Life & Health

Health Care Compliance Communiqué

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GLOBAL WAR ON CORRUPTION HEATS UP

The war on global corruption, once dominated by the US, is heating up – and not primarily because of increases in US enforcement actions. Trace International's Global Enforcement Report (GER) 2013 report states that the number of formal foreign bribery actions by countries other than the US increased by 71% between 2012 and 2013 while the formal bribery actions by the US remained flat during the same period. The changing profile of global anti-corruption enforcement doesn't stop there. In 2013, according to the report, China led in domestic bribery enforcement actions (defined as the bribery of a country's own government official by a foreign company) with South Korea and Nigeria ranking second and third.

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GLOBAL WAR ON CORRUPTION HEATS UP *(Continued)*

Compliance Risks to Business

The US Foreign Corrupt Practices Act (FCPA) remains a law to be reckoned with – no matter where a company is located – but laws enacted in other countries are rapidly creating a complex international web of intersecting, overlapping and sometimes even conflicting anti-corruption and anti-bribery laws. Some national laws allow facilitation payments; others do not. Some laws, such as the US FCPA, focus on the bribery of foreign government officials; other laws, including the UK Bribery Act, prohibit bribery in any setting.

2013 saw the passage or effective date for anti-bribery legislation in multiple countries. In some cases, the laws were new. In other cases, the laws were updated and tightened. Consider these changes to the global anti-bribery picture:

- In late 2013, the Russian Ministry of Labor and Social Protection released recommendations for how organizations could meet their legal compliance requirements. Those recommendations are consistent with the elements of effective compliance supported by the US, UK and OECD.
- Brazil's anti-corruption law, commonly called the Clean Companies Act, took effect in January 2014, creating a set of strict requirements related to the bribery of Brazilian government officials. The law also set standards for effective compliance programs and promoted self-reporting as a way of demonstrating cooperation with authorities and potentially gaining consideration in the government's enforcement actions.
- Canada has become more assertive in enforcing its Corruption of Foreign Public Officials Act (CFPOA). Just as important, the scope of the law has been expanded in several areas including the decision that an agreement to pay a bribe is enough to cause a violation of the CFPOA.
- China has emerged as the most aggressive enforcer of anti-bribery laws, particularly through the government's actions toward executives and employees of GSK. That enforcement action isn't a one-shot-deal. Global companies have been put on notice that the government will take a very stern look at foreign business operations in the country.

Beyond the enactment of new laws and increased enforcement actions by individual nations, the World Bank has upped the ante for companies found guilty of bribery. In 2013, the World Bank debarred 47 organizations that were found guilty of engaging in illegal practices. Debarment can last as long as 10 years and, given the sheer amount of funding provided by the World Bank ($31 billion in FY 2013), can cause irreparable damage to a debarred company. In light of the impact to a debarred company, the World Bank has launched a process to consider reforms to its debarment process including a possible incentive to self-disclosure.

The flood of new laws, particularly in countries without long-standing anti-corruption legislation, adds another layer of risk to the established compliance challenges created by more familiar laws such as the FCPA and UK Bribery Act. Companies that contemplate entering new, often-unfamiliar countries will need to add resources to their compliance programs and to their due diligence efforts when working with third party intermediaries.

CORRUPTION IN THE HEALTH CARE SECTOR

The European Commission (EC) has released a big-picture report on corruption in the Health Care industry in the European Union. The report ("The Study on Corruption in the Healthcare Sector") highlights the nature and impact of Health Care corruption across the EU. Although the study focused on several industry subsectors, including medical service delivery, analysis of the Medical Device and Pharmaceutical sectors exposed worthwhile information about the sectors and their specific corruption risks.

Corruption and Procurement

According to the report, the EC estimates that there are approximately 11,000 companies in the Medical Device sector. (There are large differences of opinion: Eucomed estimates 25,000 active device companies). Despite those differences, both organizations agree that small- and medium-sized enterprises account for about 80% of the total. Although the study notes that corruption in the sector occurs throughout all stages of the supply chain, one of the areas of particular attention is the procurement function. Among the types of corruption documented in the procurement stage are bribery/extortion/kickbacks; favoritism in procurement (including conflict of interest/unethical donations); collusion (e.g. bid-rigging and market division); and awarding contracts to inappropriate suppliers. Although the Pharmaceutical sector shows a number of differences, the corruption risks are also strongly evident in the procurement function.

The study reports that 10-25% of public procurement spending in health (both medical devices and pharmaceuticals) is lost globally to corrupt practices. Here's a look at the corrupt practices – and the compliance risks to companies in the industry – identified in the EC report:

- Pre-bidding: corrupt needs assessment; circumvention of tender procedures and tailored tendering;
- Bidding: bribery and kickbacks during the bid evaluation; favoritism; collusion and/or market division in bidding;
- Post-bidding: false invoicing and changing contract agreements.

The common types of bribe are identified, both involving individuals and medical institutions. Bribes to individuals include money, leisure and trips, favoring relatives and discounts. For medical institutions, bribes range from money to conference participation, free supply of materials, research funding and other forms of monetary and nonmonetary (research facilities) sponsorship.

Of particular use, the study provides capsule descriptions of specific cases representing different types of procurement corruption. Not surprisingly, a number of the case studies involve third parties and their interactions with Health Care providers.

