

Compliance challenges in China’s life sciences sector

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It seems the perfect storm for chief compliance officers: ongoing regulatory reform in China’s life sciences (LS) sector; sweeping anti-corruption initiatives by government; and a highly fragmented industry prone to using third parties, making oversight difficult. But that’s the reality for those in the LS industry in China, with many players now proactive in terms of ongoing evaluation of company operations in traversing China’s increasingly stringent regulatory regime. As such, emergent trends within this sector are worth noting given the stricter environment and the potential for corruption-related issues to crystallize in M&A deals.

Since China’s President Xi Jinping began initiatives to reduce corruption in late 2012, backed by similar sentiment at the time by the retiring incumbent Hu Jintao, numerous corruption-related allegations have surfaced, some resulting in high-profile cases implicating various multinationals (MNCs). Besides related stricter regulations in China, many MNCs must also contend with multi-jurisdictional policies such as the FCPA (US Foreign Corrupt Practices Act) and UK Bribery Act, compounding the issue.

We’ve seen several broad areas of concern affecting MNCs in China in this regard, including issues around fictitious expense claims and ‘fapiao’ (official receipts), and a desire to improve controls over cash – incorporating efforts to remove cash altogether regarding commercial and employee reimbursements.

Typically, activities via in-hospital meetings, banquets or medical talks are commonplace in China’s LS industry, involving speaker fees, sponsorship fees, travel costs, and food and beverage (F&B) expense. Given the potentially large scale of such meetings, expense claims back to the LS companies can run high. Firms are requesting ever-more detailed supporting documentation – such as hotel folios, itemized F&B receipts, matching fapiao and photos detailing various aspects of the events.

To complicate matters, creative tactics might be used by employees and subcontractors. For instance, ‘staging companies’ have been known to operate, providing sophisticated documentation – from professional photos of crowds/actors at events that never took place as claimed, to various fapiaos void of actual business substance as presented.

Credit: Nick Lindsey (Editor)

Though such levels of sophistication can be difficult to detect, in our experience the roll-out of a multi-pronged approach that cross-checks tax bureau information, bank statements and travel logs, in addition to checking actual restaurant menus and looking for ‘repeat’ actors in photographs, can assist.

Likewise, increasingly more companies are seeing a need to eschew cash from the system to mitigate the potential for giving of ‘incentives’ to doctors, instead mandating e-payment protocols for staff/third parties. Other practical controls we see being implemented include LS companies themselves providing lunch-boxes at events or organizing food deliveries, in addition to the broader aim of supplier consolidation and reducing reliance on third parties.

In our view, the stricter regulatory regime via China’s anti-corruption initiatives is welcomed, as it should simplify business conduct and improve transparency. Nonetheless, challenges remain for MNCs needing to adhere to respective compliance-related policies. We would advocate:

- holistic compliance ‘health-checks’
- due diligence on third parties
- exercising right-to-audit clauses to review commercial activities undertaken on behalf of LS companies and to assess related compliance risks.

An effective compliance program – addressing company culture, talent recruitment (with appropriate compensation and KPIs in place), protocols for assessing and actively monitoring internal controls, and an appropriate fraud response plan (focusing on supplier/subcontractor relationships and activities) – is key in terms of risk mitigating controls.

Regardless, weighing up such issues – many which can be exacerbated in a deal context when access to conduct transaction testing is limited – is pivotal. Whether determining to proceed in a deal, or reviewing current operations – these should be factored in to your post-completion integration plans or current compliance plans.

Li Fern Woo

Partner, Risk Consulting
Phone: +86 (21) 2212 2603
Email: lifern.woo@kpmg.com

Mark Harrison

Partner, Deal Advisory
Phone: +86 (21) 2212 3620
Email: mark.harrison@kpmg.com

KPMG China,
50th Floor, Plaza 66, 1266 Nanjing West Road, Shanghai 200040, China
Tel +86 (21) 2212 2888 Fax +86 (21) 6288 1889