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China's Rising Importance in Pharmaceuticals

Although regulatory hurdles remain, new policies and an expanding domestic market are luring drug giants to China

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As China's pharmaceutical market grew and advanced on many fronts in 2007, its global importance and influence became clear. In fact, sales of all Chinese and Western drugs in China hit $50 billion at the end of 2007, according to *Pharma China*, and China's Market is approaching the size of Japan's market, the world's second largest. In addition to being the dominant global supplier of active pharmaceutical ingredients (APIs) and intermediates, Chinese companies in the past year have invested heavily to expand production of generic drug formulations.

For many pharmaceutical multinational corporations (MNCs), China is becoming a leading overseas market and will likely become their largest foreign market within a decade. Moreover, several pharmaceutical MNCs, including GlaxoSmithKline plc (GSK), have increasingly relocated some of their research and development (R&D) operations to China, including some of the core and integrated research functions. MNCs are also outsourcing more R&D and manufacturing projects to China.

Stunning growth

The Chinese pharmaceutical market has grown at double-digit rates over the past three decades. Sales of drugs, including Western medicines, biopharmaceuticals, and traditional Chinese medicines, rose 61 times between 1980

and 2007, according to the PRC State Food and Drug Administration (SFDA). In 2007 alone, drug sales rose more than 20 percent.

China's total trade in medicine and health products hit $38.6 billion in 2007, up 25.6 percent over 2006. Medicine and health product exports totaled $24.6 billion, up 25.1 percent. At $13.6 billion, APIs led exports, followed by pharmaceutical formulations at roughly $780 million. Imports stood at $14 billion, up 26.6 percent, with APIs and pharmaceutical formulations again leading the way at $6 billion and $2.8 billion, respectively, according to the China Chamber of Commerce for Import and Export of Medicines and Health Products. Finally, pharmaceutical R&D work outsourced to China—usually received by contract research organizations (CROs)—was worth about ¥4 billion ($550 million) in 2007, according to a recent Xinhua News Agency report.

Quick Glance

- China's rapidly growing pharmaceutical market expanded 20 percent in 2007.
- Government policies that encourage innovation and have improved protection of intellectual property have spurred research and development in the sector.
- Regulatory changes and reforms are creating some uncertainty in the short term but should provide a more stable environment for the industry's development in the long term.

Long-term goal: An innovative drug industry

The PRC government has long wanted to build an innovative domestic pharmaceutical industry led by large and research-based companies. At the same time, the government has consistently welcomed foreign investment and encouraged the integration of local industry with international companies.

To achieve these goals, the PRC government has adopted industrial and regulatory policies, such as preferential drug pricing and hospital drug procurement policies, that favor research-based MNCs and large domestic enterprises. At the same time, it has improved market access for foreign companies and taken steps to strengthen intellectual property (IP) protection to foster innovation, including signing an agreement with the US Food and Drug Administration (FDA) last winter to jointly combat counterfeit drugs. In 2006, SFDA, which has been at the center of recent food and drug safety issues, embarked upon a six-month campaign to beef up supervision of all aspects of drug production. China has also stepped up its effort to regulate and approve APIs and audit drug production facilities.

Because of these efforts, China seems to be winning the trust and confidence of foreign companies. Most notably, R&D-based MNCs are boosting their investments in China not only to expand manufacturing and marketing operations, but also to transfer some of their critical business operations and core technologies to the country.

Today, China's pharmaceutical industry is developing in tandem with foreign R&D-based pharmaceutical companies. Thus, China will likely implement a two-pronged, long-term strategy that will support new drug innovation, the growth and development of R&D-based MNCs in the country, and the rise of its own large and innovative companies. For instance, more than a dozen Chinese drug companies have listed in the US stock market, according to ChinaBio Stock Index, and the resulting financial strength of these companies will help facilitate their rapid growth in China and globally. Moreover, PRC companies are beginning to acquire foreign companies—WuXi PharmaTech Co., Ltd.'s takeover of US-based AppTec, Inc. in March 2008, for example—in an effort to expand market share more rapidly and acquire researchers and technologies.

A string of new regulations

China issued numerous pharmaceutical regulations in 2007, following a slew of policy adjustments in the previous year. SFDA issued more than 50 regulations related to food, drugs, and medical devices last year, among which Administrative Measures for Drug Registration, Management Measures for Prescription, and rules on false drug advertising were the most noteworthy. These rules sought to improve transparency and increase scrutiny of drug approvals, standardize prescription procedures to prevent price manipulation and over-prescription, and evaluate companies' credibility by the number of misleading advertisements. Several draft regulations dealing with issues such as IP protection, contract manufacturing, counterfeit drugs, environmental conservation, recalls, and pharmacy management were also released for public comment in late 2007. All of these draft regulations, if passed, will have far-reaching impacts on the future of the pharmaceutical industry in China.

