Life & Health

Health Care Compliance Communiqué

Q2 2013

Ethical Guidelines for Sales and Marketing

Medical Device and Diagnostic companies face particular compliance risks in the marketing, sale or delivery of their products to end users. Those risks don't disappear – in fact, they may even escalate – when a company uses third party sales and marketing intermediaries to assist in the marketing, sale or distribution of its products.

AdvaMed (Advanced Medical Technology Association) and Eucomed have responded to these challenges through the Joint Guidance for Medical Device and Diagnostics Companies on Ethical Third Party Sales and Marketing Intermediary (SMI) Relationships. The Guidance makes the point of explaining, "The form of, and terminology used by companies to describe relationships with these third party sales and marketing intermediaries varies, but may include distributors, wholesalers, distribution or sales agents, marketing agents, brokers, commissionary commercial agents and independent sales representatives."

The Guidance centers on a Third Party SMI Management Compliance Program which AdvaMed and Eucomed encourage companies to adopt in addition to an overall Health Care

Professional Compliance Program. The recommended Third Party SMI Management Compliance Program should be applicable to all relevant personnel, including a company's senior leadership, and should include the following elements:

- ☑ Prepare written policy/procedures banning all forms of bribery by any person or entity acting on behalf of the company, including Third Party SMIs. (Detailed policies may be included for common risk areas such as travel, gifts, entertainment, research and capital equipment.)
- ☑ Conduct a risk assessment evaluating the risk profile for Third Party SMIs.
- ☑ Establish a risk-based pre-engagement and renewal due diligence program to identify, prevent and mitigate risks related to the market in which the Third Party SMI operates.
- ☑ Prepare written contracts with terms that require adequate controls and implementation of the company's anti-corruption policy.
- ☑ Establish initial and regular training and education for Third Party SMIs and relevant company personnel who manage SMI relationships.
- ☑ Routine risk-based monitoring, auditing or other assessment of Third Party SMI relationships for compliance, and regularly certify Third Party SMI personnel for compliance with applicable laws, company policies and relevant contract terms.
- ☑ Undertake appropriate corrective measures if a Third Party SMI fails to comply with the relevant laws, policies and contract terms, or engages in other prohibited conduct.

The AdvaMed/Eucomed Joint Guidance provides a practical roadmap for Medical Technology companies to avoid many of the pitfalls inherent in the sale, marketing or distribution of medical technology products. Equally important, it provides a harmonized approach that represents the thinking of two organizations that represent the increasingly diverse and dispersed Medical Technology industry.

UK Okays Deferred Prosecution Agreements

On April 25, the UK Crime and Courts Bill was entered into law. The new law provides for Deferred Prosecution Agreements (DPAs) to settle a specific list of economic crimes including fraud, bribery and money laundering.

The law's passage brings the US and the UK into closer alignment in the enforcement of anti-corruption laws including the US' Foreign Corrupt Practices Act (FCPA) and the UK Bribery Act.

The argument for the DPA provision in the UK is similar to the case made by the US Department of Justice: that DPAs provide an important incentive for companies to self-report possible or actual violations. In addition, DOJ consistently argues that access to DPAs and Non-Prosecution Agreements (NPAs) expands their enforcement options and enhances their ability to enforce anti-corruption laws. Critics of DPAs and NPAs counter that the enforcement method simply lets companies guilty of economic crimes off easy. The disagreement between advocates and critics has escalated over the past year, as DOJ has increased its use of DPAs and NPAs to resolve FCPA cases.

Most likely, the UK Serious Fraud Office (SFO) and the Crown Prosecution Service will not enter into DPAs until 2014. There are several important distinctions between the UK and US version of DPA. Significant distinctions include the role of the judiciary early on in the settlement process, how self-reporting will play in a DPA settlement, the elements likely to be included in a corporate agreement and the penalties likely to be imposed for any violation of those elements.

A forthcoming code for prosecutors will clarify many of the questions surrounding the new law and its application. CCOs familiar with the US Department of Justice's thinking and procedures related to DPAs and NPAs should pay particular attention to the distinctions between the two enforcement approaches.

GLOBAL ANTI-CORRUPTION ENFORCEMENT TRENDS

Transparency International recently released its Global Enforcement Report 2012, identifying trends in corruption and anti-corruption enforcement globally. Most important for CCOs, the report shows the countries that represent the greatest corruption risks for global companies – and where the greatest compliance and training resources are needed.

