Third-Party Risks in the Chinese Medical Device Market

The medical device market in China has shown unprecedented growth over the past two decades and the forecast for demand indicates no sign of slowing down. From research and development to manufacturing facilities, multinational corporations have made significant investments in the market. But these investments come with challenges. Foreign companies doing business in China must navigate an uncertain and fluid operating environment, facing a distinct set of issues related to third-party relationships.

For companies already engaged in the Chinese medical device market or those considering expansion, TDI Compliance has prepared five critical questions to consider:

1. Who is really behind your third parties?

When evaluating third-party risk in China it is critical to understand the unique challenges around beneficial ownership. Features of the tax code combined with a desire to keep a low profile can make it difficult to connect the dots. For example, if a company was associated with a bribery issue or other improper business practice, the controllers of the company can easily obscure their relationship by standing up a new entity.

2. What are the risks associated with health care providers (HCPs) and third-party foundations?

AdvaMed and MedTech Europe released recent guidance regarding the direct sponsorship of HCPs to attend educational events. The guidance indicates that such sponsorship should be done through a third-party foundation which then selects the HCP. While most companies have already started to comply with this, issuing grants or payments to third-party foundations in China, even if done to mitigate concerns around HCP sponsorship, poses unique risk to your organization including political exposure.

3. What are some of the recent and upcoming regulatory changes and how might they impact our distribution channels?

When managing third-party risk in China, it is important to understand the dynamics of sub-distributors and maintain an awareness of the regulatory changes that may affect these relationships. Recent discussion around the implementation of a two-invoice policy—aimed at improving transparency and pricing—may increase consolidation of distributors or even reclassification of company type.

4. Will the increased use of centralized procurement platforms simply shift the potential for corruption?

In 2012, the National Health and Family Planning Commission released its Standards for the Central Procurement of High-Value Medical Supplies which required the process to be managed centrally at the provincial level and conducted via a government-led bidding process. In some cases, the third-party risk appears to be shifting from the doctor/distributor relationship to the procurement/supplier relationship which may require you to refocus your screening efforts.

5. How do companies reconcile the marked increase in anticorruption efforts by the Chinese government with the increased focus on privacy and data protection in China?

The Chinese government has increased regulatory oversight in the procurement of medical supplies and issued two recent directives focused on intensifying punishments for anti-unfair competition in the medical field. At the same time, there has been recent regulation around the disclosure of personal information, cybersecurity, and information flow through electronic channels. This represents a significant challenge for risk managers due to a reduction in the information that is available to mitigate risk.