



# Inside China: staying whiter than white

In his first article for *Clinica's* new column on the hottest issues concerning the Chinese medical device space, Michael Alper of NeuvoMedica discusses China's recent corruption clampdown and what medtech execs should do to brace themselves for any potential impact

Due to the recent allegations against GSK and heightened investigations among foreign pharmaceutical companies in China, many people have been asking what is the impact on the medical device industry and what should med tech executives do if they are doing business or planning to do business in China.

First of all, despite all the media coverage, the impact to medical device companies so far has been minimal. Mostly, sales reps and distributors have been asked by hospitals to minimize their visits and only to come to the hospital when there is good reason to do so. Also, some previously planned marketing events have been cancelled at hospitals' requests. However, after the current investigation among pharmaceuticals is complete, it is possible that such investigations could happen in the medical device market. If such investigations were to occur, it would likely have an impact on sales of foreign medical device products.

From a higher level, starting even before the GSK scandal, there has been continuing efforts by different parts of the Chinese government to reduce corruption, over diagnosis and over subscription among medical devices and equipment. The National Development and Reform Commission (NDRC) was pushing efforts to cap the margin between import/manufacturing price and sales price in order to help reduce prices and reduce the potential for bribery. Fortunately, this effort was not passed, as it would, for a number of reasons related to marketing investment, taxes and other issues, have put foreign manufacturers at a significant disadvantage. Recently, however, the China Association for Medical Devices Industry (CAMDI), a government backed industry association, was commissioned to

carry out a detailed survey of medical device companies including import pricing and dealer pricing. It is possible that this information will be used to revisit the proposed margin capping in the future.

In order for the government to truly root out corruption in the health care system, it will need to make major changes, specifically related to physician wages in the public hospital system. Overall, physician wages are extremely low, with many physicians making salaries on level with taxi drivers. In fact, one major criticism of the recent healthcare reform was that it did not address the physician wage problem. I imagine that this will be addressed in a future iteration of healthcare reform policy.

Unfortunately for multinational companies, not only are they put under higher scrutiny by Chinese regulators as compared to their local brethren, they are also governed by the strict anti-corruption policies of the US Foreign Corruption Practices Act (FCPA) and the UK bribery act. Thus, if such companies wish to deal in the Chinese market, which has an estimated value of US\$17-20bn, they need to be very serious about proactively managing the risks related to corruption.

For companies with operations in China or those planning to establish operations in China, they should carefully evaluate their current compliance and auditing systems. First of all they should ensure that their current business conduct standards (BCS) meet the requirements of the three major anti-corruption legal frameworks: Chinese anti-corruption laws, US FCPA and the UK Bribery Act. Next, they should ensure that all of their employees, partners, distributors and related persons all understand and agree to the BCS and that there

is continuous education related to these standards. Most importantly, all of this needs to be appropriately documented. All contracts with partners, distributors and employees need to contain clauses that bind them to abide by the company's BCS as well as the repercussions should it be found that the BCS is not abided by. Furthermore, the company should take pains to conduct regular audits, both internally and among their partners and distributors using independent and reputable compliance firms.

For those companies not yet in the Chinese market and are looking for a national distributor to help sell their products in China, it is very important to choose a partner who understands multinational companies' compliance needs. The partner itself must be compliant with FCPA and the UK Bribery Act and open to audits by third party companies. Some medical device companies have learned the hard way of being complacent in this area and have faced multi-million dollar fines, delays in conducting an IPO as well as many other issues. For those companies which already have a national distributor, they should ensure that the partner is compliant via third-party audits if they haven't already done so. They should have contingency plans to make their partners compliant or look to switch to another national distributor that is compliant.

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