profile
Changing China

ALTHOUGH IT HAS 16% OF THE WORLD'S POPULATION, CHINA'S PHARMACEUTICAL MARKET ACCOUNTS FOR ONLY 2% OF WORLD SALES. THIS FIGURE MAY SOON INCREASE AS ACCESSION TO THE WORLD TRADE ORGANISATION (WTO) AND SIGNIFICANT DEVELOPMENTS IN THE GOVERNMENT'S DOMESTIC POLICIES FOR HEALTHCARE INSURANCE AND DRUG REIMBURSEMENT – AMONG OTHER ISSUES – TRANSFORM THE HEALTHCARE SYSTEM AND PHARMACEUTICAL LANDSCAPE. *JAYSHREE RAMSURUN REPORTS.*

Rapid changes are already being seen in China: pharmaceutical industry output was valued at US$28.2 billion in 2000 (2.6% of GDP), a 22% increase over the previous year. Pharmaceutical expenditure now represents around 70% of total healthcare expenditure.

Box 1: China at a Glance

Population	1.27 billion
GDP	RMB9,591 billion (US$1,157 billion)
GDP per capita	RMB7,536 (US$909)
Rate of Inflation	1.9%

Source: The Economist Intelligence Unit forecasts for 2002

Over the period 1978-2000, annual growth in pharmaceutical sales averaged 16.6%, ranking China among the fastest growing markets in the region. This can be split further into Western type drugs, making up 65% of the pharmaceutical industry, and the traditional Chinese medicine (TCM) sector, which accounts for 21.5% of sales. (See *PPR* May 2001, pp128-132) Biomedicine and medical apparatuses account for the remaining 14%. The Western and TCM sectors grew in 2000 by 15% and 21%, respectively, although the rate of TCM drug applications has dropped significantly over recent years. China's pharmaceutical industry developed more steadily in 2001, with sales increasing by 8% and exports by 15%.

Joint Ventures – A New Phenomenon

The growth in pharmaceutical productivity over recent years can, in part, be attributed to the increase in foreign firms' activity in the industry. While this inevitably deals a blow to smaller domestic manufacturers, the government is clear that these joint ventures (JVs) are necessary in order for domestic firms to compete on the international market, enabling them to access better products, improved technology and enhanced management skills.

The first foreign JV pharmaceutical firm in China opened for business in 1980; by the end of 2000, the number was approaching 1,800. About 40% of domestic pharmaceutical firms currently have co-operative projects with foreign manufacturers. A total of 20 out of the 25 largest international manufacturers now have operations in China (see Table 1), with investment in the sector hitting US$1.5 billion in 2000. In addition, 40 of the 50 best selling brands in 2000 were produced by Sino-foreign ventures and pharmaceuticals produced by these companies now account for around 30% of sales. No single brand has more than a 1% share of sales (see Table 2).

Recently, incentives to encourage further foreign-invested firms to enter the Chinese market have been extended. The current tax break policy for foreign and JV firms is 0% capital gains tax for the first two years of operation, rising to 7.5% for the following three years, says Bill Liang, managing director of China Healthcare Consulting. After five years, the capital gains tax increases to 15%, but this is still considerably lower than the 33% payable by domestic firms. According to Mr Liang, the Ministry of Finance has hinted that after five years, capital gains tax for foreign and JV firms will be adjusted to the same rate as that imposed on domestic companies,

Table 2: Top Selling Products (2002)

Product	Market Share (%)	Manufacturer
Rocephin	1	Roche
Losec	1	AstraZeneca
Intralipid	1	Beijing Fresenius
Zienam	1	Merck

Source: IMS Health

Table 1: Foreign Manufacturing Presence in China Through Joint Ventures (2002)

