

China: Access All Areas?

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China is an intriguing but uncharted territory for many western pharma companies. Across the four most economically advanced provinces where healthcare is most advanced (equating to more than 290 million citizens), the 2009 Chinese medical reform has started to allow the reimbursed use of high-priced drugs that meet important medical needs. Oncology is a case in point.

Pope Woodhead recently discussed the opportunity to access this growing sector with those close to policy reform and the provision of hospital oncology care in China. This market – traditionally dominated by cytotoxics and to a degree traditional Chinese medicine – is now moving towards targeted therapies and orally administered products (as in the West). Together with our local experts, we highlight three key steps on the path to accessing China.

Factor China into the clinical strategy

Clinical data in the local population is mandatory in order to obtain an import license (requirements are relaxed somewhat for products that already have FDA or EMA approval). Early planning is needed, given the significant time (9–12 months) required to get clinical trial approval from the SFDA.

Understand the national context and regional nature of the Chinese market

Drug funding is provided via three main sources: national insurance (eg government employees, national institutions, schools, universities, military), city social insurance, and employee/company insurance contributions.

The MoHRSS publishes the Catalogue of Drugs for Basic National Medical Insurance that lists all reimbursed products. These are either Type A (fully reimbursed, essential generics) or Type B (patients pay 10–20% depending on provincial government policy and insurance coverage) – see figure 1.

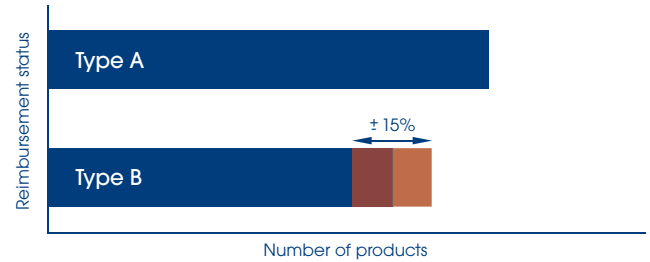
Importantly, provinces are given the power to customise, expand or reduce the central Type B drug list by up to 15% of products to reflect the local budget and healthcare priorities. For example, Zhejiang province and the Beijing and Tianjing area have a higher than average rate of lung cancer, and reports indicate that they may supplement the Type B list with newer therapeutics to meet this priority.

Outside the privately insured market, reimbursement is a key determinant of access for costly branded products in chronic indications, given the low ability of patients to pay out-of-pocket. The opportunity for reimbursement is greatest in the four most economically advanced provinces who have the ability and willingness to add or exchange newer products into their Type B list.

Engage locally – regionalise the market access strategy

The lack of a national level mechanism or infrastructure for evaluating product cost-effectiveness or benefit is an area of hot debate among policy makers (ie whether to introduce a form of NICE adapted to work in the Chinese market). The industry should look to engage with this debate, since it is currently challenging to demonstrate the value of higher priced products to justify reimbursement.

Figure 1: Provinces are able to expand or reduce the Type B drug list by up to 15% of products



In the absence of a transparent policy, the recent healthcare reform noted that for severe/chronic disease requiring long-term treatment, the government may be willing to explore a 'drug negotiation mechanism' around some form of cooperation or risk sharing with manufacturers.

Leading companies are already learning how to build such initiatives. For example, AstraZeneca organised a summit in 2009 with 400 clinical and academic lung cancer experts in the Guangdong province to discuss targeted cancer therapy and its place in therapy. Iressa® (gefitinib) is now expected to enter the Guangdong province Type B reimbursement list in 2012 (for patients who have low response to chemotherapy or EGRF mutation).

With a few notable exceptions, a navigable route to national reimbursement remains some way off for most high cost drugs. However, Pope Woodhead believes there is a clear opportunity for pharma to work with provincial decision makers to design hospital- or city-based pilot programmes that demonstrate product value to obtain local Type B reimbursement listing. Targeting oncology and other indications of high unmet need appears to be an excellent starting point.

'Access all areas' is still a little ambitious. However, unlocking regional opportunities for reimbursement in China is viable, given the ability to engage and understand the needs of provincial decision makers and influencers.

SFDA, State Food and Drug Administration
MoHRSS, Ministry of Human Resources and Social Security



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