Why the Bribery Bill may turn out to be a bitter pill for the industry to swallow

On 1 December 2009 Robert Dougall, a former vice-president at DePuy International Ltd, was ordered to stand trial for conspiracy to corrupt. The Serious Fraud Office (SFO) alleges that between 2002 and 2005 Mr Dougall paid bribes to entice Greek health officials to buy medical equipment. The case was referred to the SFO by the US Department of Justice as part of a wider investigation into five healthcare companies.

Three months earlier, Pfizer agreed a civil settlement of $1bn with the Department of Justice, following allegations that it illegally promoted Bextra, Geodon, Zyvox and Lyrica. The US government also alleged that Pfizer paid kickbacks to healthcare providers to induce them to prescribe and market these and nine other drugs. The Pfizer settlement (part of a larger $2.3bn settlement covering the activities of a subsidiary) is the largest ever civil fraud settlement agreed with a pharmaceutical company.

These two cases illustrate how the pharmaceutical and healthcare industries are firmly on the radar of UK and US investigators. Indeed, the US Assistant Attorney General declared in November 2009 that the pharmaceutical industry would be the focus of criminal enforcement “in the months and years ahead”. There is a perception that corruption permeates the medicines chain.

In the UK, bribery and corruption is firmly on the political agenda. Criticised over allegations that it exerted pressure on the SFO to drop its corruption investigation into Saudi arms deals, and castigated abroad over the UK’s abysmal track record in prosecuting bribery, the Government is hoping to silence its critics with the publication of the Bribery Bill, expected to become law later this year.

The Bill modernises and simplifies the existing archaic law by creating three basic offences:

- Paying or offering a bribe
- Accepting a bribe
- Failure by a corporate to prevent bribery

Once in force, there will be few UK businesses not affected by the new law.

What is the level of corruption in the pharmaceutical industry? Given the covert nature of corruption there are, unsurprisingly, few reliable statistics. Transparency International asserts that annually corruption amounts to tens of billions of dollars. The US government believes that 5–10 per cent of its healthcare programmes are lost to “overpayments”. Fraud, including corruption, is estimated to cost the NHS £2bn per year.

The pharmaceutical industry is highly competitive and heavily regulated. These factors make it particularly susceptible to fraud and corruption at all levels, from the research and development of new medicines to their final delivery. There are a number of particular danger areas about which those involved in the chain of supply should be particularly alert.

Inducements, gifts and hospitality

The first danger area relates to the giving and receiving of gifts and hospitality or other inducements. Lunches, dinners, drinks parties and the like, often given at educational events and medical conferences, are regarded by pharmaceutical companies as innocent marketing tools. However, these are obviously not provided for purely altruistic reasons, but with a view to promoting a company’s products and boosting its profits. That is not intrinsically improper, but the danger is that a sense of indebtedness is created by the recipient. The level of hospitality received by clinicians from pharmaceutical companies is cause for

John Benstead is partner, business crime and commercial fraud, at McGrigors LLP
(e-mail john.benstead@mcgrigors.com)
The academic would undertake his research because it could reasonably be expected that favourable results about a particular medicine, the person is expected to perform it improperly; or as a reward for the performance of a function. Conversely, a person will commit an offence if he requests, agrees to receive or accepts an advantage in order to perform a function improperly; or for the improper performance of a function.

"Facilitation payments" is left undefined in order to prevent loopholes. "Function" covers activities of a public and a commercial nature, as well as those performed in the course of employment. The function must meet one of the following conditions:

- The person performing the function is expected to perform it in good faith.
- The person is expected to perform it impartially.
- The person is in a position of trust by virtue of performing the function.

So, an offence might be committed if a pharmaceutical company offers funding for an academic in return for suppressing unfavourable results about a particular medicine, because it could reasonably be expected that the academic would undertake his research on the drug objectively and impartially. The Regulations remain in force, but it will be noted that the offences under the Bribery Bill are considerably wider in their scope. The sentences are more severe, too. Pharmacists found to be in breach of the Regulations will pay a fine of no more than £5,000. However, for a conviction of bribery the maximum sentence will be 10 years’ imprisonment, an unlimited fine, or both.

**Failing to prevent bribery**

The Bill provides that a company commits an offence if a person working for or on behalf of the company, the provisions of the US Federal Corrupt Practices Act 1977 (FCPA) come into play. The FCPA makes it an offence for an individual, firm, officer, director, employee or agent of a firm to bribe foreign government officials. In 1998 the FCPA was extended to cover foreign companies and nationals if they cause, directly or indirectly, a corrupt payment to take place within the territory of the US.

