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Held to Account

The scene is set: a Western pharmaceutical company enters an emerging market and rapidly wins a series of lucrative contracts. Senior executives are delighted – until they get hauled in front of an investigating panel on bribery charges. While this sequence of events is becoming increasingly common, it is a scenario that can, and should, be avoided through due diligence procedures

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Regulators such as the US Securities and Exchange Commission (SEC) are starting to stand up to, and take notice of, financial and governance malpractices. Authorities are clamping down on impropriety taking place in distant lands, even in circumstances where the Western company charged with wrongdoing has little direct knowledge of such activity.

Emerging markets have been key to fuelling the growth of pharmaceutical companies in recent years, as rapidly increasing populations, coupled with higher rates of disposable income, have propelled the demand for drugs, medical devices, healthcare services and lifestyle products. However, in markets that lack the necessary infrastructure and controls to combat corruption, firms are facing

heightened risks, often compounded by regular interaction of employees and partners with state-owned entities, health ministries and government officials.

US and UK Legislation

Across the industry, from pharma and biotech firms, to medical equipment and services providers, organisations operating in emerging markets face several unique integrity risks: reliance on third parties, such as local agents and distributors that operate beyond their direct control; high level of interaction with government officials; and the need for regulatory approval. One of the primary risks concerns third-party agents' regular contact with doctors, pharmacists and administrators from public hospitals in other countries – people who are often classified as foreign officials under the US Foreign Corrupt Practices Act (FCPA), and who regularly decide what products public hospitals or pharmacies will purchase.

Third parties are often indispensable when entering an emerging or frontier market, either because a Western organisation does not have the necessary local knowledge and contacts, or because many countries insist on a local partner being involved. However, US authorities have made it increasingly clear that they will hold corporates responsible for the behaviour of these third parties. Most Western pharma firms have dealings in the US so will be within the SEC's reach. Meanwhile, the UK Bribery Act is also theoretically capable of holding to account those companies with operations in Britain. So far, UK authorities have been less active than their counterparts across the Atlantic, but that could change rapidly now that legislation is in place.

Types of Misconduct

Faced with a wide range of challenges, the pharma industry has perhaps disproportionately attracted the attention of US authorities. Earlier this year, the Director of the SEC's Division of Enforcement set out three of the most common types of misconduct in pharma FCPA cases, when companies: pay doctors or public hospitals to prescribe their products; pay bribes to government officials to help place drugs on a government insurance reimbursement list; and/or make charitable donations to obtain or retain business.

Payments have not always been in cash: exclusive clubs bringing a range of benefits to doctors who subscribe to a product, or points systems that allow officials to obtain gifts or cashback after placing an order, fall into these categories. Similarly, supporting officials' pet projects has been seen as a form of bribery, even when they are independent charities.

Firms also need to be careful that the local third parties they work with are not using untoward means to gain business for the partnership. This includes using family ties or favouring companies with which they have connections. The UK Bribery Act makes clear that ignorance is no excuse – but a defence can

be maintained on the premise that all possible attempts were taken to ensure that no corruption occurred. In other words, evidence of a robust internal compliance programme which can demonstrate that no stone was left unturned.

Avoiding Violations

Most organisations set out to win and retain contracts and clients without the slightest intention of acting unscrupulously. However, many that commit unethical business practices do so inadvertently, because they fall prey to relationships with the wrong third parties.

It is critical to gain a clear understanding of the reputations and track records of third parties, so that these risks can be mitigated. Organisations should put in place an enterprise-wide anti-corruption framework, complete with all the right procedures. Deploying an effective top-down compliance programme and anti-bribery strategy is crucial. Importantly, this must permeate every aspect of the company's day-to-day operations.

The anti-corruption framework should be geared towards evaluating all third parties the firm is contemplating working with, insisting on full accountability and transparency from potential partners and placing the highest level of scrutiny on the riskiest relationships. A sound due diligence operation can remove elements of a deal that are likely to lead to difficulties further down the line, and allow a company to enter a lucrative new market at minimum risk.

Due Diligence

The due diligence process should start with an overall assessment of individual risks. This will depend on the value of trade and business involved, the nature of the specific deal being considered, and the corruption profile of the country in question. Once these are put into perspective, it is possible to determine the level of resources to commit to research. Even a third-party relationship that has been assessed as low risk will call for a basic review to be carried out, such as 'red flag' searches of sanctions, watch lists, media – proficiency in the local language will be required for this – and court records.

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If nothing else, it may turn out that your potential business partner is worryingly litigious. Where the risk is deemed to be higher – for example, a large business investment in a country where corruption is known to be widespread – more detailed investigations will be necessary, to protect the company as well as comply with anti-bribery legislation.

Intelligence into a potential partner’s experience, integrity and reputation can be built up by searching public records, although it is worth noting that in many countries it is still only possible to do this ‘on the ground’, as archives will not necessarily have been digitised. As well as analysing the results of more basic searches, it is also sensible to speak discreetly with people with knowledge of a company or who have a relevant network in the particular sector. These may include, for example, former business partners, associates, clients and employees; diplomats, officials and embassy representatives; and sector-focused journalists, consultants, lawyers and business professionals. While such information may be biased or unreliable, the key is to be thorough and balanced, and to corroborate any adverse findings. In many emerging and frontier markets, such human source enquiries may be the only real source of information available.

Collusion

Due diligence may seem like an unwelcome expense, but it has the potential to save considerable cost and trouble further down the line. Take, for instance, a global pharma organisation that recently screened a potential distributor in Iran. Available public records and discreet on the ground enquiries found the targeted company to have links to Iran’s Revolutionary Guards, a paramilitary force and the subject of strict US sanctions. These ties were obscured through bonyads – the webs of charitable trusts that control up to a quarter of Iran’s economy. The findings enabled the client to re-evaluate its proposed deal in light of the risks from the firm’s ownership structure.

This case illustrates one of the core objectives of due diligence research in countries where corruption is endemic or political risk is high: to determine a potential business partner’s ties to foreign governments and politically exposed persons. It is not always clear – sometimes deliberately so – where governments exert influence on management, dictate key appointments, or have a crucial funding role that brings with it considerable influence. Family ties to individual government members or

senior state figures are another way in which control can be exerted indirectly, or ownership and interests concealed.

In the case of countries with the highest risk profiles, it is crucial to investigate the relationships among all parties involved in a deal. By joining the dots, further risks may be brought into focus. In some nations, records may not be open to public scrutiny. Given disparities in privacy and disclosure laws from country to country, it is important to ensure that the due diligence process accesses public records both legally and ethically.

What action a pharma company eventually takes, having procured a thorough due diligence report, will ultimately depend on its risk appetite and the other options available. Often, a number of potential partners will be vetted and considered together before a decision is made.

Be Prepared

Of course, it is possible that bribery may take place even in companies with the most vigorous global compliance programmes. Nonetheless, in the event of a regulatory investigation, having an integrated and thorough programme in place will count greatly in that business’s favour.

Moreover, when a company does due diligence right, the rewards are tangible: it gets to expand into lucrative new markets with the best of possible local partners, without having to worry about skeletons in the closet coming back to haunt it in the future.

About the author



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