A challenge for China

China's pharma industry has recently experienced startling growth despite the threat of foreign competition. But its home-grown companies still have much to learn, says Susan Capie


Photograph supplied by Susan Capie

Workers at a Shijiazhuang Group factory. China is working hard to ensure its factories meet GMP standards.

The statistics relating to growth in China's pharma industry over the past few years are dazzling – 20% in 2002 – with estimated growth of 15% in 2003, according to the State Economic and Trade Commission. Recent regulatory changes and China's entry to WTO promise even greater opportunities for the country's pharma industry.

China's entry to the WTO was greeted with much fanfare, but for the country's pharmaceutical factories there was trepidation. It was believed that reduced import tariffs and tighter intellectual property regulations would lead to more competition from imported and innovative drugs. Seminars were held throughout China to discuss survival tactics for competing against multinationals with big R&D capabilities, new products in the pipeline, formidable promotional machines and long established business histories. Nevertheless, many firms are positive about the changes and have developed strategies for meeting these challenges.

Meeting the challenges

One strategy is to increase their investment in R&D. Large companies typically invested about 1% of their total sales revenue in R&D, but by 2002 companies such as Shandong Lukang and Xinhua had announced increased R&D spending of up to 5% of sales revenue. Companies will continue collaborating with Chinese universities on contracting out R&D until their own facilities can meet the demand.

Consolidation, alliance and acquisition are buzz words for growth and rationalisation. The government continues to encourage regional mergers. Recent examples include the formation of the Shijiazhuang Group in 1999, a combination of Weisheng Pharma, a Hong Kong-listed joint venture and Hebei Pharma Factory, a leading antibiotic factory. The Shanghai New Asiatic Pioneer Group, which was formed in 2002, combines three major API factories: New Asiatic, Shanghai Pioneer and Shanghai No 3. And the recent retirement of Lu Weichuan, former CEO of NCPC Group, will pave the way for the reopening of discussions about a merger between the SJZ Group and NCPC. This would be a formidable combination. NCPC reported sales of US$720 million (RMB6 billion) in 2002, up 7.1% from 2001, while SJZ reported sales of US$500 million (RMB4.16 billion) in the same year.

Meanwhile, big, profitable factories are buying smaller ones in financial difficulties, as well as upgrading their own facilities and building anew. He Duanshi, CEO of Shandong Xinhua, lists acquisitions as part of his five-year strategic plan. In addition, NCPC acquired the Taiyuan Pharma Factory, and United Laboratories bought shares in the Sichuan Antibiotic Company.

Not only do domestic manufacturers need to improve their facilities and processes, they must also obtain registrations abroad. Foreign consultants are active in China, along with a growing number of Chinese companies that prepare dossiers for drug master files and Certificates of Suitability. As little as four years ago, Chinese factories did not have regulatory departments. But under new SDA guidelines, companies must have units devoted to studying, training for and implementing GMP rules. These departments have been expanded to handle foreign registrations.

This strategy appears to be paying off. Harbin Pharmaceutical Factory has registered several finished-dosage forms (FDF) in South Africa and is working on a number of COS filings. Shandong Xinhua has FDA approval for hydrocortisone and is filing COS in Europe.

Many companies want to work with the West, not to secure the capital China sought in its joint venture drives of the late 1980s and 1990s, but for exposure to modern management and quality control practices. Ping Zhicun, President of NCPC Beta Company, notes: "It is not the technology we lack anymore, but the management techniques which have already been implemented and followed by the Western pharma factories for years. For us to get up to speed will take years – a co-operation will enable us to lessen the gap quickly".

According to a government official, companies and governments are recruiting foreign experts to work in China to "revitalise the traditional industrial base". The new Chief Operating Officer and president of Hubei Biocause, David Zhou, returned to China after six years working at Merck in the US and brings Western education and experience in quality assurance to the job. He has already invested significant resources in facility upgrade, quality assurance systems and employee GMP training at Biocause. Many companies have established, or plan to establish, rep offices overseas to be closer to the markets they serve.

Companies also want to broaden their manufacturing capabilities in various ways. Expanding their product portfolio is important to all the leading producers, many of whom are investing in the emerging biotech industry. NCPC boasts a state-of-the-art biotech facility imported from Pharmadule (NCPC Genetech) and is seeking to increase exports to new markets. Liu Cunzhou, CEO of Harbin Pharma Group, a leading antibiotics producer, is investing in biotech, as well as R&D into cardiovascular diseases.

