw talent, significant effort needs to be put into training, development, and retention of R&D personnel. China lags behind other leading pharma countries in R&D personnel (see Figure 14.20).

In summary, China is emerging as a major player on the global stage of R&D. Despite the myriad challenges noted above, China is making steady progress toward innovation in biopharmaceuticals. Companies who are planning to invest in R&D activities in China need a long-term view, well-calculated areas of investment, and a healthy dose of patience and commitment.

## The Emergence of Therapeutic Biologics

Beyond chemically-based pharmaceutical products, China's life sciences sector also includes other

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product categories such as biologics, vaccines, and traditional Chinese medicines (TCMs). The distribution of sales across these categories is difficult to accurately represent, since available sales figures are based on a mix of retail prices and ex-factory prices.[6] This section discusses biologics; the following two sections consider the vaccine and OTC markets.

The Chinese government has designated biotechnology as one of the seven strategic emerging industries. The therapeutic biologics segment is a key pillar within the biotechnology sector.[7] In 2010, China's therapeutic biotech sector accounted for roughly 18 billion RMB, less than 2 percent of the global total; by comparison, the Chinese pharmaceutical sector accounted for 7 percent of the global total. By 2014, the biologics sector achieved $47 billion in ex-factory sales. China's biotech products are generally less complex molecules such as albumin and immunoglobulin; several innovative therapies are not yet marketed in China. Leading biologics worldwide such as monoclonal antibodies (mAbs) account for only a small share (10 percent). The country's biotech sector is also quite fragmented and underdeveloped. Except for mAb and insulin, there are a large number of Chinese players in the most commoditized product categories.

Nevertheless, the therapeutic biologics sector holds significant promise due to strong government backing, large unmet clinical need, and a rapidly evolving industry ecosystem. Compared to the small molecule sector, where some past policies have resulted in a largely fragmented and less competitive industry with no innovation, the therapeutic biologics sector is still embryonic. It has the potential to become world class if government policy can properly stimulate demand, reward and protect innovation, and set high standards for the quality of production. A number of challenges exist in today's policy environment for biologics innovators and manufacturers. These include market access, affordability, current regulatory framework, and IP protection.

*Market access* for therapeutic biologics takes much longer than for small molecules. Biologic drugs require an average 19–22 months to receive clinical trial approval in China, compared to only 10–18 months for small molecule drugs. Factors contributing to this delay include (1) a lack of reviewer resources within SFDA and CDE and (2) the biological sample test requirements necessary for a clinical trial at the National Institutes for Food and Drug Control (NIFDC). Such testing is unique to China among major markets like the United States, Europe, and South Korea.

The *high price* and thus the affordability of biologics products remain challenging. Most cutting-edge therapeutic biologics are still expensive with quite limited public insurance reimbursement. Adoption rates for innovative therapeutic biologics in China are low. In the case of rheumatoid arthritis, approximately 7 percent of eligible Chinese urban patients receive the biologics treatment of DMARDs (Disease-Modifying Anti-Rheumatic Drugs). By contrast, approximately 67 percent of US Medicare patients diagnosed with RA receive the biologics treatment. Companies are seeking creative solutions to enhance affordability and improve access. Roche formed a strategic partnership with Swiss Re to enroll oncology patients in an insurance program that covers oncology treatment. The government is also working on several solutions to improve the affordability of high-cost therapies. Some provinces have listed mAbs onto their PRDLs. There are also discussions on creating a new RDL list (RDL-C) in addition to the RDL-A and RDL-B lists to cover high-priced products.

The *current regulatory framework* does not require non-innovative biologics to prove similarity in efficacy, quality, and safety through systematic comparability exercises with the originator. Instead, it allows non-innovative biologics to be registered as new biologics products but with less stringent requirements. This could potentially pose risks to patients as the lower quality alternative could have unwanted immunogenicity and lower efficacy. Recognizing the importance of patient safety and quality, China is now considering the possibility of developing a biosimilar pathway to mitigate these risks.

Furthermore, to properly incentivize and protect innovation, China is looking to improve the *IP system* for biologics. Currently the scope of patent protection is narrower than global standards, making it easier for companies to obtain patents with only slight modification. For example, three similar

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molecule patents from different manufacturers coexist for Rituximab. In addition, there is no clear data exclusivity protection for biologics in China. Discussions are under way to broaden the scope of protection for biologics and to grant data exclusivity that is longer than chemical drugs. A more in-depth review of the China biologics industry can be found in Chapter 16 and online.[8]

## Vaccines

China's vaccine industry is another strategic priority for the Chinese government. China is the largest manufacturer of vaccines in the world, producing 1 billion doses each year – roughly 20 percent of the global supply. However, China's immunization expenditure per capita is among the lowest in the world ($20 per person, 2009 currency). The vaccine sector has two distinct segments that operate very differently. The public segment continues a legacy system in China's Center for Disease Control (CDC) system that brings an adequate supply of mandatory immunizations to 16 million newborns each year. The private segment arose out of unexpected events rather than deliberate strategy; key industry policies have yet to be well defined. These two sectors are discussed below.

