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Challenge No 3: Policy issues

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Govt policies an issue for life sciences businesses in APAC



Government policies are among the major challenges before companies operating in the life sciences sector in the Asia Pacific region. For larger multinationals, policies favouring local companies prove to be hurdles. While for smaller companies, stringent and fat-changing guidelines are a problem. (Read about all 10 challenges for businesses in APAC)

One of the issues is that local governments often have policies favoring local companies with only some relief for MNCs that bring in huge investments. They also enforce strict new Good Manufacturing Practices (GMP) guidelines that are too costly for many small domestic players to implement. Then there are issues like high customs duties and taxes on imported goods. Another issue, although not unique to Asia, is the purchase of products through tenders by the governments that limits competition.

Dr Joseph Santangelo, CEO, Inviragen, Singapore, gives an example to elaborate on such issues. "A company can perform clinical trials for unlicensed biologics in China only if they are a registered Chinese company and the materials are manufactured in China. In my opinion, this is not in agreement with the World Trade Organization commitments," he says, adding that some Asian countries, for example Japan, also do not recognize clinical data on (some) studies conducted outside their country.

"Businesses in India are done generally through government tenders and hence include lengthy processes and formalities. Funding is based on Central Government budget and fund distribution is not even. Purchase process is long and funding not available for reagents. These should be simplified,"says Dr Bhuwnesh Agrawal, Roche Diagnostics India.

Mr Ling Sun explains some of the trends in the Asia Pacific. "Anhui Model, a pilot healthcare reform program, introduced during the 2009-11 healthcare reforms, is the "double-envelope" tendering mechanism, requiring that government officials first select drugs with good "quality", and then a different independent panel chooses the tenderer with the lowest bidding price," he says. "This encourages manufacturers to provide extremely low bidding prices to win contracts, sometimes lower than the cost itself. As a result, quality and safety issues arise, or manufacturers later choose to stop producing the product at a loss and drug shortages ensue."

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Beijing adopted a model similar to Anhui in 2006, but abandoned it soon after since it met considerable resistance from regional medical facilities. After a three years pilot program, stakeholders in the healthcare system are questioning whether such the model should be adopted in other administrative regions.

Besides government tendering, Dr Bhuwnesh Agrawal of Roche Diagnostics says custom duties on healthcare products increase the cost for patients "who have to deal with emotional issues, health problems and also huge costs, pushing many below the poverty line". He suggests a waiver on duties to help reduce financial burden on patients and make healthcare more affordable.

Dr Mallik Sundaram, CEO, Mitra Biotech, India, has a similar view on costs. "High taxation for imported goods in India means most equipment that we use in our labs cost us almost twice as it does in the US."

Continuing to share trends in China on new GMP guidelines, Mr Ling Sun says, "In February 2011, the State Food and Drug Administration (SFDA) in China issued Order 79 on GMP for pharmaceutical products. These guidelines are the strictest in China's history, and will lead to major changes in the Chinese pharmaceutical industry."

According to him, "all new pharmaceutical manufacturing facilities must obey the more stringent standards, effective immediately, while existing manufacturing plants that produce sterile drugs, including blood products and vaccines, must implement the new standards and practices before the end of 2013". The new GMP guidelines will put great pressure on small- and medium-sized (SME) domestic drug manufacturers, which account for nearly 90 percent of the 5,000 pharmaceutical companies in China, he points out. "Furthermore, the SFDA made public statements warning that at least 500 SMEs will be shut down if they do not comply with the guidelines. As a result, it is expected that pharmaceutical companies will need to invest $ 31.6-47.4 billion (CNY200-300 billion) to fully meet the new requirements."

Given the situation, Datamonitor expects significant industry consolidation, providing a good opportunity for MNCs to make acquisitions and expand their business in China, says Mr Ling Sun of Datamonitor Healthcare, China.

Intellectual Property Protection is another major issue in the emerging markets, such as India, China and Thailand. Mr Ling Sun says though the situation is improving, it is still troublesome for the MNCs. "Traditionally, MNCs have only launched off-patent drugs in China rather than going ahead with their branded products due to concerns over intellectual property protection. However, MNCs have begun to launch innovative drugs in China along with their launch in major global markets to try and gain first-to-market advantage," he says, adding that it makes robustness of intellectual property protection in China a key issue.

Although the situation regarding intellectual property rights has improved since China joined the World Trade Organization in 2001, the State Intellectual Property Office still does not provide patent extensions, and the updated 2008 patent law provides an infringement exemption for generic drug makers (meaning local generics manufacturers could begin manufacturing, though not selling generics before patent expiry of a product). "There are also indications that the data exclusivity provisions are not implemented in practice, although they are required by law (King & Wood, 2012). Compulsory licensing, counterfeiting and drug piracy also remain significant concerns for branded pharmaceutical companies in China," says Mr Ling Sun.

Most of the Asian high-tech start-ups with cutting edge technology need to build IP portfolios and the ownership of this portfolio plays a crucial role in increasing market value of the company. "Companies such as HistoIndex, which enter into research collaborations need to make great effort to own any foreground IP in a manner that is fair and equitable. That, at times, is a challenge by itself," adds Dr Noel Moore, chief executive officer, HistoIndex, a Singapore-based company.

Commenting on the recent decision of the Controller General of Patents of India and the Indian government to bust the monopoly of Bayer's anti-cancer drug Nexavar through compulsory licensing of Bayer's patent, Mr Rahul Dev of Tech Corp Legal LLP, says, "It has opened the field for the generic industry to follow suit and could well pave the way for availability of cheaper drugs for lifestyle diseases. In the near future, more generic companies could invoke the compulsory licensing clause of the Indian Patents Act. The landmark judgment by the Indian Patent Office is now being seen as a test case and it is almost certain that Bayer will go to court on this issue."

He says this will force MNCs that are keen on investing in the emerging markets to think twice about where to invest in the region.

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