China's top 40 pharma manufacturers, January–September 2002

Rank	Company	Total sales: Sales value (RMB million)	Total sales: Change %	Total profits: Profits (RMB million)	Total profits: Change %
1	Harbin Pharma Group	5,018	16.71	348	9.77
2	North China Pharma Group	4,742	17.09	282	37.72
3	Xinhua-Lukang Pharma Group	3,448	12.22	190	19.24
4	Beijing Double-Crane Pharma	3,081	17.27	145	24.18
5	Shenzhen Nanfang Pharma Factory	3,038	-6.64	243	33.21
6	Shijiazhuang Pharma Group	2,985	4.26	268	63.26
7	**Xian Janssen Pharma**	1,934	14.04	511	25.91
8	Tianjin Pharma	1,464	26.09	191	132.61
9	Zhuhai Livzon Pharma Group	1,135	14.73	107	75.76
10	Xian Lijun Group	859	9.35	102	48.06
11	Guangzhou Baiyunshan Enterprises Group	745	18.51	70	24.35
12	Zhejiang Xinchang Pharma	713	44.68	71	105.31
13	Zhejiang Haizheng Group	668	20.38	36	-36.28
14	**Shanghai Squibb Pharma**	645	-12.59	37	-57.19
15	Zhejiang Jianfeng Pharma	614	13.76	40	-5.45
16	**Tianjin SmithKline & French Labs**	576	2.11	75	37.96
17	Zhejiang Conba Group	576	-10.42	49	-16.87
18	Zhangjiakou Pharma Group	502	14.51	33	62.61
19	Shanghai New Asiatic Pharma	468	14.03	61	60.84
20	**Shanghai Sine Pharma**	459	23.98	23	-16.96
21	Henan Tianfang Pharma	457	26.91	53	-20.22
22	**Jiangsu Sino-Swed Pharma**	401	13.93	66	20.79
23	Shandong Qilu Pharma Factory	382	6.90	80	37.61
24	Kunming Pharma Joint-stock	372	2.25	42	3.50
25	Zhejiang Xianju Pharma Factory	362	25.40	27	-14.03
26	Jiangsu Huayuan Pharma	355	15.27	26	88.83
27	Shenzhen Pharma	351	-2.83	35	-16.22
28	Sichuan Pharma Joint-stock	292	3.43	21	-2.29
29	Hangzhou Minsheng Pharma Group	269	11.07	31	70.47
30	**Hangzhou Sino-American Huadong Pharma**	261	0.29	32	84.07
31	Guangzhou Tianxin Pharma Joint-stock	220	15.64	19	72.26
32	Changzhou Pharma Joint-stock	210	37.92	28	95.50
33	Chongqing Yaoyou Pharma	199	14.98	21	92.19
34	Ningxia Qiyuan Pharma	190	39.23	34	315.33
35	Southwest Pharma Joint-stock	160	20.13	24	143.74
36	**Tianjin China Otsuka Pharma**	149	6.84	42	25.93
37	Tianjin Lisheng Pharma Group	139	2.55	29	0.69
38	Shanxi Yabao Pharma	139	43.49	22	11.79
39	Anhui Xinli Pharma	122	-8.01	29	68.75
40	Qinghai Pharma Group	121	11.77	26	5.60

Notes

1. The ranking is based on China Pharmaceutical Industry Association audits of 137 key chemical pharmaceuticals manufacturers. Companies in bold are foreign-invested enterprises (FIEs). The % change from the same period in 2001 is shown alongside the sales figures for 2002.

2. About 20 brandname FIEs, each with 2001 sales in excess of RMB 100 million, are not listed here, simply because they have not been included in the audits. Among them are Shanghai Roche, Hangzhou MSD, Dalian Pfizer, Whyeth-Whitehall, Beijing Bayer, Hangzhou Sanofi-Synthelabo, Shanghai Schering-Plough, Eli Lilly (Suzhou), Shanghai Johnson & Johnson Pharma, Basf (Shenyang), Beijing Fresenius Kabi, Eisai (Suzhou), Beaufour Ipsen (Tianjin), Guangzhou Baxter, Schering (Guangzhou), Shanghai Nycomed and Tianjin Takeda.

Source

The China Pharmaceutical Report

Photograph supplied by Irene Sharper, AlteCopia

China's pharmaceutical industry has undergone continuous improvement over the past 20 years.