### *Public Vaccine Segment*

The public segment contributes 70 percent of the volume but less than 30 percent of the total value of the market ($2 billion in 2011, $3 billion in 2014). The high level of growth in volume in the public sector reflects the inclusion of additional vaccines over time. From 1978 to 2002, China had four vaccines in its public program: BCG, Oral Polio, Measles, and whole cell DTP. From 2002 to 2008, Hepatitis B was added to curb the hepatitis B epidemic and the associated high incidence of liver cirrhosis and liver cancer. In 2008, the State Council announced a fourfold expansion and upgrade of the public program: (1) enlarge the inoculation population of HBV to 15 years old and under instead of only newborns; (2) upgrade two vaccines by changing Measles to MMR and whole cell DTP to acellular DTP which is the international standard; (3) convert four Class II vaccines to Class I (Hepatitis A, Meningitis A and Meningitis A&C, Japanese Encephalitis); and (4) make three vaccines available as part of the public program to certain regions or when there is a disease outbreak (Endemic Hemorrhagic Fever F, Anthrax, Leptospirosis). The expansion boosted the public market by 34 percent in a single year from $365 million in 2007 to $492 million in 2008. By contrast, steady-state growth in the public sector had been a more modest 15 percent. The government kept prices low for the Class I mandatory pediatric vaccines. For example, the price of the DTP vaccine to the CDC was as low as $0.03 per dose, whereas the UNICEF/GAVI price was more than $0.15 per dose. The SOE China National Biologics Group (CNBG) accounted for 75 percent of the public market volume; other local companies made up 20 percent, with MNCs accounting for about 4 percent, mainly to answer calls to relieve local supply shortages.

### *Private Vaccine Segment*

The private segment arose unexpectedly following the 2003 SARS outbreak that propelled the Chinese government to decentralize vaccine production and distribution in order to meet the needs of such pandemics. Coupled with the rise of a private equity industry and the inflow of foreign funds, the private sector mushroomed across China. By the end of 2012, there were 35 private Chinese vaccine companies, many of them established by former SOE employees (CNBG in particular). With a large number of players (more than any other country in the world), the industry competed on price; some companies inevitably cut corners on quality and safety. Flu vaccines account for over half of the volume in the private market. SOE manufacturers have 30–40 percent volume share, with the rest contributed by other local firms (40 percent) and MNCs (20 percent).

### *Issues with Vaccines*

There are several issues and trends in China's vaccine industry. First, there is *evolving demand with a low rate of adoption*. Vaccine demand is maturing

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and aligning with developed countries, as more vaccines are included into the National Immunization Program (NIP) and combination products are developed. The adoption rate is still very low in the private segment. Consumers and parents are increasingly aware of the importance of Class II vaccines; however, there is no systematic education regarding Class II vaccines by providers. Affordability poses another barrier to adoption, especially when consumers do not understand the value and the benefit of the vaccines. For example, the flu vaccine adoption rate among the urban elderly remained below 1 percent for many years, compared to more than 60 percent of people 65+ years in the United States. Similarly, adoption rates for Hib (Hemophilia Influenza B) and Rotavirus are also quite low compared to developed countries. Adoption of the pediatric Pneumococcal vaccine (Prevenar) is a major challenge because the country lacks good epidemiological data on the disease burden. In the absence of demand generation by the government, companies must undertake significant market building efforts.

Second, *customers are changing as the point of vaccination (POV) integrates into CHCs*. Vaccine provision in China used to be separate from the hospital system. The country has 31 provincial CDCs, 390 municipal CDCs, 2,700 district CDCs, and 65,000 POVs that handle the distribution and administration of Class II vaccines. Since healthcare reform, CHCs have been strengthened to form a pseudo primary care system. The government is now moving vaccine POVs into CHCs so that primary care and preventive care can be managed together. However, implementation of such change varies geographically, as do CHC development and CDC operations. Most major cities where CHCs are up and running are integrating POVs; other provinces and cities are still in transition. During this transition, the financial and administrative responsibilities between the CHC/MOH system and CDC system remain to be streamlined.

Furthermore, vaccine *distribution channels and market access are complex*. When the government decentralized the vaccine distribution system in 2004 following SARS, responsibility for procurement cascaded down to city-level CDCs and POVs. This contributed to significant variation in implementation at the local level. As of 2012, an estimated 30 percent of vaccines were sold directly to city-level CDCs without having to go through the provincial CDC (and thus perhaps centralized tenders). As a result, the overall channel markup for vaccines remains high, leading to higher retail prices for the consumers. For prescription drugs, total channel markup from manufacturers to end patients is about 25 percent; for Class II vaccines, the markup can range from 50 percent to 200 percent in most provinces.

