SUNSHINE GOES GLOBAL

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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 of 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.

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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.

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