Local Company	Foreign Owning Company	Domestic Owning Company/Partner
Bayer	95% Bayer	5% BETIDC
Beijing Fresenius	75% Fresenius-Kabi (Fresenius, Germany)	25% Beijing Fresenius Pharmaceutical Co Ltd
Boehringer Ingelheim Shanghai	90% Boehringer Ingelheim	10% Sine
China Otsuka	50% Otsuka, Japan	50% China National Pharmaceutical Corporation
Gruenenthal-San Huan	75% Gruenenthal, Germany	25% San Huan
Roche	70% Roche, Switzerland	30% Shanghai Sunve Co Ltd
Sino-American Shanghai Squib	50% Bristol-Myers Squibb	50% Shanghai Trust Corp State Pharmaceutical Administration of China
SSPC	51% Pharmacia Corporation, USA	49% China National Pharmaceutical Industry Corporation
Xi'an-Janssen	52% Janssen, Belgium (Johnson & Johnson, USA)	48% Shanxi Provincial Corp of Pharmaceutical Industries

Source: IMS Health/Pharmaceutical Company Director

as laid out in the terms of WTO accession. But as tax at this rate would act as an investment disincentive, the speculation is that a compromise will be reached settling at around 24%. Further details are not yet available.

What is known is that from 2003, foreign firms will be permitted to operate both retail and wholesale businesses. Currently, products are delivered through domestically owned, licensed drug distribution companies. Over a three-year transition phase (starting in 1999), Sino-foreign JV trials have been under way in key cities including Beijing and Guangzhou. 'As a result, OTC drug sales have increased and OTC stores have boomed. In addition, leading pharmaceutical manufacturers have increased their investment in marketing and advertising for their non-prescription drugs, putting pressure on cash-strapped small players producing the same products,' explains Bill Liang.

Entry criteria for foreign firms wishing to access the wholesale market are stringent: they must achieve an average sales volume of over US$2 billion for three consecutive years before applying to set up the joint venture, and total assets must exceed US$200 million during the year prior to their application. Conditions for Chinese firms vary by region, but annual sales should exceed RMB50 million (US$6.0 million) and total assets RMB300 million (US$36.1 million). If the partnership involves a Chinese wholesaler, the domestic equity for the joint venture must exceed 51%. The prospect of success is a huge incentive. 'In general, Chinese firms are eager to enter joint ventures with foreign counterparts on the premise that such business structures will be a win-win situation for both parties,' adds Bill Liang.

Since December 2001, pharmaceutical manufacturers also have been obliged to meet GMP standards by 2004. Upgrading their current facilities to GMP standards is a costly business. Bill Liang estimates the average cost at around RMB20-30 million. It is expected that more than half of today's 6,000 pharmaceutical companies will be either eliminated or acquired by 2004.

Imports and Exports

Both pharmaceutical imports and exports were up in 2001. Imports were valued at US$2.6 billion, an increase of 18.7% on the previous year, while the figure for exports was up 14.7% to US$2.1 billion. Although at the beginning of the year the import tariff on drugs was halved to 4.2%, Bill Liang

does not foresee a precipitous rise in demand for imported products. 'Unless imported drugs have better efficacy and quality compared to domestic products, their premium prices will make it difficult to compete with domestic products.'

By the end of 2000, the Chinese government had issued more than 2,000 registration certificates for imported pharmaceuticals. Meanwhile, exports of traditional Chinese medicines have fallen off in recent years, principally because of the sluggish economies in Japan, the Republic of Korea and Taiwan, all of which are major TCM export markets.

Industry Targets and Reforms

While developments continue apace on the manufacturing side, the government has prepared a formal list of objectives for the industry. The latest Five-Year Plan released by the State Economic and Trade Commission contains specific targets up to 2005. Among other things, the plan calls for the industry to produce 10 new drugs for launch on the international market, complete the clinical testing of 50 others and develop 20 types of modern TCM drugs, with 2-3 launching internationally.

Setting such ambitious targets is a risky undertaking for a country still lacking some basic elements of healthcare infrastructure (see Box 2). However, the state is committed to delivering a modern healthcare system and has taken positive steps in this direction, beginning with plans announced in January 2001 by the Economic Restructuring Office of the State Council (SERO) to introduce a new basic national healthcare insurance system, the Urban Employee Basic Medical Insurance System. This should be set up for employees/workers in urban areas within two or three years but is being rolled out in the main urban areas in the first instance.

Under the Urban Employee Basic Medical Insurance System both employees and employers pay contributions. Employers typically contribute about 6% of annual payroll into the system, 50% of which goes into a central 'social fund'. The remainder is allocated to individual employee accounts, topped up by workers who contribute around 2% of their salary into their own account. Patients must contribute both towards the cost of their treatment and for any pharmaceutical expenses not covered by insurance.

