The 2010 Physician Payments Sunshine Act created a new standard of transparency for financial relationships between pharmaceutical companies and health care professionals in the U.S. Now, countries across Europe are following suit by rolling out their own sunshine rules. But these rules differ from country to country, which means navigating a challenging regulatory patchwork of nation-specific regulations, managing press around existing relationships, and dealing with new costs related to compliance.

Hein Van den Bos, partner in Hogan Lovells’ European Life Sciences and Health Care Regulatory Group, and Ron Wisor, partner in Hogan Lovells’ U.S. Health Group, say that while rules are still evolving, the industry needs to know that the transparency enforced by these regulations is here to stay.

While U.S. rules mandate federal-level reporting requirements, the sunshine rules in Europe don’t fall under a single blanket of jurisdiction. The result is different levels of regulation, which means companies must have a country-by-country working knowledge of the requirements. “In some countries, sunshine rules are laid down in the law itself and there are penalties for non-compliance,” says Van den Bos. “But in other countries the rules are (established) by industry or physician codes of conduct and it’s softer regulation, often without any penalties. And in some other countries, there aren’t really sunshine rules at all.”

Another major challenge for companies is navigating sunshine rules within the context of existing hospital and physician partnerships. “Reporting on very specific payment data can oftentimes put a strain on these relationships,” says Wisor. “Part of this challenge is dealing with physicians who may not like their names and the payments they received to be disclosed, even though it may be mandatory. This is both a PR problem and a data privacy issue for those physicians. We’ve seen many well-respected physicians dissolve industry relationships because they didn’t want payments disclosed.”

Van den Bos says the biggest challenge for most companies when it comes to Europe’s sunshine rules is the overall cost associated with compliance. “The cost of sunshine rules is enormous and keeping track of detailed payment data is labor intensive,” he says. “There have been a number
of software tech companies that have tried to come up with solutions. But at the end of the day, this is a very costly exercise. Many of our clients have several employees whose exclusive job is to track sunshine act payments.”

Van den Bos and Wisor warn that the new rules – which give journalists, competitors, and even the government visibility into payment information – may lead to an increase in investigations. “Once the government knows what payments have been made, that can often trigger deeper investigations,” Wisor says, adding that while these new reporting mechanisms provide information about payments and relationships, they don’t tell the larger story. “That can lead to flashy headlines about those relationships, but no context.”

While the overall reach of Europe’s sunshine rules isn’t yet clear, Van den Bos and Wisor say it is essential that companies stay current on new developments, and make sure they understand the potential implications sunshine rules could have on their businesses. “I urge all of my clients to be evaluating their payments closely to make sure that they comply with anti-kickback statutes and the other laws that govern those financial relationships,” Van den Bos says. “It’s not just about complying with the technicalities of the sunshine rules, but also fully understanding and appreciating that all of their financial relationships are now open to public scrutiny.”

For additional insights from Van den Bos and Wisor on Europe’s new sunshine rules, watch the video above.

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