Construction of new GMP-compliant, finished-dosage form facilities are also in the strategic plans of most Chinese pharmaceutical plants. Almost all API plants have FDF facilities, but none are yet capable of gaining FDA and EP approval. Several Chinese manufacturers participated in bids for a newly-constructed FDF plant in Suzhou that had been built by a multinational and then put up for sale. Pioneer's CEO Wu Jianwen explains: "We recognise the importance, business-wise, of potential collaboration on finished-dosage forms for exports, but we know it will take some time for us to become familiar with the regulations, even from the standpoint of design and engineering. An acquisition would enable us to acquire a state-of-the-art facility from the beginning."

There has been heavy investment and promotion of FDF within China as well. As the traditional state-owned three-tier distribution system fell apart in the early 1990s, many companies saw the potential in developing their own sales and distribution companies. In the past three years, SJZ chairman Cai Dongchen has invested significantly in "branding, promotion and training of [the company's] own sales force".

NCPC's former CEO, Lu Weichuan, announced in 2002 that a key strategy for NCPC Group, a leading producer of antibiotic injectables, would be to become a low-cost producer of oral FDF, "The long-held concept in China that injectables are faster, more effective, diminishes with a growing well-educated, middle-class".

Custom-manufacturing is another area factories are trying to develop, particularly for intermediates where there are fewer foreign regulatory requirements. Zhejiang Hengdian Group, for example, is constructing an R&D and contract manufacturing plant in Chengdu.

On the personnel side, companies are seeking people with different educational backgrounds. An unofficial policy, but one that is certainly being pursued, is to 'encourage' the early retirement of older managers – women aged 50 or over and men between 60 and 65. Factories are recruiting younger managers who speak English and have MBA degrees. All the factories covered in this article have a tuition reimbursement programme for junior and senior management to obtain MBAs. The new CEO of Shanghai Pioneer, Wu Jianwen, holds an MBA from China's leading business school, CIEBS.

Government policy

The government is also playing its part to help China's pharmaceutical companies. In July 2000, it announced it would be encouraging non-pharma enterprises to invest in pharmaceuticals. One of the most active companies in this respect has been Hong Kong-based Huayuan (World Best). Initially engaged in textiles, World Best has continued to diversify its pharma holdings, establishing its own R&D centre and acquiring whole or partial shares in Anhui Bengbu and Jiangsu Jiangshan. In October 2002, Huayuan paid US$132.9 million for a 40% stake in the Shanghai Pharma Group Corporation – the largest restructuring in China's pharma industry and a milestone in its history. The government also wants foreign investment in state-owned enterprises. In 2002, it announced foreigners could buy shares in listed state-owned corporations and has recently allowed them to invest in unlisted stated-owned ones.

Remaining problems

Even though China's pharmaceutical industry has improved, there are still a number of problems. Although investment is encouraged in state-owned enterprises, the regulations governing this investment are new and untested. There are an array of unprotected areas in the Chinese constitution with respect to the protection of privately-owned assets, while a recent amendment favorable to privately-owned companies was barred.

IP regulations have been tightened, but foreign companies still complain about huge losses from counterfeiting. Nevertheless, Mr He Duanshi, CEO of Shandong Xinhuai, says that better IP protection has encouraged many factories to invest heavily in new product development.

Sales volumes continue to rise, yet profits are still being eroded because of duplication, inefficiency and high production costs. Statistics compiled by the China Pharmaceutical Commercial Association show that between January and August 2002, pharmaceutical sales rose 12.7%, but profits decreased by 25%.

Objective, transparent financial information about non-listed companies is difficult to obtain. Foreign companies that depend on website research about China may be frustrated because many of the better companies do not yet put resources into websites, even though struggling firms have done so.

The major barrier that remains for western companies moving into China is GMP compliance. Compliance problems have resulted in numerous factory shutdowns. During an interview in March, SDA officials reported that 799 factories lost production licences in 2001.The deadline for GMP certification is June 2004 and, of 5000 pharma plants under SDA supervision, so far only 35% have been certified.

According to the SDA, the GMP regulations in force in China are largely based on WHO guidelines. It should be noted that with the exception of the small percentage of Chinese factories that have been inspected by the FDA, those advertising themselves as GMP-compliant are referring to Chinese and not US GMPs. Their understanding of Western GMPs should improve with a greater knowledge of other languages and more contact with foreign companies and consultants.

China is determined to become a major player in pharma. When asked to identify the major Western misconceptions about China, Zhang Jianhui, CEO of Shandong Lukang, says "Foreigners continue to underestimate the capabilities of China, both in terms of technical and quality but moreover speed. They fail to recognise the significance and impact of 20 years of continuous improvement and change in China's pharma industry."

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