



Unravelling China's healthcare sector

How will health reforms, the tightening of regulations and the emergence of a domestic drug industry impact global pharmaceutical companies?

While some Western countries are struggling to prevent the economy from shrinking, GDP growth in China has not fallen below 7 per cent since 1991. In healthcare, China is now placed among the top rows in most global pharmaceutical companies' strategy planning chart, for its large ageing population, improving coverage of public health insurance and a budding private insurance industry. In fact, by 2016 total drug sales in China are expected to reach \$100bn with an annual growth rate of 20 per cent, overtaking Japan and so becoming the second largest pharmaceutical market in the world.

Unlike the personal computer or home appliance markets, there is no Lenovo or Haier equivalent among the Chinese domestic players posing an imminent threat to the multinationals in the branded prescription and even off-patent prescription market. But with the advancing drug regulatory standards and intensifying healthcare reform, will the domination by global pharmaceutical companies continue over the next 20 years? To answer this question, one must understand the rationale behind the much hyped health reform and how China's pharmaceutical landscape will transform.

Healthcare reform

The one-child policy implemented since the 1970s has effectively prevented explosive growth of the Chinese population, but the policymaker then probably did not foresee the challenges faced by a sizeable fast-ageing population half a century later. To provide 1.3 billion ageing people with adequate health protection is no easy task. China's healthcare reform, initiated about a decade ago, has so far made substantial progress. The national coverage of co-payment-based public health insurance increased from 34.3 per cent in 2004 to 95 per cent in 2012. But surprisingly, today many Chinese find medical treatment less affordable and sometimes less accessible. The reasons behind the irony are multifactorial, but over-prescription and imbalance of healthcare infrastructure are the predominant causes.

Over-prescription has been a common phenomenon, often dubbed as *dà chù fang* (literally, big prescription) in China. The share of spending on drugs out of China's

total healthcare expenditure is at a striking 50 per cent, compared to 13 per cent in the US in 2009. Such a tradition of over-spending on drugs has taken its root from the profit-driven model adopted by public hospitals (where most Chinese people seek medical treatment), and the ultra-low consultation fees charged to the patients (therefore severely underpaid medical practitioners tend to prescribe more to earn kickback).

Besides over-prescription, the accessibility to healthcare services has been compromised by the uneven allocation of resources across hospitals. Large tier-3 hospitals, often equipped with the best talents and facilities, stand in a stark contrast to community hospitals, which appear second-class in every aspect. Consequently, patients with any form of illness, tumour or fever, compete for treatment in large tier-3 hospitals, severely impacting the operational efficiency and quality of service.

New leadership

With the new era of politics unveiled by election of the country's fifth generation of leadership earlier this year, the Chinese government strives to address the healthcare issues by 2020, thus driving further evolution of China's pharmaceutical landscape. The expected changes and associated impact on global pharmaceutical companies are summarised in Table 1.

More stringent pricing controls on drugs are expected as the healthcare reform moves to the next phase. While the government is trying to eradicate the drug margin imposed by public hospitals, scarce government funding has made public hospitals rely heavily on generating profits from drug sales. According to a director of a tier-3A hospital in Eastern China, the annual government funding merely covers the operational cost of his hospital for one month. Therefore, a substantial increase in government support is needed in order to truly separate the drug prescription and sales in hospitals - which will not happen overnight. But it is inevitable that, in order to divert more resources to the hospital operation, the government will implement more pricing restrictions on drugs and devices. Locally manufactured generics and biosimilars will be favoured against the innovator drugs carrying a premium price tag. Not surprisingly, big pharmaceutical companies such as Pfizer and AstraZeneca have already set foot in the branded generics market by entering agreements with Chinese domestic companies. Second-brand strategy, for example, creation a low-end local brand, also appears in companies like Johnson & Johnson to cater for the needs of second or third tier cities.

Domestic industry

In the last few years, not only the coverage of health insurance received its boost in China, the pharmaceutical regulatory framework, from API manufacturing to clinical trial regulation, has been improved enormously. The new GMP guidelines published in 2011 greatly facilitated the domestic pharmaceutical companies to expand to overseas markets. Vaccines made by China National Biotec and biosimilars by Shanghai CP Guojian are already found in less regulated markets such as India, Southeast Asia and South America. Not surprisingly, the made-in-China labels, which are commonly printed on toys and electronics in the supermarkets, will be seen in pharmacies of Western countries.