The US Department of Justice regards state-employed healthcare professionals, including pharmacists, as "foreign officials". Thus any UK company or individual falling within the remit of the FCPA rash enough to bribe an NHS employee could face criminal proceedings in the US. In recent years the US government has not been shy in seeking the extradition of UK nationals. From the close co-operation between the US and UK agencies, as illustrated by the DePuy investigation referred to above, it is not inconceivable that we may one day see the extradition of a UK company executive in connection with corruption in the pharmaceutical industry.

**Compliance with the new law**

As we have seen, the consequences of a conviction for bribery are serious. For individuals a sentence under the new law will be potentially significantly larger than under the Regulations. Individuals who can be shown to have benefited financially from bribery may find that they also face proceedings for confiscation of their assets.

For corporates, the consequences are equally serious. Quite apart from the adverse publicity that would inevitably follow a conviction, the company would also face financial penalties. As we have seen, the recent settlement in the US these can run into billions of dollars. In the UK, recent corruption settlements negotiated with the SFO have been more modest, but still run into millions of pounds.

**What to do?**

What should the pharmaceutical industry now do to avoid a breach of the new law? Pharmaceutical companies will need to review critically their gifts and hospitality policies in light of the new law. The current director of the SFO, as part of his publicised aim to create a new corporate culture in the UK, has announced a "zero tolerance" policy towards excessive gifts and hospitality by corporates. It is likely that much of the largesse that has characterised the industry will need to change.

As explained earlier, pharmaceutical companies will need to implement adequate procedures to prevent bribery. The prerequisite for an effective policy is management buy-in. Without strong management leadership on the issue, a company will always be at risk if there is a lax corporate culture on bribery. A recent example from the insurance sector is the case of Aon, which was fined £5.25m by the Financial Services Authority for failure of the management to prevent bribery risks.

Robust, clear and unambiguous anti-bribery policies will, therefore, need to be implemented that focus on those relationships where there may be a risk of corruption. In the pharmaceutical industry these relationships will be those conducted with...
intermediaries: doctors (in particular those doctors benefiting from paid consultancies) and other prescribers; those who purchase a company’s medicines; and, where a company operates abroad, its agents, foreign business partners and subsidiaries.

A thorough due diligence exercise on all proposed third party relationships should be implemented. Existing relationships should be audited and the reviews should be properly documented.

Education and training should be given to all staff in departments where the risk of bribery may be an issue. All staff should be required to attend regular refresher training as part of their appraisal procedures. It should be made a disciplinary offence to fail to comply with the policy, and a dedicated management body should be established responsible for implementing and reviewing the policy on a regular basis.

Given that it will also be an offence to receive a bribe, it will not just be the pharmaceutical companies that will need to review their policies. Any commercial organisation employing staff that has regular contact with pharmaceutical companies should, as a minimum, launch education campaigns and review their gifts and hospitality policies. As for the pharmaceutical companies, these other organisations will need to put in place adequate procedures to prevent bribery. There is at least the comfort of knowing that the Bill does not propose to make it an offence for a corporate to have failed to prevent the acceptance of a bribe.

What action should be taken if bribery is uncovered? Subject to a few exceptions, there is no general principle of law which requires a person to report a crime to the authorities. That said, last year the SFO introduced a leniency policy in cases of suspected overseas corruption. Under the policy, if a company self-reports corruption and cooperates with the SFO’s investigation, it may agree a civil settlement with the company rather than prosecute (though this will not necessarily prevent individuals in the company from being prosecuted). The policy only applies to overseas corruption. Nevertheless, a pharmaceutical company that suspects UK corruption might be wise to consider self-reporting rather than risk it being uncovered by another route, resulting in a wide-ranging criminal investigation.

Conclusion

Given the heavy regulation already faced by the pharmaceutical industry, the provisions of the Bill may indeed be regarded as a bitter pill, but it is at least one which all UK businesses will need to swallow. Once in force, however, the new law will be a great improvement on the current archaic laws. Inevitably there will be additional costs to organisations as they implement, review and regularly update their anti-bribery policies. Individuals, including pharmacists, will need to be equally alert to the dangers posed to them by the new law. It is hoped that the new law will encourage, as the director of the SFO envisages, a new corporate culture in the UK and that the perceptions that have dogged the pharmaceutical industry will become a thing of the past.