*Vaccine regulatory standards are in strong need of improvement*. The year 2011 represented a milestone year for the Chinese vaccine industry. The country passed the World Health Organization (WHO) vaccine regulatory assessment, which allowed Chinese suppliers to qualify for UN procurement. Pharmacopeia quality standards were subsequently raised and new GMPs were issued. The government is now actively working to refine its Class II vaccine policy. The policy is expected to address the government's roles in demand generation (funding and reimbursement) and thereby formalize the process for NIP inclusion.

*Local companies' capability is improving*. Responding to the government's call to innovate in strategic industries such as vaccines and to foster globally competitive companies, leading local players are actively seeking to upgrade R&D and manufacturing quality improvement. Hualan and Sinovac are gearing up the Prequalification for WHO program. China National Biotec Group (CNBG) institutes with historical strengths in R&D are developing new vaccines. CNBG Lanzhou Institute successfully launched its monovalent Rotavirus vaccine. The rapid development of the H1N1 vaccines is another sign of indigenous vaccine R&D capability.

## OTC and Consumer Health

China's consumer health market is a rare combination of size and growth. By 2010, the market size had already reached roughly $10 billion for OTC products and another $6 billion for vitamins, minerals, and supplements (VMS). By 2014, retail sales

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of OTC products reached $31 billion. Compared to the prescription drug market, the OTC and VMS markets are much smaller in absolute revenues. However, in terms of global penetration, China's OTC and VMS markets are much stronger: OTC and VMS represent 11 percent and 12 percent of the global market, respectively. By contrast, China's prescription medicines account for only 4 percent of the global total. The OTC/consumer health market has also slightly outpaced GDP growth (roughly 10 percent), driven by the increasing trend toward self-medication and improving regulations on the distribution, labeling, and advertising of OTC drugs.

A unique feature of the Chinese OTC market is that TCM products play a prominent role. Three-quarters of approved OTC drugs are TCM products. These products represent no less than 40 percent of the total OTC market by value. Chinese consumers are discrete in their OTC use of western medicines versus TCM medicines. Chinese resort to western medicines for acute and more severe conditions such as anti-fungal treatment and stomach discomfort. TCM products command more than 90 percent of the OTC market for milder conditions such as sore throat and cough. The appeal of TCM brands to the consumer lies in indications and claims that are deeply rooted in health beliefs. For example, to address constipation problems, an over-the-counter TCM product will assert on its label the following: "detoxifies the body, beautifies the skin." It is believed that if the body is not detoxified periodically, harmful substances will have multiple negative effects on the body, including slow bowel movement, dull skin, and acne.

Another unique aspect of the China's OTC market concerns uneven regional development. Unlike prescription medicine, the 50 largest cities among China's total of 350 cities comprise less than 40 percent of the total market. The remaining majority share is fairly dispersed across the country. The rise of lower-tier cities will serve as an important future growth driver for the OTC market.

To understand the consumer health market, it is important to understand the behavior of Chinese consumers. Several of their behaviors are unique and relevant to the OTC and consumer market. China is the only country where "trading up" (consumers opt for more expensive goods rather than less expensive ones) still beats "trading down" in the purchase of consumer goods. Chinese consumers are increasingly investing in health and wellness. In recent years, in the face of several prominent food safety and environmental pollution scandals (see Chapter 3), citizens have taken extra care in selecting consumer products. Brand is also very important to the vast majority of the Chinese due to its association with quality and product integrity. The perception of higher quality is further associated with higher price. Finally, internet penetration has significantly increased to become an indispensable part of life – extending to online shopping for OTC drugs and consumer health products.

These trends have several implications for the consumer health and OTC business. First, companies can embrace the public health mantra of "from treatment to prevention" as a way to capture the public's rising awareness of the virtues of health and their greater willingness to spend on consumer products. Second, understanding different consumer behaviors and preferences will allow companies to cater to regional variations in the trade-up trend across provinces and city tiers. Third, companies can take advantage of opportunities to charge premium prices via branding as brand becomes critical to assure consumers about product quality and efficacy. Fourth, companies need to pursue new channels to reach and educate consumers about personal healthcare and medications.