China's domestic pharmaceutical companies traditionally lack innovation and compete in the 'risk-free' field of generics and biosimilars. However, leading companies are no longer satisfied with the increasing competition and diminishing profit margin. Shanghai Fosun Pharma and Jiangsu Hengrui have both established R&D hubs in the US and partner with top research institutions for innovator drug research.

Impact on the global industry

The financial statement of global pharmaceutical companies has already responded to the changes in the healthcare space. Novo Nordisk, one of the best performing pharmaceutical companies in the Chinese market, experienced a 3 per cent quarter-on-quarter drop in sales in 2011, despite a full year growth of 15 per cent. Such a loss would be unimaginable a few years

back. Nonetheless, the Chinese per capita spending on medicines, being one of the world's lowest at \$35.1 in 2009, will be growing steadily with its booming economy, increasing middle-class population, and improving healthcare infrastructure in both urban and rural areas. The pharmaceutical landscape in China will keep evolving in every aspect, from the infrastructure to local competition and regulation. Global pharmaceutical companies will have to understand the local market dynamics better and include China in global planning earlier in order to keep growing, which may help serve as the key to fight the patent cliff.

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 **Table 1. Anticipated changes and associated impacts on global pharmaceutical companies in China**

Category	Current situation	The future	Impact	Timeline	What's happening
Infrastructure	Profit-driven public hospitals mark-up the drug price, leading to over-prescription	Drug sales, especially for outpatients, will eventually run independently from the hospital and prescribers	••	10-20 years	More and more patients now turn to standalone pharmacies rather than hospital pharmacies to buy prescription drugs
	Ultra-low consultation fees: it typically costs USD 1.5-3 for one consultation session with a specialist	Increase of consultation fees, and increase of income for medical practitioners	••	5-15 years	In the last decade, many tier-3 hospitals have started to provide maximum service to the wealthier population by setting up "special service clinics", where the consultation fees can go as high as USD50.
	Irrespective of condition (e.g. fever or tumour), patients only attend tier-3 hospitals for treatment, creating over-crowding and possibly a unique profession in China: the hospital ticket tout	More community hospitals and neighbourhood clinics will be built; the concept of a general practitioner (GP) will be introduced	•	10-20 years	Some global companies have strategically diverted resources away from large hospitals. Johnson & Johnson established a 100% subsidiary, Mai Si Qiang, focusing on the low-end medical device market at second and third tier territories in China
	The healthcare service in China is largely monopolised by state-owned public hospitals	More foreign and private hospitals will be established, catering to segmented healthcare needs	•	5-10 years	In the "Catalogue for the guideline of foreign investment industries" (2011 edition) jointly published by China NDRC and MoC, foreign investments in hospitals have been "allowed" since Jan 2012.
	Multi-layered drug distribution contributes to the high drug price	Vertical integration of drug distribution networks will reduce the cost of selling	•	5-10 years	Global players have started along the integration pathway, such as acquisition of Zuellig Pharma by Cardinal Health, and Alliance Boot's joint venture with Guangzhou Pharma
Competition	Most Chinese pharmaceutical companies compete in the domestic generics market	Increasing investment on innovator drug research and overseas expansion of domestic pharmaceutical companies	•	5-10 years	Generics are no longer a comfort zone for domestic players. Jiangsu Hengrui Pharma and Hutchison Medi Pharma are running clinical trials in overseas regulated markets including the US
Payer	Underdeveloped commercial health insurance, which is restricted only to the rich	Commercial insurance will complement the public insurance for a wider public	•••	10-20 years	Integration of commercial health insurance with public insurance has started trials in certain regions in China
Regulatory	Extra-long IND review time, typically between 9 to 15 months, has hindered China being included in global clinical trials and caused delayed approvals	The IND review will be shortened, and early stage trials will be allowed.	•••	5-10 years	Being one of the first among global pharmaceutical companies, Novartis received SFDA approval to commence a global multi-centre early phase trials in China for its novel cMET inhibitor in May 2013