Dancing with the Dragon

A recent news article proclaimed "China to become third-largest medical technology market by 2010", while in the same vein PricewaterhouseCoopers has predicted that the country could overtake the US as the top drug market by 2050. These forecasts are not unfounded, but a closer look at the reality might suggest otherwise, argues James Shen.

China's sheer size, its ageing population and rapid economic growth have charmed many experts into offering fascinating predictions about its healthcare and pharmaceutical market. In fact, a number of challenges are threatening to derail it from the fast-track growth predicted by many observers.

To grasp the scope of these challenges, it is important to realise the changes in China's drug sector that have occurred over the past 25 years. Understanding these may help foreign companies to "dance with the dragon".

Before the modern republic was founded in 1949, China's population relied primarily on traditional Chinese medicine (TCM), comprising mainly herbal preparations dating back thousands of years. But this long period of clinical experience was not systematically recorded and there was little standardisation of herb growth and preparation.

Efforts to build a modern pharmaceutical industry focusing on western medicines began after 1949, thanks largely to a trade embargo by western nations and then the Korean War. The Chinese pharma industry developed synthesis capabilities to copy western medicines quickly and efficiently, and also built up formulation capability for primary dosage forms and for TCMs in western dosage forms. By 1979, it was capable of producing almost all essential western drugs.

But it was built up as a welfare industry, and was not supposed to make profits. Research was shared by all companies, with products made in accordance with central government plans, sold at government-subsidised prices and distributed by the state network to hospitals and retail pharmacies. Almost all people in urban areas had free access to healthcare and rural residents were covered by a heavily subsidised co-operative scheme. Health prevention was emphasised in order to save on huge treatment costs, and as a result life expectancy rose sharply from 35.0 years in 1949 to 67.9 years in 1981.

> "Unprecedented growth in the past two decades"

China began to reform its economic system to build a "socialist market economy" in the late 1970s. The industry and healthcare system were not spared the changes, despite fitting well with a socialist ideology. In the early 1980s, Shanghai Squibb Pharma, a joint venture, became the first company to carry out commercial drug marketing activities in the country. Since then, the industry has been transformed and is now driven by market forces – the government has been cutting healthcare funding, forcing providers to become economically independent and financially motivated.

...3,000 companies

By 2005, China had 3,731 pharma manufacturing companies fully compliant with compulsory local GMP standards. These serve nearly 300,000 medical institutions (including 18,396 hospitals) and around 230,000 retail pharmacies. Most companies now have their own hospital detailing forces and handle the marketing of prescription and OTC drugs to the retail sector.

Fully or majority state-owned companies now account for just 27.4% of all pharma manufacturers, compared with almost 100% in the 1970s. The distribution sector was entirely state-owned in the 1980s but has been liberalised to allow private investment since the mid-1990s. A ban on foreign investment in the sector has been lifted in phases since 2001.

International trade in pharmaceutical and healthcare products experienced unprecedented growth in the past two decades, from under $300 million annually in the early 1980s to more than $20 billion in 2005. The state monopoly on foreign pharma trade was relaxed in the 1990s and completely dismantled after China's entry to the World Trade Organization in 2001, and 27 of the world's top 30 multinational pharma firms now have manufacturing and sales operations in China.

Against a background of improvements in intellectual property protection, firms such as Lilly, Pfizer, Novartis and Organon (Akzo Nobel) have begun moving parts of their R&D operations there to cut R&D costs, speed up new launches and improve market access.

...stunning growth

Meanwhile, the market has consistently grown at double-digit rates. Sales, including those of western medicines, biopharmaceuticals and TCMs, rose 50-fold from Yuan5 billion ($620 million) in 1980 to around Yuan220 billion in 2005, according to the State FDA. Various sources suggest that the drug market was worth $20 billion last year. Hospital pharmacies account for around 80% of the total market for prescription drugs and retail pharmacies make up the remainder.

Overall growth should be around 17% this year, on a par with 18% in 2005. The State Council has predicted that China's healthcare spending will rise to 7-8% of GDP by 2010, from 5.7% in 2004, triggering another round of positive forecasts, including one that China's drug consumption would double between 2005 and 2010.

But despite all the bullish sentiment, the local and multinational pharmaceutical industry sectors are facing serious challenges.

There is no doubt that government economic policies and reforms have spurred growth, but some policies seem contradictory and many structural problems have remained untackled for the sake of short-term benefits. Some of these are caused by a lack of research, planning and co-ordination by the central government at the macro-economic level.

