Client Alert

July 2013

Sunshine in Europe for Pharmaceutical Companies?

On June 24th, the European Federation of Pharmaceutical Industries and Associations (EFPIA) adopted a "Disclosure code of transfers of value to healthcare professionals and organisations " (the Transparency Code). The Transparency Code supplements the two current EFPIA codes of conduct, i.e., the "Code of Practice on the promotion of prescription-only medicines to, and interactions with, healthcare professionals" and the "Code of Practice on relationships between the pharmaceutical industry and patient organisations." Until now, only the public disclosure of contracts for service with, and financial and other support provided to, patient organisations was mandated by EFPIA. The new code is a reply to the society's expectations for greater transparency in the interactions between the healthcare sector and the pharmaceutical industry.

Mandatory disclosure under the Transparency Code applies to transfers of value made as of 1 January 2015, so pharmaceutical companies have time to get organised with regard to the collection and publication of the relevant information. This, however, may prove a challenge in light of the different requirements that still exist in Europe and in light of data privacy rules.

Harmonisation in Europe? The EFPIA Transparency Code follows the adoption or near adoption of legal provisions in several EU countries (such as Denmark, France, Germany, the Netherlands, Portugal, Slovakia and the United Kingdom) and therefore does not ensure a full harmonisation of the transparency rules in Europe. Yet, it imposes transparency requirements and creates some harmonisation in the European countries where such rules do not yet exist (and there still are many such countries), as well as in Russia, Serbia, Switzerland, Turkey and Ukraine.

Addressing data privacy issues? The Transparency Code does not address the data privacy issues that public disclosure of personal data can raise, except for suggesting that privacy protection is a reason for reporting requirements on an aggregate rather than an individual basis. The national transparency codes may deal with those issues, for example by explaining to companies how best to handle them.

No Europe-wide transparency obligations yet exist for medical device or cosmetic companies, but such obligations have been imposed locally in some jurisdictions, such as in France.

Applicable National Transparency Codes

As with other codes of conduct, the provisions in the EFPIA Transparency Code will be imposed on pharmaceutical companies through the adoption of transposing transparency codes by the national trade associations that are EFPIA members. The national transparency codes obviously may not conflict with national legal provisions if national legal provisions have been adopted, but they may impose more stringent rules than the EFPIA Transparency Code or address issues that are not dealt with in the Transparency Code. Deviations from the EFPIA Transparency Code, however, must be approved by EFPIA.

As a general rule, companies are bound by the national transparency code of the country where both the recipient and the company are established; if they are located in different countries, the transparency code of the country of the company applies.

Scope of Application

The scope of application of the Transparency Code is very broad, on several counts. It applies to any transfers of value from EFPIA member companies to healthcare professionals and healthcare organisations.

Companies. When used in EFPIA codes of conduct, the term "company" refers to the companies that are members of EFPIA, including the biotech arm of EFPIA (EBE) or the organisation's vaccine arm (VMA). It refers to the company itself and to its parent companies, subsidiaries and even affiliates who have accepted the codes.

Recipients. Schedule 1 of the Transparency Code defines the terms "healthcare professional" (HCP) and "healthcare organisation" (HCO) very broadly. They may include any third parties who, in the course of their professional activities, may prescribe, purchase, supply or administer a medicinal product including, for example, any official or employee of a government or any other organisation.

Transfer of value. Transparency is required for the transfers of value listed in Article 3, regardless of the purpose of the transfer of value or whether it is direct or indirect (by contractors, agents or partners) or in cash or in kind. The transfers of value subject to disclosure depend on the recipient. Hospitality (registration fees, transportation expenses and accommodations) in relation to a scientific, promotional or professional event and fees for services must be disclosed when paid to both HCPs and HCOs. On the other hand, only donations, grants and sponsorship to HCOs must be disclosed. Thus, small gifts, samples, items of medical utility and promotional items are not included. Moreover, certain transfers of value are expressly exempted, i.e., those relating to over-the-counter drug products or to purchase agreements.