Some of the most significant highlights from the report:

- Foreign bribery enforcement actions by the US continued to show a downward trend from 2011 to 2012;
- Nearly 25% of foreign bribery enforcement investigations and actions by the US between 1977 and 2012 involved companies headquartered outside the US;
- Companies showing the highest level of domestic/inbound bribery in 2012 were South Korea, Nigeria and China;
- The four business sectors subject to the most bribery enforcement actions were the extractive industry, manufacturing/service providers, aerospace/defense/security and health care.

While the report doesn't provide any shocks, it does provide a solid snapshot of where the greatest risk of bribery is likely to be and where the most aggressive enforcement is. The report could be especially useful for CCOs of existing operations in analyzing the risk of established facilities or new suppliers. In addition, companies considering international expansion or relocation might want to check the Global Enforcement Report 2012 for insight into some of the business and compliance risks they may face in specific locations.

SUNSHINE GOES GLOBAL

In February 2013, the US Centers for Medicare and Medicaid Services (CMS) published the long-awaited final rule implementing what is most commonly called the Physician Payment Sunshine Act (or just the "Sunshine Act"). The rule affects the interactions between Health Care Professionals (HCPs) and the medical products industry, with the goal of minimizing the potential for conflicts of interest among HCPs.

Pharmaceutical, and to a lesser extent Medical Device companies, have already grappled with state laws that preceded the federal legislation. Compliance problems were significant for companies with operations that crossed state lines and, in the process, crossed regulatory requirements. The federal law will resolve some of those issues even though some states may impose requirements beyond those contained in the new federal Sunshine Act.

The Sunshine Act imposes a number of new requirements that are likely to affect even those organizations that have diligently complied with industry standards for best practices for interactions with health care providers. It will be important to update corporate policies, Codes of Conduct and employee training to reflect the specific requirements of the federal Sunshine Act.

The movement toward greater transparency and accountability in the relationships between medical products companies and HCPs isn't simply an American issue. In fact, "sunshine" is becoming part of any discussion about global regulatory and legislative trends in the health care community. Countries including France, Slovakia, Japan and Australia have enacted legislation regulating the interactions between health care providers and the Life Science industry. Other countries are considering legislation.

Even beyond national laws, international association organizations such as the International Federation of Pharmaceutical Manufacturers and Associations (IFPMA) and the European Federation of Pharmaceutical Industries and Associations (EFPIA) have adopted stringent Codes governing the promotion of medical products to HCPs. EFPIA, for example, includes national industry associations of 32 countries as well as more than 30 Pharmaceutical companies. Member associations commit to implementing the EFPIA codes of conduct related to the promotion of prescription medicines and HCPs and the relationship between the Pharmaceutical industry and patient organizations.

The expansion of Sunshine laws and standards signals the growing importance of transparency in the global business environment. It is a trend that directly affects the compliance of Life Science companies. Compliance with the US Sunshine Act may not meet compliance requirements in all other jurisdictions around the world, but it is a necessity in the US and a signal of what is emerging globally.

Sunshine Act

Engaging New Course Available for All Employees

If you need an easy way to distribute important Sunshine Act training to a wide audience, UL is pleased to introduce a new web-based course, **Physician Payment Sunshine Act**. This course is part of a curriculum in our Health Care Compliance Learning Solution, and includes promoting products to HCPs and reporting adverse events.

View the Course for Yourself

To schedule a demo of the course, contact Pat Thunell at pat.thunell@ul.com or call 609.627.5302.

The Office of Inspector General for the U.S. Department of Health and Human Services (HHS-OIG) issued its Final Rule, effective April 9, 2013, explaining how the Sunshine Law would be implemented.

Pharmaceutical and Medical Device companies (formally known as "covered entities") will be required to begin tracking payments or other transfers of value.

The first disclosure reports for the period of August 1 – December 31, 2013 will be due. On every subsequent March 31st, data must be reported for the preceding calendar year.

The Centers for Medicare and Medicaid Services (CMS) will begin to publicly post the reported data.

About UL Quality, Compliance and Learning

UL Quality, Compliance and Learning is a business line within UL Life & Health's Business Unit. UL is a global independent safety science company offering expertise across five key strategic businesses: Life & Health, Product Safety, Environment, Verification Services and Enterprise Services.

UL Quality, Compliance and Learning 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 Quality, Compliance and Learning 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.