## Cleaning up in the Pharma Industry: Profit or Principle?

### The Size of the Problem

The global pharmaceuticals industry is reckoned to have a value of around 1 trillion US dollars. Market growth was between 3%-6% pa during the five years to 2016 and is estimated to reach or exceed that level through to 2020[[1]](#footnote-1). Rising global demand for healthcare and medication makes the pharmaceutical industry an attractive and lucrative place to do business. But the potential for large profits brings with it heightened corruption risks.

As at 19th April 2007 [TRACE International](https://www.traceinternational.org/compendium/) lists a total of 60 alleged corruption cases against pharmaceutical companies, ten relating to 2016/17 actions. The case against Bio-Rad Laboratories Inc is not atypical in terms of the type of alleged misconduct and the scale of the penalties imposed. Bio-Rad was alleged to have paid disguised payments (in effect bribes) to foreign intermediaries whom they had retained specifically to influence public officials and help secure lucrative government contracts. The alleged offences took place in Thailand, Singapore, Vietnam and Russia. The charges were raised in the US (Bio-Rad is a US-registered company) under the [US Foreign Corrupt Practices Act (FCPA)](https://www.sec.gov/spotlight/foreign-corrupt-practices-act.shtml).

Following an internal investigation Bio-Rad admitted to ‘likely’ violations and to a number of material deficiencies in its controls including:

* Lack of a comprehensive anti-corruption policy and training programme
* Lack of formal, effective arrangements for whistleblowing
* Inadequacies in its risk assessment and risk management arrangements for doing business in high-risk emerging markets
* Failure to conduct appropriate due diligence before entering into material contracts with certain parties
* Inadequacies in enforcing its Code of Business Ethics and Conduct in certain countries and in disclosing significant exceptions to compliance with company policies
* Deficiencies in the expenditure processes and accounting practices of its subsidiaries in certain countries.

The alleged payments to foreign public officials totalled around US$ 7.5 million. The total business advantage allegedly obtained as a result of these payments was around US$ 35 million – nearly a 500% return on investment. The profit motive behind the alleged activities is clear, even though the company has to date paid fines and penalties in excess of US$ 55 million.

### The key risks

Is the pharmaceutical industry *really* at greater risk than other sectors? In fact the level of risk is probably much the same for *all* companies that do business internationally and can be attributed to three main factors[[2]](#footnote-2), outlined below.

#### Multiple Interactions with Foreign Governments

The long-arm jurisdiction of laws such as the FCPA and the [UK Bribery Act](https://www.justice.gov.uk/downloads/legislation/bribery-act-2010-guidance.pdf) prohibit bribes to foreign public officials anywhere in the world. This is a risk to which pharmaceutical companies in particular are exposed, given the level and number of interactions they are likely to have with foreign governments and their agents. The company’s activities are monitored by government regulators in the countries where they do business. Their clients include state-owned hospitals, clinics or health-care trusts. Their in-country distributors include state-licensed physicians whose job it is to prescribe drugs to patients. Company representatives may face pressure from any of these to offer or make corrupt payments in exchange for business advantage.

#### Heavy Reliance on Intermediaries and Agents

Anti-corruption legislation places a duty on companies to regulate the activities of agents and holds companies liable for any corrupt practices that might have been carried out by third parties on their behalf. Given the global reach of the pharmaceutical market it is only natural that pharmaceutical companies will delegate much of their in-country business to subsidiary companies and agents. The problem here is that monitoring and controlling what third parties actually do can be quite difficult. There can be a world of difference between a subsidiary company’s stated commitment to the parent company’s ethical standards and the actual day-to-day practice of how they carry out their business. Inability to monitor and control third party activities constitutes a very significant corruption risk.