The PRC government is also likely to intensify and broaden its regulatory control over drug prices. Not only do regulators hope to control prices of all prescription drugs, they also plan to step up control of drug prices by setting ex-manufacturer prices and regulating profit margins from factory to retail. The National Development and Reform Commission, the central-level agency responsible for price control, among other functions, is studying a strategy that would make patients pay for the price difference between generic drugs, largely made by Chinese companies, and originator drugs, largely produced by MNCs—a policy that would likely reduce MNC sales in China.

Another recent regulation will affect exports. In January 2008, under pressure from foreign governments, particularly the US FDA, the PRC government introduced an export-licensing system to regulate, on a trial basis, 10 categories of drug exports, including direct and ancillary mate-

rials used in manufacturing drugs. Companies producing the listed drugs must receive export approval from the relevant authorities.

Business prospects improve for R&D-based MNCs

After a slew of new drug rules in 2007, growth in China's pharmaceutical sector resumed in a big way. Although most large and medium-sized domestic pharmaceutical companies fared much better in 2007, anecdotal evidence indicates that R&D-based MNCs experienced significantly sharper growth, largely a result of hospital drug procurement policies favorable to MNCs and a cleaner market environment with less chaotic competition.

Responding to positive market environments and mounting opportunities, MNCs are strengthening their sales and marketing networks, expanding manufacturing facilities, and accelerating R&D relocations (see the *CBR*, March–April 2008, p.42). For example, in late 2007, German pharmaceutical giants Bayer AG and Novartis AG announced ambitious plans to expand their over-the-counter (OTC) drugs businesses in China, while Wyeth decided to expand its facility in Suzhou, Zhejiang; Sandoz (part of Novartis) acquired a new manufacturing facility in Zhongshan, Guangdong; and Sanofi-Aventis began construction on a new vaccine plant in Shenzhen, Guangdong. Meanwhile, Eli Lilly and Co. and GSK expanded their R&D operations in China, and Merck KGaA and Novo Nordisk AS signed major research deals with Chinese research institutions.

In addition to business expansion, three other trends seem to have developed in 2007. First, because of the more favorable regulatory climate and pro-R&D policies, MNCs are increasingly willing to relocate some of their key R&D functions to China, as evidenced by GSK's bold move to relocate its entire neurodegenerative diseases research component to China. A second trend appears to be that MNCs have taken an interest in exploring traditional Chinese medicines (TCMs) to find new drug leads. For instance, Merck and Hutchison China Meditech Ltd. joined forces to find cancer cures among TCMs, and GSK also announced its interest in finding leads from TCMs. The third trend—expected to intensify in the coming years—is on the outsourcing front. MNC R&D outsourcing to China has risen sharply in recent years, with major CROs, such as Wuxi PharmaTech, recording triple-digit revenue growth. In addition, MNCs such as AstraZeneca plc, Pfizer Inc., and GSK

Healthcare Reform: Impact on Pharmaceuticals

The rising cost of healthcare ranked as a top concern among the Chinese public in recent polls conducted by the National Bureau of Statistics and Xinhua News Agency. This concern is unsurprising: In 2007, Chinese individuals spent more than ¥1 trillion ($144 billion) on healthcare, up 11.3 percent from 2006, and the average healthcare expenditure per capita was ¥828 ($118.6), up 10.4 percent, according to the PRC Ministry of Health (MOH) estimates. In addition, individual healthcare spending as a percentage of China's gross domestic product (GDP) has fallen from 5.6 percent in 2003 to 4.8 percent in 2007, according to MOH. This suggests that healthcare spending has grown more slowly than GDP in the past few years, thus leaving considerable room for the future expansion of healthcare consumption.

Jolted by the severe acute respiratory syndrome outbreak in 2003, the PRC government began to seriously re-conceptualize public healthcare over the next two years, culminating in the publication of a lengthy report on the state of healthcare in China in 2005. Jointly released by the State Council Development Research Center and the World Health Organization, the report concluded that China's healthcare reform in the past two decades had been largely unsuccessful and triggered a heated public debate. As a result, China in 2006 formed an interagency group, the Healthcare System Reform Coordinating Group, to develop a new healthcare reform plan. Unable to settle disputes among various government agencies within the group, the PRC government contracted nine external organizations to help develop healthcare reform plans in 2007 (see p.18). The external organizations presented separate proposals to the government in June 2007, but the officials and scholars involved in the process disagreed on major issues such as the model for hospital financing and how government funding should be funneled.

