

Responding to Anti-Corruption Concerns in Brazil: Considerations for the Pharmaceutical and Medical Device Sectors

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Brazil's booming economy includes a dynamic pharmaceutical sector, with numerous private and government owned pharmaceutical companies, rapidly growing retail sales, and an expanding system of health care coverage through the country. Multinational pharmaceutical companies are investing in Brazil both for marketing and sales directed within the country and as a platform for sales exports throughout South America, and local companies are working hard to maintain and increase their market shares. Estimates of the size of Brazil's pharmaceutical and medical device sectors vary, but it is likely in the range of about \$25 billion annually.

Opportunities for participating in Brazil's robust economy may be tempered by concerns about corruption, however, particularly in heavily regulated sectors such as pharmaceuticals and medical devices. Potential risk areas for corruption in the sector include everything from government approvals and oversight of manufacturing and distribution systems to marketing and sales of products to individual procurement officials, many of whom are government employees. Brazil's complex tax laws and its customs regulations mean that companies sometimes engage consultants to act on their behalf, and corruption risks also may arise in those types of scenarios. While many of these issues are of course not unique to the pharmaceutical and medical device worlds, the nature of the sector and the sheer magnitude of the business opportunities means that corruption related problems can attack a company from many directions. Effective compliance to prevent, detect and respond to these risks is a must.

One area where corruption risks may arise in the pharmaceutical and medical device sectors is during public procurement of products. Brazil's Constitution establishes a Universal Healthcare System (UHS). The Unified Healthcare System (SUS) is the official governmental vehicle for management of UHS and procures products via bids, a system that has proven susceptible to improper influence by the private sector. Public procurement is not centralized in a single national entity, so Federal, State and Municipal authorities organize tenders. That the system involves multiple points of access to decision makers leads to corruption risk, because it gives would-be bribers multiple avenues to use improper payments to encourage or influence corrupt conduct of decision makers, including health authorities responsible for budgets or procurement decisions.

Interaction with State and Municipal authorities all over Brazil highlights business conduct risks. In this connection, the time consuming and complex regulatory process for obtaining authorizations for the operation of a pharmaceutical or medical device company generates an atmosphere where bribes could be offered or made. Such State or Municipal health authorities are widely referred in Brazil to as "VISA locais", i.e., Local Sanitary Authorities and they present another risk area for companies.

Interactions with healthcare professionals also present risks in Brazil. These interactions, including financial interactions with potential key decision makers or opinion leaders also present corruption risks. Taken all together, the regulatory landscape, the business environment and the past history of corruption, present risks for good government as well as for businesses operating in the country.

To address broad concerns about corruption, the Government of Brazil recently enacted broad new legislation called the “Brazilian Clean Companies Act” (BCCA), which subjects not only Brazilian companies but foreign (non-Brazilian) entities to civil and administrative sanctions for bribing public officials both in Brazil and elsewhere. To be subject to the law, a non-Brazilian company need only have an affiliated or representative office in Brazil, “established in fact or of law, even temporarily.” (Art. 1 of BCCA). Accordingly, most pharmaceutical or medical device companies who conduct business in Brazil will likely be subject to the BCCA.

The new law will take effect January 29, 2014, and builds on prior Brazilian anti-corruption laws. Brazilian law now both tracks in many respects analogous provisions of the U.S. Foreign Corrupt Practices Act by prohibiting bribery of foreign public officials, and also goes beyond those provisions by addressing such issues as bribery of domestic officials, strict liability, corruption in public procurement, and large administrative sanctions.

Given the broad scope of the law and its fairly low trigger for jurisdiction over non-Brazilian companies, any pharmaceutical company doing business in Brazil would be well advised to understand its provisions, follow closely enforcement cases under the law, and develop an appropriate compliance program, as contemplated by the law.

The following are some highlights of the new law:

- The BCCA incorporates strict liability for Brazilian and non-Brazilian companies subject to Brazil’s jurisdiction (a low bar) that “promise, offer or give, directly or indirectly, any undue advantage to a public servant or a third person related to him.” Thus, a company can be liable even if its senior management didn’t know of the bribery, and (like the FCPA) liability can arise through the mere promise or offer of a bribe, including those made through third parties.
- The BCCA applies fully to the public bidding process, so that bid rigging and other fraudulent conduct are encompassed.
- Civil fines can be substantial. Violations of the BCCA can lead to penalties of as much as 20% of the entity’s gross billings for the fiscal year prior to the initial of enforcement proceedings. If the 20% figure cannot be calculated, a fine of up to 60 million Reals (about US\$26 million) can be assessed, plus (in appropriate cases) other penalties such as disgorgement of the improper gain. Penalties can be reduced if the company has developed and implemented a corporate compliance plan.

- Companies found to have violated the anti-bribery law will be prohibited from contracting with Brazilian Public companies for up to 5 years. Such a penalty can be specifically problematic for those companies for which the Government and its related entities (e.g., academic and medical centers, and medical doctors) are the primary or sole client.
- The BCCA contemplates that the existence of a robust compliance program will be taken into consideration by Brazilian authorities when assessing penalties for violations of the law.

Responding to the challenge

Many global pharmaceutical companies that are operating or considering operating in Brazil will have an established compliance program with the generally recognized compliance program elements. It can be expected that, as the Brazilian law becomes effective and as enforcement begins, Brazilian authorities will recognize the same types of compliance program elements that are currently recognized by U.S., British, and other governments worldwide.

Yet the different operating environment in Brazil likely will require some consideration of how to mitigate specific corruption risks in the market. A prime example of these risks is the use of third party business consultants for a wide variety of services that involve government interactions, such as permitting, procurement tenders, tax consultants, and logistics providers. Ensuring that a third party diligence program is in place and evaluates these types of consultants thoroughly would be warranted.

A closer review and monitoring of procurement efforts by a company's own personnel also would be in order. In that context, a review of meals, entertainment, charitable contributions and business relationships with government officials should be a high priority, as should monitoring of these interactions by the compliance and internal audit functions.

The design and operation of a company's compliance effort in Brazil therefore must be adapted to take into account how these risks arise. A detailed risk assessment of a company's business model in Brazil will enable the company to design controls that can better reflect the risks in the market and which may not have been fully accounted for in a company's global compliance program.

Conclusion

The recent promulgation of Brazil's new anti-corruption law and the government's commitment to more vigorous enforcement in this area are significant, and reflect that Brazil has entered a new era of heightened anti-corruption efforts. Companies must adopt, implement and maintain robust corporate compliance policies, especially in the heavily regulated health care areas. Brazil is a vital and growing market in the pharmaceutical and medical device areas, and with the new opportunities come challenges that will need to be met with care and vigor.