Box 2: Overview of Healthcare Provision

- A network of hospitals, health centres and outpatient clinics provide healthcare services in concentrated urban areas
- In rural areas, doctors are the primary contact. They may refer patients to health centres or hospitals. In urban areas, patients to directly to hospitals.
- Three-quarters of the population lacks access to health insurance coverage (55% of the urban population has some coverage, falling to under 13% in rural areas).

Source: PPR Communications Ltd

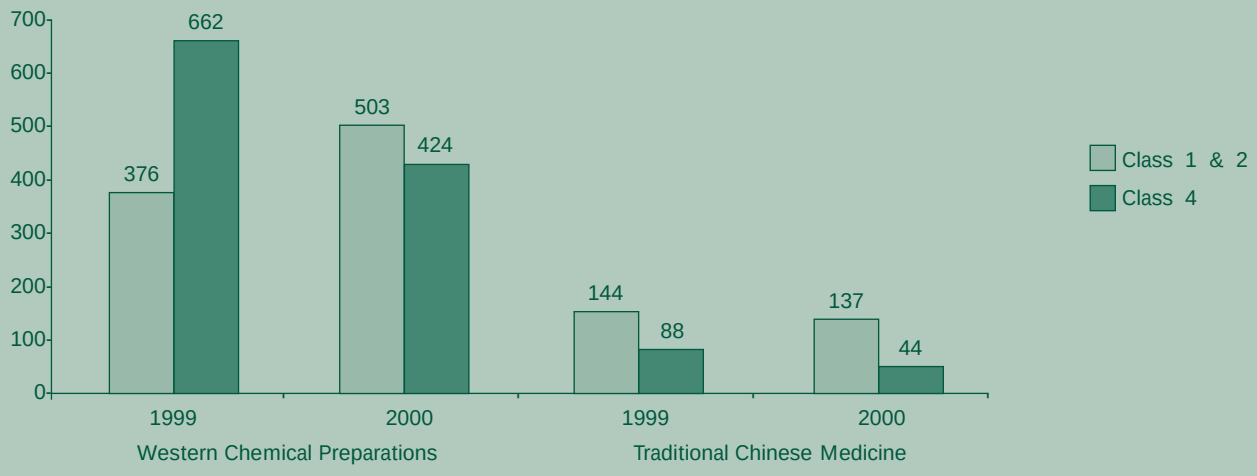
Product Registration Review

As part of the task of bringing China into line with WTO requirements, the State Drug Administration (SDA) has made a determined effort to establish and adhere to a model for the review of drug product registration applications by standardising the review procedures through new drug registration laws. The inception of the Implementing Methods for China's Pharmaceutical Association Law, acting as an umbrella law, and the regulations and methods within it are primarily designed to:

- reinforce executive legislation thereby creating a more efficient and seamless regulatory procedure
- enforce stricter administrative procedures to prevent the production and distribution of counterfeit drugs
- establish a classification system for prescription and OTC drugs
- oblige manufacturers to follow GMP guidelines
- prohibit the advertisement of prescription drugs.

As a result, the number of drug product applications has been steadily falling. In 2000, the SDA's Drug Registration Department reported that it examined 5,219 registration documents (see Figure 1). Of these, 1,175 were approved to start clinical studies, and 973 were approved to start production. Of 4,373 new TCM applications, 50.2% were rejected after the initial examination.

Figure 1: Drug Product Registration Applications (2000)



Class 1: Pharmaceutical products which have not been previously approved for sale in China or overseas.
Class 2: Pharmaceutical products which have been approved for sale overseas, but have not been included in China's Pharmacopeia and are not yet imported into China.
Class 4: Pharmaceutical products which have been included in a pharmacopeia outside China or biopharmaceutical products which have been approved for import into China, or with new prescription or new method of application.

Source: PRN Publishing Services, Inc, 2002

The Implementing Methods for China's Pharmaceutical Association Law is to be followed up with nine new regulations and methods scheduled for successive implementation in 2002 and 2003. The first of these, Methods for Regulating Drug Product Registration, is due to take effect in December 2002 and will specify registration procedures and requirements for all new drugs, expected to be defined as any drug product which has not been marketed in China before (including imported drug products).

