

## Sunshine Abroad: **International Transparency**



### **Holland. The Original Cool.**

By D. Jeffrey Campbell, Esq. and Brian P. Sharkey, Esq.

October 23, 2013

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“Holland. The Original Cool.” That is the slogan of a recently launched marketing campaign by the Netherlands Board of Tourism and Conventions and its partners. The campaign is intended to show travelers that what is now considered “cool” in other parts of the world, e.g., green energy and organic farmers’ markets, has been part of the Dutch culture for centuries. Like that historical cultural experience, the Dutch pharmaceutical industry has also been ahead of the curve with respect to self-imposed transparency requirements. Although there may be some disagreement about how “cool” such disclosure requirements are, there can be no dispute that the pharmaceutical industry prefers an industry-generated solution over a governmental-imposed transparency scheme. There also can be no dispute that the Dutch pharmaceutical industry has proceeded with self-regulatory transparency measures far more quickly than its counterparts around the world.

In 2009, the Dutch Minister of Health requested that the pharmaceutical industry develop a mechanism to disclose financial relationships between industry members and Dutch healthcare professionals. This request was motivated not only by the U.S. Sunshine Act, but

also by public and political attention in the Netherlands that had focused on the relationship between industry and healthcare professionals. As a result of the request, the Dutch pharmaceutical industry worked with healthcare professionals in a cooperative manner to develop a self-regulatory system that addressed the issues and concerns of all stakeholders, ultimately developing a code that includes disclosure requirements for pharmaceutical companies.

The Dutch code requires pharmaceutical companies to report in 2013 on amounts spent in support of healthcare practitioners -- on an individual level -- in 2012. Companies must disclose two different types of financial relationships with healthcare professionals: 1) service agreements; and 2) sponsorship agreements of meetings between a company and associations of professionals/institutions that directly or indirectly improve healthcare to patients or promote medical science. There are five types of service agreements: 1) consulting; 2) advisory; 3) speaker; 4) non-speaker research; and 5) other.

The substance of the mandated disclosure depends upon the nature of the agreement, service, or sponsorship. For a service agreement, the company must provide the personal information of the healthcare professional, including: name; specialization; work address; amount paid to the professional; and name, business address and/or registration number of the association or institution that employs the healthcare professional. For sponsorship agreements, the company must disclose the name, business addresses and registration number of the recipient group, along with the amount paid to the group during the calendar year. Not

all financial relationships between companies and Dutch healthcare professionals must be disclosed. Rather, the Dutch Code set the threshold amount at 500 Euro per calendar year.

The first reports have already been submitted by companies to a central register set up by the Dutch pharmaceutical group. Disclosures were made pursuant to the following disclosure schedule:

- companies were to upload the requisite information to the central register by the end of the first quarter of 2013;
- healthcare practitioners and healthcare organisations could review the accuracy of the information submitted by pharmaceutical companies until April 12, 2013;
- to the extent there were any disputes or discrepancies regarding the reporting of financial support, they were addressed between April 12, 2013, and April 19, 2013;
- the register was made available to the public on April 25, 2013, on the website [www.transparantieregister.nl](http://www.transparantieregister.nl)

The website can be searched by healthcare practitioner, but it cannot be searched by company. Thus, if a person were interested in learning how much (fictional) “Dr. John Smith” received from pharmaceutical companies in 2012, that person could search for Dr. John Smith and see how much support was given to him. However, a similar company-based search cannot be performed on the website if a person was interested in learning how much (fictional) “Pharma Company X” spent on Dutch healthcare professionals in 2012.

The Dutch industry group issued a press release on April 25, 2013 – the day the register was made available to the public – to tout its success in achieving a system that provided

greater transparency into the relationships between the pharmaceutical industry and healthcare professionals. In that regard, the press release pointed out that the Dutch system actually provided more transparency than the scheme promulgated in the United States under the Sunshine Act. The release also stressed that the Netherlands was leading the way in Europe with respect to self-regulation and that other countries, including the United Kingdom, were looking to the Dutch scheme as a model.

Not only did the press release trumpet the development of the Dutch transparency system, it also provided data about the financial information that had been disclosed by companies to the register. According to the press release, more than fifty pharmaceutical companies submitted reports. Combining those reports from all the reporting pharmaceutical companies revealed the following: 1) there were approximately 7,600 financial relationships reported involving more than 2,100 physicians and 1,200 institutions and associations; 2) the total reported value of those relationships was more than 30 million Euro; and 3) of the approximately 30 million Euro, approximately 4 million went to individuals and 25 million to institutions and associations. While acknowledging the success of its system, the Dutch industry group acknowledged that there could be minor errors in the registry, but pledged to work with all the relevant stakeholders to clarify any unclear issues and to further improve the system.

One of the potential difficulties associated with being a trailblazer is having to adjust when peers begin to catch up. The Dutch pharmaceutical industry may be experiencing that now in light of the June 24, 2013, adoption of a disclosure code by the European Federation of

Pharmaceutical Industries and Associations (“EFPIA”). EFPIA’s code requires pharmaceutical companies to publicly report their 2015 financial relations with healthcare professionals and organisations in 2016. The code further requires that member associations incorporate the provisions of the EFPIA disclosure code into their own national codes. As a member of EFPIA, the Dutch industry association is bound to incorporate EFPIA’s disclosure provisions into its existing code. Thus, to the extent that it differs in a material way from EFPIA’s new reporting provisions, the Dutch system must be harmonized with EFPIA’s new disclosure Code. In view of the proactive way the Dutch pharmaceutical industry has dealt with the issue of transparency, it will undoubtedly find an innovative approach to making its code consistent with EFPIA’s code.