To capitalize on market fundamentals, OTC/consumer health companies must be fully tuned into the complex and evolving dynamics in the retail channel. There are six types of retail channels at play: hospitals, retail pharmacies, modern trade (e.g., supermarkets), health and beauty specialty stores, internet shopping, and direct sale. The modern trade, health/beauty specialty stores, and online platform are growing quickly. They offer new sales platforms but also require new capabilities to manage these channels. The pharmacy channel is still the largest, however, and the retail pharmacy sector itself is undergoing continuous consolidation and upgrades in its management capability. Manufacturers who can collaborate with retail pharmacies to achieve common goals stand to reap

long-term benefits. These collaborative goals can focus on pharmacist training/education, capability upgrades in specific therapeutic areas of interest to the manufacturer, and improved category management. The hospital channel should not be overlooked, as in some categories brand equity and provider-prescribing habits in the hospital carry over into the retail pharmacy setting. For the sale of VMS products, the modern trade and online pharmacy channels are gaining importance. Taobao cooperated with five State-approved B2C medicine companies to sell OTC and healthcare nutrition products in 2011. Direct sale could also become a powerful channel; however, the government is highly guarded about this channel and restrictive in granting licenses, particularly to foreign companies.

The China OTC and VMS markets are crowded and fiercely competitive. Of the 500 players, the top five possess less than 25 percent market share (and falling). While local companies have much higher aggregate share, the top three positions are held by MNCs in three out of the five largest categories (except cough & cold). Amway leads in VMS; Xi'an Janssen leads in dermatology (Daktarin for vaginal fungal infection and athlete's foot); and GSK leads in analgesics (Fenbid for pain relief). Companies employ three distinct businesses in this sector:

- Media-focused players have significantly increased "above-the-line" (ATL) spend to build brand and generate consumer pull;
- Balanced players rely on differentiated branding, product positioning, and a "balanced" marketing and sales approach; and
- Distribution-driven players focus on broad channel/geography coverage and strong in-store promotions/executions.

The front-runner in the Media category is Hayao – a short name for Ha'er bin Pharmaceuticals in the northern Heilongjiang Province. Hayao spends around 45–50 percent of its revenue on media advertising and branding. Their followers also spend a minimum of 30 percent of revenue on A&P expenditures. Competition is so strong that collectively the group members play leapfrog in spending, raising the bar against each other year after year to generate demand via media such as the CCTV (national).

The prescription drug manufacturers "invented" the distribution pull model. Since their primary business is in prescription medicines, they lack the resources to compete against companies like Hayao on ATL spend. Instead they offer higher margins to distributors and retail pharmacies to gain business. Yangzijiang is an exemplar of this model: they spend a limited amount on marketing but provide large incentives to strong and capable distributors to push for coverage and penetration of their product. This model has been successfully used to sell their three leading TCM/OTC drugs. Yangzijiang is able to leverage the legacy brand and strong word of mouth in hospitals to negotiate better deals with distributors who cover both the hospital and retail channels.

Multinational companies such as Wyeth (now Pfizer), GSK, and Xi'an Janssen followed the balanced model. They are stronger than the others in strategic marketing. They also spend a large amount on A&P to build a strong brand equity that, traditionally, then creates leverage in the pharmacies and the distribution channel. At the same time, MNC OTC players extend the rigor of sales force effectiveness into the retail pharmacy channel as well. This holistic approach allows them to gain significant share in key categories.

Three critical elements are needed to achieve success to achieve a sustainable and profitable position in the OTC and VMS market. These include: (1) identify the right anchor platform (consumer segment and functional benefit) to enter; (2) achieve meaningful scale in a reasonable time frame; and (3) build strong competitive differentiation and leadership via product innovation and professional brand building. These are themselves based on deep consumer knowledge and strong channel and distribution management.

## Conclusion

China's pharmaceutical sector is on its way to becoming the second largest in the world. However, prior success factors that have enabled

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its rise differ from factors necessary to win going forward. Companies need to commit to a better understanding of the nature of future market opportunities and the evolving operating environment, adopt flexible and adaptive approaches to actively shape the future environment, and create win–win solutions.

## Notes

1. Lawton R. Burns. 2012. *The Business of Healthcare Innovation* (Cambridge, UK: Cambridge University Press).
2. Market value at ex-factory price.
3. MAC population refers to "middle and affluent consumers" with annual household disposable income of more than 75,000 RMB, in 2010 real renminbi.
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6. Retail price data suggest the total Chinese pharmaceutical market in 2014 was roughly $202 billion; of this, OTC accounts for $31 billion and vaccines another $3 billion. Ex-factory sales data suggest a market size of $100 billion for TCM products and $47 billion for biologics. Sources of these data include the CFDA Southern Medicine Economic Research Institute and McKinsey.
7. Therapeutic biologics includes substances that are produced by or extracted from a biological source and intended for therapeutic purposes. Recombinant DNA technology is often used. Examples include recombinant proteins, monoclonal antibodies, and advanced therapy medicinal products. Therapeutic biologics as used here excludes vaccines.
8. China Association of Enterprises with Foreign Investment R&D-based Pharmaceutical Association Committee (RDPAC). *Building a World-Class Innovative Therapeutics Biologics Industry in China*. Available online at: www.rdpac.org/UpLoad/UpLoadFileDir/201402/14/20140214611000652.pdf. Accessed on December 12, 2015.

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