

Heeding the Warning: Increased International Scrutiny of the Pharmaceutical and Medical Device Industry

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The Department of Justice (DOJ) under the Obama administration has announced on more than one occasion that it is targeting the healthcare industry for Foreign Corrupt Practices Act (FCPA) investigations, with a particular focus on pharmaceutical and medical device companies.

In November 2009, Lanny Breuer, DOJ Assistant Attorney General, spoke at the 10th Annual Pharmaceutical Regulatory and Compliance Congress and Best Practices Forum and warned the big pharma industry that DOJ would be “intensely focused on rooting out foreign bribery in [the big pharma] industry.” In the first eight months of 2010, Breuer’s warning has proved true. During this period, the DOJ or the U.S. Securities Exchange Commission (SEC) has sent letters of inquiry to a dozen of the leading pharmaceutical and drug device manufacturers in a broadening bribery inquiry into whether the companies made illegal payments to doctors and health officials in foreign countries.

The United States, however, is not alone in its increased scrutiny of potential anticorruption and bribery schemes in the pharmaceutical industry. Recent developments in anticorruption law in Germany and China are presenting new risks specific to pharmaceutical companies. These developments make it clear that regulators all over the world are targeting the drug and medical device industry.

The FCPA criminalizes bribes offered to, promised to, or accepted by foreign public officials. In many countries, doctors are state employees or hospitals are state-owned entities, but this is not true in every instance. The recent developments in China, Germany, and the United Kingdom discussed below address commercial bribery schemes where drug companies or their representatives are allegedly offering or paying benefits to private physicians in exchange for an increase in prescriptions for particular drugs.

China

Based on a growing concern that pharmaceutical companies are paying bribes to doctors, in June 2010 the Ministry of Health of China (MOH) released the Notice on Further Combating Commercial Bribery in the Area of Drug Purchase and Sales (Notice), which requires local health authorities to implement several key measures to help detect, deter, and punish bribery and corruption in the pharmaceutical industry. To help detect bribery, the Notice requires, among several other measures, that hospitals create

and implement early warning systems for doctors writing excessive prescriptions. Additionally, the Notice forces hospitals to protect the confidentiality of the volume of drugs prescribed by physicians and high-value disposable medical supplies used. This measure addresses the fear that drug companies, upon accessing this information, will use it to determine kickbacks to physicians based on the volume of drugs prescribed and supplies used.

One of the most potent measures in the Notice is the requirement that local health authorities establish a publicly available blacklist for companies that are guilty of commercial bribery in the purchase or sale of pharmaceutical products. Once blacklisted, a drug manufacturer would not be allowed to submit bids to drug-centralized procurement programs for two years, and hospitals in China would be prohibited from purchasing any drug, medical device, or disposable medical supply from the company for two years. The Notice requires the blacklist system to be established in all localities by the end of 2010.

In an effort to strengthen enforcement against commercial bribery, the Notice also requires that local health authorities report commercial bribery attempts to the appropriate enforcement agencies for investigation and penalization. This means that the MOH and medical institutions now have an obligation to notify prosecutors if they believe that criminal laws have been violated.

This Notice is a clear indication that China intends to be more aggressive in its investigation and punishment of bribery in the pharmaceutical industry. Many pharmaceutical companies are increasing their presence in China in an effort to gain an advantage in China's growing, lucrative market. These companies need to be prepared to protect themselves against an increased risk of enforcement by the Chinese government.

Germany

A recent decision of the German Higher Regional Court in Braunschweig could considerably widen the scope of the criminal liability regarding commercial bribery in the healthcare sector and the pharmaceutical industry. This is the first decision of a German Court of Appeal ruling that doctors in private practice are agents of the statutory health insurance companies, which are created and organized by German public law. This decision is significant because it could lead to a paradigm shift in how physicians—private practitioners as well as those employed by hospitals—and companies in the healthcare industry relate.