Cost-containment

The government has also attempted to reduce soaring pharmaceutical expenditure through the financial separation of hospitals and hospital pharmacies. Drug sales through hospital pharmacies account for 80% of total drug consumption in China. The goal is to diminish these sales, but this will be difficult because they account for more than 60% of the hospitals' revenue. 'Hospital reform is the most complex and difficult,' says Bill Liang (see Table 3). 'By separating hospitals from the retail sector, the government has taken a huge step towards reforming hospitals from government-supported ventures to financially independent entities focusing on providing quality services to their patients.' However, the desired effect of reducing the level of over-prescribing may well be countered by increased charges to patients for other services, as hospitals attempt to compensate for lost revenue. Complete separation will take another three to four years, but the pressure is certainly on the hospitals, he concludes.

In a further bid to save costs in the hospital sector, tender bidding is being used increasingly for the procurement of commonly used drugs. National regulations exist to ensure a unified approach to tendering but its overall success is likely to hinge on the effective separation of hospitals from pharmacies.

Reimbursement

Hospital pharmaceutical revenues are also affected by the creation of positive reimbursement lists, at both national and

local levels. Reimbursement is limited to drugs included in the National Drug Reimbursement Bulletin, which comprises approximately 90% of the products included on the National Essential Drug List (NEDL). The latest list includes many new products and a far greater proportion of imports and drug products from foreign-invested enterprises. The list is divided into two groups:

- Class A: Essential drugs, commonly used, therapeutically efficacious, low in price. They are reimbursable nationwide, and may not be changed or substituted by regional governments.
- Class B: Selective drugs, therapeutically efficacious but more expensive. Regional governments may modify or substitute no more than 15% of class B drugs. These are likely to be imported or JV developed products that are used less commonly.

All Class A drugs are fully reimbursed by the Urban Employee Basic Medical Insurance System nationwide. B-list products are only partially reimbursed, as they tend to be more expensive.

Price Controls

The State Development and Planning Committee (SDPC) regulates the retail prices of NEDL-listed products only. It uses a cost-plus methodology to determine the retail price ceiling, taking either the manufacturer's production cost (or cost of importation) and then adding a profit margin of between 8% and 40% depending on the nature of the product. Few imported or joint venture products appear on the fully reimbursable list. These manufacturers are therefore free to price their products at a level at which they think the market will sustain.

Table 3: Top Five Corporations in Hospital Market (March 2000-March 2001)

Corporation	Sales (US$m)	Market share (%)
GlaxoSmithKline	114.0	3
Roche	76.3	2
AstraZeneca	73.9	2
Johnson & Johnson	72.7	2
Novartis	65.6	2
Others (1,875)	3,711.1	90
Total	4,113.6	

Source: IMS Health MIDAS (figures rounded)

The debate on how the price ceiling should be set is highly contentious. In its pricing law of 2000, the SDPC specified that there should be no more than a 30% difference between the originator and the generic product (35% for injectables). In the first case of its kind, Guangzhou Beishi Pharmaceuticals Co Ltd (GBP) filed a lawsuit against the SDPC in January 2002. GBP alleges that the SDPC's pricing practices are 'unfair' and in breach of China's Pricing Law. Under dispute is the price discrepancy between three identical products: GBP's domestically manufactured generic, ofloxacin, and two other ofloxacin products, a generic from Shanghai Sine and Tarivid produced by Daiichi. The price of GBP's product was set at 2.64 times lower than Daiichi's identical product, even though, according to the SDPC's Guidelines on Price Control Reforms for Drug Products, there should be transparency in determining drug product pricing and that similar products should be treated in the same way. No date has yet been set for a court hearing.

Future Challenges

The next challenge facing the pharmaceutical industry will be how to maintain its strong growth momentum over the next decade. The GBP case will be watched particularly closely, as China's pricing policies come under the spotlight. 'Pharmaceutical companies are under pressure to upgrade their facilities to meet GMP, develop better quality drugs in order to compete not only globally but domestically too, and adjust their business strategy in what has become a rapidly changing market,' concludes Bill Liang PPR

Bill Liang is managing director of China Healthcare Consulting in California. For more information contact bliang@chccgroup.com