Minister of Health Chen Zhu delivered an official report on healthcare reform to the National People's Congress in late 2007. The report outlined the framework and basic ideas of China's healthcare reform and set the objective of establishing a healthcare system that provides safe, effective, convenient, and low-cost public health and basic medical services for all urban and rural residents.

Healthcare reform in China will significantly affect the pharmaceutical industry and will likely cause the industry to restructure. As the country's economy grows and healthcare and other reforms strengthen China's social safety net, the demand for new medicines and high-quality healthcare could rise. Although large domestic companies are best-positioned to fulfill essential healthcare needs of the public in the short and medium terms, innovative MNCs are well-suited to satisfy demand for higher-end products and services.

Despite short-term regulatory corrections, administrative changes, and healthcare reform uncertainties, the long-term direction and present development path of China's pharmaceutical sector are unlikely to be significantly impeded.

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announced major reorganization initiatives that led them to outsource more manufacturing to China. Even small foreign companies, such as AlphaRx Inc., Helicon Group Ltd., Organogenesis Inc., and Novelos Therapeutics, Inc., began to move aggressively into China through various licensing and collaborative research deals in 2007.

China's recent IP policies have benefited companies that are dedicated to innovation and explain, in part, pharmaceutical MNCs' eagerness to expand in China.

More emphasis on IP protection

Over the last decade, the PRC government has gained a greater understanding of the importance of IP protection to innovation and economic growth. As a result, it has instituted various policies that encourage the development of IP. These policies have benefited pharmaceutical companies that are dedicated to new drug innovation and explain, in part, pharmaceutical MNCs' eagerness to expand in China. Despite such policies, however, foreign companies remain concerned with certain areas of IP protection in the pharmaceutical sector.

Specifically, the central government has not

- Clearly defined "new chemical entity" in a drug (which would make ensuring data exclusivity during drug registration difficult);
- Adequately protected against unfair commercial use of undisclosed test and other data submitted by pharmaceuticals companies;
- Developed a more robust system of patent linkage under which the filing of a lawsuit will automatically suspend the registration process of a product suspected of infringement; or
- Adopted a system of patent-term restoration to help innovative companies recover patent-term losses due to long development time and regulatory delays.

Overseas generic drugs market: Growth area for PRC companies

Compared with their MNC counterparts, large Chinese companies generally achieved less impressive growth in 2007. Although their revenues grew at a reasonable clip, profit margins were nonetheless squeezed, in part by rising costs and government-mandated price cuts. Medium-sized local companies face even more pressure for both revenue and profit growth, and many small pharmaceutical companies are being driven out of the market by recent regulatory corrections, stringent product registration requirements, and repeated government price cuts.

These challenges and falling profit margins in the domestic market are forcing companies to re-evaluate their growth opportunities and strategies. The more successful local drug companies are looking toward potential public listings and the overseas market for APIs and generic drugs for growth. But most Chinese companies are still only just preparing to expand drug exports by upgrading their formulation manufacturing facilities to meet international standards. In addition, new environmental regulations for the pharmaceutical industry, rising raw material and energy costs, and an appreciating Chinese currency could raise export prices and erode the low-cost advantage of China's API sector.

Outlook: Continuing high growth

The Southern Medical Economic Research Institute forecast that in 2008, the total output of the Chinese pharmaceutical industry will grow 18 percent to reach roughly ¥710 billion (about $100 billion). In another projection, IMS Health Inc. predicted that the combined pharmaceutical markets of Brazil, China, India, Mexico, Russia, South Korea, and Turkey will grow 13 percent this year to nearly $90 billion. Prescription drug sales in Brazil, China, Mexico, Turkey, and other emerging economies will account for 25 percent of the global market in 2008, according to IMS. IMS also suggested that oncology is becoming the single most important therapy area driving China's pharmaceutical market growth. Another area of high growth in China is diabetes drugs, with sales of this therapeutic class expected to reach $700 million by 2010, according to IMS. (IMS's data on China reflect only the urban hospital market.)

The three biggest drivers for increasing future drug consumption in China are sharp hikes in government spending on healthcare; continued expansion of the rural, suburban, and urban community healthcare markets; favorable government policies for R&D; and recent policies and regulations that offer incentives for well-positioned large and innovative companies to expand.

Despite anticipated growth, the Chinese pharmaceutical industry in 2008 will continue to be heavily influenced by new government policies in areas such as healthcare reform, drug pricing, drug registration, basic medical insurance, and healthcare administration. As China's pharmaceutical industry grows in importance and fortifies its bond with the world, it will no longer develop in isolation and will have far-reaching impacts on the global pharmaceuticals market. 完

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