The Chinese government wants the industry to become internationally competitive, with strong R&D capabilities, advanced technologies, and high quality standards. But it has also cut back state investment, repeatedly slashed prices and squeezed profit margins through various cost-containment moves. As a result, most local pharmaceutical companies can barely afford to upgrade their facilities to comply with continuously rising regulatory requirements, let alone carry out new drug research.

The government has also cut healthcare spending sharply, forcing healthcare providers to rely on profits from drugs. The share of government spending in the country's total healthcare expenditure fell from 36.2% in 1980 to 17.2% in 2003.

There have been 17 rounds of major price cuts between 1996 and 2005, causing the drug retail price index to fall by 1.5%, 3.5%, 1.7% and 3.6% in 2001, 2002, 2003 and 2004 respectively. The state has also expanded the scope of products subject to price setting, so that today the central government directly controls the prices of more than 2,400 drugs, compared with only 30 important products in the early 1990s.

Furthermore, as pressures from price cuts, rising costs and competition increase, some manufacturers may cut corners on GMP compliance. This is a particular risk in bulk manufacturing, where regulatory control is weak.

A heated discussion on healthcare reform began in May 2005 following a report by the State Council, which concluded that the changes of the previous two decades had been largely unsuccessful. A survey by the China Youth Daily last year found that more than 90% of the public was dissatisfied with the reforms of the past 10 years.

Future reforms have become a subject of wide and heated public and government debate, with most seeming to agree that healthcare should not be market-driven, and that the state should play a leading role.

The direction of change will have a huge impact on the industry and is likely to cause another round of restructuring. In the short run more instability is likely, but there may be future benefits from successful reforms which address the current flaws.

Makeup of Healthcare Expenditure in China, 1980-2003

	1980	1990	1995	2000	2001	2002	2003
Total health spend (Yuanbill)	14.3	74.7	215.5	458.7	502.6	568.5	662.3
Govt health spend (%)	36.2	25.1	18.0	15.5	15.9	15.2	17.2
Social health spend (%)	42.6	39.2	35.6	25.5	24.1	26.5	27.3
Personal health spend (%)	21.2	35.7	46.4	59.0	60.0	58.3	55.5
Health spend as % of GDP	3.17	4.03	3.69	5.13	5.16	5.42	5.65
Per capita health spend (Yuan)	14.5	65.4	177.9	361.9	393.8	442.6	512.5

Source: ministry of health; healthcare expenditure financed by employers, insurance systems, etc.

...small enterprises

The domestic industry, once dominated by large state-owned enterprises, has disintegrated over the past 25 years into a large number of small enterprises with similar product portfolios. There were only 1,377 pharmaceutical manufacturing companies in 1985, but this figure rose to nearly 4,000 in 2005 despite ongoing consolidation and compulsory GMP compliance.

This has led to intense competition and the rise of unethical and illegal sales practices, while cut-throat competition among local generic drug manufacturers has shortened product life spans.

The state has been encouraging consolidation and the formation of larger, more competitive groups. For example, many large state-owned enterprises have become private companies over the past 15 years so that they can tap into capital and expand faster.

However, this "support the big and let go of the small" strategy has not produced the desired results. Many state-owned enterprises simply became bigger rather than stronger, and valuable new capital has largely been under-utilised.

One good example was Worldbest Group (Huayuan), which took over dozens of state-owned drug enterprises, including two of the largest conglomerates, Shanghai Pharmaceutical and Beijing Pharmaceutical. The growth did not improve profitability or market share and the group came close to running out of cash in 2005. The central government was forced to step in and ordered another state-owned conglomerate to rescue its ailing operations.

...full control

Many multinationals have been pushing for full control of their joint ventures, at the risk of appearing unethical under Chinese culture and causing resentment in the local industry.

Another major issue here is differential pricing of local and multinational drug products. Multinationals successfully lobbied the government for the creation of a new pricing category for off-patent originator drugs, which often receive prices several times those of locally made drugs. But local companies contest that such a policy is groundless and unfair and they are lobbying against it.

IP protection is another area of heated dispute. While foreign firms complain about infringements, discriminatory legal interpretations and weak enforcement, local companies are quick to challenge any weakness in patents or drug administrative protection.

Counterfeiting is also a huge problem – it has been estimated that 10-15% of drugs sold through the retail channel in China are fakes, and the country has become a major exporter of such products, which can be of high quality.

Multinationals complain that the legal system is too weak on counterfeits and makes it hard to bring criminal cases, and the issue stands to have far-reaching economic and trade consequences if it is not addressed.

So while growth prospects may indeed be attractive, market players should beware. A Chinese proverb sums up well the outlook for the industry in China: while the future is bright, the path to it is zigzagged.

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