Under German bribery law, persons who offer bribes in a commercial context can only be held criminally liable if the bribe is offered to and/or accepted by an *employee or an agent* of a commercial business (in this instance, the commercial business is the statutory health insurance company). Prior to the June 2010 decision, German courts consistently ruled that physicians were not employees or agents of the statutory health insurance companies. This meant that pharmacists and representatives of pharmaceutical companies could offer benefits to the physicians without risking criminal liability under German bribery law.

The Higher Regional Court decision has essentially closed this loophole. The court reasoned that a physician is a "key figure in the supply of pharmaceuticals" because the legal claim for certain drugs and other healthcare supplies and devices only arises when the physician prescribes the drug or device to the patient. The court held, therefore, that a physician is an agent of the statutory health insurance companies. This means that pharmacists and representatives of pharmaceutical companies can be found

guilty pursuant to the German bribery law if they grant benefits to physicians in return for the physician favoring the pharmacist or a particular drug when prescribing medicines or medical devices.

Therefore it is necessary for companies active in this industry to evaluate and, where necessary, adjust their business relations with physicians and hospitals to ensure that they protect themselves and their agents against this new risk.

United Kingdom

On July 20, 2010, the United Kingdom Ministry of Justice announced that the UK Bribery Act (the Act), which includes a new strict liability corporate offense of failing to prevent bribery, will come into effect in April 2011. This is later than originally proposed, but reflects more recent expectations as to the likely timetable for implementation.

Given its potentially wide territorial application, the Act has far-reaching implications not just for UK-based entities, but also for many international corporations. In many ways it is more extensive than many existing regimes in other jurisdictions, including the FCPA. For example, it does not limit bribery offenses to public functions or activities, but extends them to the commercial sector, with potential implications for industries such as the corporate hospitality industry. Similarly, there is no carve-out permitting the payment of customary facilitation payments.

While corporations will need to be generally aware of the new regime, they should in particular take notice of the new offense created by section 7 of the Act. Under this section, a commercial organization will commit a criminal offense if a person associated with such an organization bribes another person with the intention of benefiting the organization. *This is a strict liability offense.*

Additionally, the potentially broad definition of the phrase “associated with” in the context of this new section 7 offense may lead to businesses being responsible for supervising and establishing policies governing not only the actions of their own companies and employees, but also the actions of third parties. Pharmaceutical and medical device companies will be particularly vulnerable to this offense if their representatives are providing benefits to physicians in exchange for an increase in prescriptions for particular drugs or devices.

The Act provides a defense, however, for organizations that can show that they had in place “adequate procedures” to prevent bribery from taking place. In essence, the UK is now mandating the kinds of FCPA compliance programs that U.S. corporations have implemented over the last decade. Given the wide scope of the offenses as set out in the Act and its extensive territorial reach, multinational corporations need to take steps now to ensure that they are fully prepared for the new regime.

Conclusion

The increase in foreign corruption regulation throughout the world reflects a growing recognition in the global business community that bribery is detrimental to business. There is also a perception that bribery in the pharmaceutical industry has long gone undetected and unpunished. Due to this increased regulation, it is no longer sufficient for companies to understand and comply with the FCPA. It may be that international anticorruption laws are more restrictive than the FCPA, meaning that companies can encounter unique difficulties if they are not aware of the attendant risks.

Also, more than ever before, regulators throughout the world are sharing information and assisting each other in their investigations. Officials from the Netherlands, Germany, the United Kingdom, Thailand, and many other countries have joined DOJ in recent investigations. Thus, a problem with international regulators can quickly turn into a problem with U.S. regulators. The developments in Germany and China represent examples of the kinds of potholes that pharmaceutical or drug device manufacturers can fall into if they are not vigilant in staying ahead of the changing developments in anticorruption law. Companies that have a multinational presence need to ensure they are in compliance with the corruption laws wherever they conduct business.

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