

Sunshine Overseas: Transparency Rules For Life Sciences

In the wake of the U.S. Physician Payments Sunshine Act (signed into law in March 2010), European, Asian and Australian governmental bodies and trade associations have been rapidly adopting “Sunshine-like” transparency and disclosure requirements applicable to life sciences companies.

These new requirements vary in scope, rigor and reporting deadlines — creating a patchwork of international requirements — and present significant compliance challenges for life sciences companies that conduct ex-U.S. activities such as clinical trials and international advisory boards, among others.

For instance, in December 2011, France adopted legislation similar to the Sunshine Act, requiring that certain health product companies (a term that includes pharmaceutical, medical device and medical supply manufacturers, among others) disclose any contract with certain types of entities, including health care professionals, hospitals, patient associations, medical students, nonprofit associations, companies with media services or companies providing advice regarding health products.

Under a draft decree that would implement the requirements of the French statute if and when finalized, companies would be required to post their disclosures on their own websites using a preset form.

Likewise, the Netherlands' Code of Conduct on Transparency of Financial Relations, which came into force on Jan. 1, 2012, requires pharmaceutical manufacturers to disclose certain payment types by pharmaceutical companies to health care professionals, partnerships or institutions in excess of €500 in the aggregate through a centralized “transparency register” within three months of the end of each calendar year.

The Japan Pharmaceutical Manufacturers Association requires member companies to disclose certain payments to health care professionals and medical institutions on their websites, beginning in 2013. Similar legal or trade association requirements also exist in the United Kingdom, Australia and Slovakia.

Moreover, early signs indicate that additional disclosure requirements may be forthcoming in key emerging life sciences markets. For example, India does not currently impose

reporting obligations on the life sciences industry, but several industry and regulatory initiatives indicate a potential shift in that direction. In an effort to self-regulate, the Medical Council of India has barred its physician members from accepting gifts from pharmaceutical companies since 2009; however, gift-giving practices reportedly remain prevalent.

As a result, the Indian government is developing a code of conduct for the pharmaceutical industry to enhance compliance, according to news sources. Additionally, the Indian income tax department is drafting a provision to tax the amount that pharmaceutical and allied health sector companies spend on gifts for physicians. Physicians accepting such gifts would also be taxed under the proposal. While these initiatives may not yet reflect the breadth of the Sunshine Act, they suggest that India may be preparing to impose stricter disclosure requirements in the near future.

The proliferation of international transparency requirements will increase pressure on multinational life sciences companies to establish global systems of record to allow for efficient, consistent reporting and to promote compliance with applicable disclosure requirements as well as related laws such as the U.S. Foreign Corrupt Practices Act, U.K. Bribery Act and laws protecting the privacy of individual physician payment information.

The U.S. Department of Justice and U.S. Securities and Exchange Commission have recently entered into several settlements with pharmaceutical and medical device companies over alleged misconduct under the FCPA, including impermissible gifts to overseas government-employed physicians. FCPA investigations of several other life sciences companies are currently underway.

In addition, as with the U.S. federal and state transparency and disclosure requirements, there will likely be significant challenges to ensure accurate, complete, consistent and timely reporting, given the breadth of requirements and varying due dates for reports. Many life sciences companies continue to compartmentalize compliance, auditing and monitoring functions on a country-by-country or regional basis, while some companies erroneously believe that development of systems that comply with the U.S. requirements will effectively address the proliferation of global transparency requirements.

Effective global coordination will be difficult to achieve absent a centralized strategy to establish flexible global systems of record that can track payments in accordance with current requirements and accommodate new or modified ones. Robust monitoring and

auditing activities will also be necessary to mitigate risks under the FCPA and other potential theories of liability under global anticorruption regimes.

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