#### Operations in Emerging Markets

Corruption risks are generally thought to be much higher in emerging markets than they are in more mature markets which already have well-established anti-corruption frameworks. Companies seeking an arena in which to test their new drugs may encounter less regulatory control in the emerging markets. Reduced regulation also creates the opportunity to make huge profits from cheaper to make, lower quality and less effective drugs. Add to these factors the perceived ‘acceptability’ in some countries of gifts and payments as a means to secure business advantage and what you have is a business environment where corrupt practices can flourish unchecked, with the complicity of those involved. The pharmaceutical sector has seen sustained growth in its global markets in recent years, but nowhere has this growth been greater (between 9 – 12.5% pa[[3]](#footnote-3)) than in the emerging markets of Asia and Africa. Its position as a major contributor to these markets clearly heightens the level of risk.

### Anti-corruption measures

[Transparency International](http://www.transparency.org.uk/) has identified six areas of activity which are especially vulnerable to corruption risk in the pharmaceutical sector and where anti-corruption measures could therefore make a real difference[[4]](#footnote-4). These activities are:

* Research and development including the trialling of new drugs
* Manufacturing, including adherence to Good Manufacturing Practices or GMPs
* Registration of medicines, including conflict of interest guidelines and approval procedures
* Marketing
* Procurement
* Distribution.

Transparency International recommends a number of steps which the pharmaceutical sector as a whole and companies individually can take to protect themselves from corruption risk in these areas. Recommendations include:

* Mandatory clinical trial registration and publication of results
* Reporting of all financial contributions made to research bodies
* New procedures to ensure the independence of clinical trials
* Global legal enforcement of Good Manufacturing Practices
* Regular inspections of manufacturing facilities by independent inspectors
* Public naming and shaming of non-compliant manufacturers
* Wider use of public online databases for medicines under review and those that have already been registered
* Increased fines and penalties to deter unethical marketing practices
* Wider use of legislation to mandate the prescription of generic over brand-name medicines where value for money dictates
* Wider use of Integrity Pacts (agreements to conform to anti-corruption standards when bidding for government contracts).

### Thinking towards the future

There is much evidence to suggest that corruption risk is and will continue to be a significant issue for the pharmaceutical sector. In effect, companies have two options. They can mark themselves out as leaders in integrity by setting and enforcing the highest standards and by taking active steps to act on the anti-corruption recommendations of Transparency International and others. Or they can pay lip service to standards and put their global reputation at risk.

Most importantly of all, companies that want to be seen as ethical and good to do business with need to be unswerving in their support of employees. Bio-Rad Laboratories admitted to a number of deficiencies in this respect. The company did not have strong, effective anti-corruption policies. It did not provide adequate training on anti-corruption issues. It did not have adequate support and protection in place for staff wishing to disclose concerns. It did not adequately monitor or control what its subsidiaries and agencies were doing overseas. In short the company failed in its duty to enable, equip or support its employees in making appropriate, effective ethical decisions as they went about their work. Without robust support from their employers it can be very difficult for individuals to take a stand against corruption when they encounter it. Employees need to know that their employers will support them in standing up to corrupting pressure, wherever in the world they do business.

1. Sources: [www.statista.com](http://www.statista.com); [www.ibisworld.com](http://www.ibisworld.com); [www.imshealth.com](http://www.imshealth.com) [↑](#footnote-ref-1)
2. Source: DAVID-BARRETT, E et al, (2017), [A Bitter Pill? Institutional Corruption and the Challenge of Antibribery Compliance in the Pharmaceutical Sector](http://journals.sagepub.com/eprint/d6qQKA4ax22pYG2S6fIX/full), Journal of Management Inquiry [online], 1-22 [↑](#footnote-ref-2)
3. Source: [www.imshealth.com](http://www.imshealth.com) [↑](#footnote-ref-3)
4. Source: [Corruption in the Pharmaceutical Sector: Diagnosing the Challenges](http://www.transparency.org.uk/publications/corruption-in-the-pharmaceutical-sector/), Transparency International June 2016 [↑](#footnote-ref-4)