The 300+ page report provides a good look at the most common types of corruption present in the EU's Medical Device and Pharmaceutical industries and consequently, the most pronounced compliance challenges for those companies. After a page-by-page review of the report, some of the most powerful takeaways include the risks posed by third party intermediaries, procurement of services and products and interactions with Health Care providers. Adding to the training and compliance challenges is the need to understand country-specific regulations in addition to the broader FCPA and UK Bribery Act. The EC report notes specifically that corruption risks are not consistent across all member states.

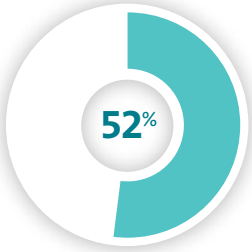
Corruption isn't going away. In fact, it is increasing as the Medical Device and Pharmaceutical industry and markets expand into countries that are just entering the global battle against corruption. In the EU, with 28 member states that have a wide range of perspectives and business approaches, the need to maintain a high level of knowledge among employees and third party intermediaries is critical to ensure compliance and minimize the potential for corrupt behavior.

For the full study, click http://ec.europa.eu/dgs/home-affairs/what-is-new/news/news/docs/20131219_study_on_corruption_in_the_healthcare_sector_en.pdf

MANAGING THIRD PARTY RISKS

More and more, Life Science companies are outsourcing essential business functions to Third Party Intermediaries (TPIs) who perform services on behalf of the company. TPIs can range from attorneys and accountants to customs facilitators, procurement agents, distribution companies, travel agents and government advisors. The use of TPIs is being integrated into the modern business model – and into the modern risk model for global Life Science companies. Consider this:

90% of Foreign Corrupt Practices Act (FCPA) investigations brought by the US Department of Justice in recent years have been related to third parties, while 2/3 of the cases brought by the US Securities and Exchange Commission were related to third parties. SEC ranked TPIs and travel/entertainment as the two biggest issues in their FCPA unit's enforcement actions.



More than half of the respondents in a survey by Control Risks ("International Business Attitudes to Corruption") linked their risks of corruption and fraud to their third party relationships.

30% of respondents in an AlixPartners Annual Global Anti-Corruption Survey said they had stopped doing business with certain parties because of corruption concerns.

Managing TPI Risks

Managing TPI risks requires companies to examine issues based on "*where*" and "*what.*"

Where: As companies expand their reach into new markets, it is inevitable that they will enter markets with unfamiliar cultures, governments and business practices. Resources such as Transparency International provide valuable information that ranks the corruption risk of countries. Not surprisingly, the "riskiest" countries typically include those without strong, long-term anti-corruption laws and enforcement actions or nations in which corruption has been historically accepted in the business world. Companies need to consider how familiar they are with local customs and legal structure, whether there are unique issues that affect the Life Sciences community (such as government-controlled Health Care), whether the country has enacted or enforced anti-corruption laws, and how closely the nation is working with international agencies on anti-corruption measures. Finally, companies need to determine if the country is on the radar of the US, UK and other countries with strict anti-corruption laws.

What: Staff downsizing and market expansion converge to promote outsourcing but companies must be especially aware of the business functions they are outsourcing, the risk posed by those functions, and the TPIs they retain. A customs facilitator will rank high on the risk scale, for example, while a small printing company may not pose the same risk. Is the specific TPI willing to open its records? Does it have a strong compliance program? Has it been audited and found lacking? Is its anti-corruption training and compliance program current and adequate to support compliant behavior?

BONUS – Download our white paper, "***Managing the Risks of Third Party Intermediaries***" for an in-depth look at assessing and managing TPI risk, anti-corruption training, monitoring and reinforcement, and the cost of noncompliance.

MANAGING THIRD PARTY RISKS *(Continued)*

Training for Compliance

Once risks have been assessed, training should be designed to target those risks. Training must be relevant to the job function, specific risk, culture, traditions, literacy and language of the target audience, whether on-site employees of the company or employees/subcontractors of the TPI. Training should be followed by testing that demonstrates knowledge of the new material. Just as important, training should be reinforced consistently based on risks related to the territory, TPI structure and regulatory climate.

Often overlooked is the need to train corporate employees, arming them with the knowledge to identify "red flags" among TPIs. Employees who are committed to a strong corporate culture of integrity are the most important resource a company has in identifying questionable actions. Continuing to support those individuals, through reinforcement of the company culture and related training, will translate into positive results for companies as they endeavor to monitor and manage third party intermediaries.

About UL EduNeering

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UL EduNeering develops technology-driven solutions to help organizations mitigate risks, improve business performance and establish qualification and training programs through a proprietary, cloud-based platform, ComplianceWire®.

For more than 30 years, UL has served corporate and government customers in the Life Science, Health Care, Energy and Industrial sectors. Our global quality and compliance management approach integrates ComplianceWire, training content and advisory services, enabling clients to align learning strategies with their quality and compliance objectives.

Since 1999, under a unique partnership with the FDA's Office of Regulatory Affairs (ORA), UL has provided the online training, documentation tracking and 21 CFR Part 11-validated platform for ORA-U, the FDA's virtual university. Additionally, UL maintains exclusive partnerships with leading regulatory and industry trade organizations, including AdvaMed, the Drug Information Association, the Personal Care Products Council, and the Duke Clinical Research Institute.