Europe. The Transparency Code covers more than the European Economic Area, as EFPIA's remit extends to Russia, Serbia, Switzerland, Turkey and Ukraine.

In Practice

What? The information to be disclosed is described on the disclosure form. It includes (1) the name, address and registration information of the HCP or HCO and (2) the amounts transferred to that HCP or HCO, aggregated per category (hospitality, fees for service, etc.). Itemised disclosure must be available upon request by an authority or the recipient concerned. Aggregate disclosure of the amounts paid per category is allowed in case individual disclosure is prohibited by law, and it is mandated for transfers of value relating to research and development activities. In such cases, the number of HCPs or HCOs and percentage of all recipients as well as the aggregate amount must be disclosed.

Companies also have to publish the methodology they used for meeting the transparency obligation.

When? Public disclosure must occur once per year, by 30 June. The first disclosures will occur in 2016, covering transfers of value made during 2015.

How? Disclosure must be done using the form contained in Schedule 2 of the Transparency Code and in the language required by the relevant national transparency code.

Where? Companies must disclose the information on their websites or on a central platform (government, regulator, professional body, etc.).

For how long? On the one hand, the disclosed information will remain accessible to the public for a minimum of three years from the time such information is initially disclosed. On the other hand, companies must keep the records of the disclosures for a minimum of five years after the end of the reporting period, subject to a shorter period mandated by data privacy rules.

Enforcement

Enforcement of the Transparency Code is left to the national trade associations through the enforcement of the national transparency codes. The publication of national decisions is encouraged, in particular for cases that may have precedential value or those that are of international interest. EFPIA will report annually on the code's implementation in various countries and on enforcement actions taken.

Implementation by Companies

The new EFPIA Transparency Code will come into effect in a European and worldwide environment that already has several transparency regimes operating at varying levels of stringency.

Obviously, the EFPIA transparency rules will not prevail over the legal provisions that, in some countries, set up more stringent transparency regimes. Most likely, the number of those countries will increase, and pharmaceutical companies will be left with an even larger and more complicated patchwork of requirements with which to comply. Most companies active in Europe have already begun to get organised internally in order to secure the collection of the relevant information. This exercise, however, is a challenge, as the scope of transparency obligations and the information to be collected is not uniform throughout Europe.

A similar issue exists for global companies that operate on both side of the Atlantic Ocean. The overall objectives of the new EFPIA Transparency Code accord nicely to those of the United States' National Physician Payment Transparency Program, though there are numerous discrepancies in the regimes' formats.

The US "sunshine" program was established after the US Congress enacted the Physician Payments Sunshine Act in March 2010. As such, its payment disclosure provisions are mandatory for all manufacturers of drugs, devices, biological products and medical supplies who operate in the United States. Like the Transparency Code, US law defines "covered recipients" of manufacturer payments, but does so somewhat differently. In the United States, "covered recipients" include a variety of physicians (i.e. doctors of medicine and osteopathy, dentists, podiatrists, optometrists and licensed chiropractors) as well as teaching hospitals (i.e. hospitals that receive certain US government funding).

Both the EFPIA Transparency Code and the US sunshine program define "transfers of value" broadly, but then provide different exemptions and reporting requirements for different types of payments. For example, gifts and promotional items are not exempt from reporting under US law, while certain research-related payments are subject to delayed reporting. Finally, enforcement under the two regimes is very different: in the United States, a knowing failure to report payments in a timely, accurate and complete manner can subject a company to substantial fines of up to $1 million per year.

How Hunton & Williams Can Help

Hunton & Williams' Food and Drug practice has extensive experience developing and advising on comprehensive pharmaceutical compliance programs, including those required by transparency laws and codes of conduct. Our lawyers have helped guide pharmaceutical companies through difficult investigations, settlements and post-settlement compliance activities. We have advised pharmaceutical clients on a wide array of enforcement and regulatory proceedings. If you need assistance in developing, revising or implementing your organisation's compliance practices, please contact us.

Contacts

Geneviève Michaux
gmichaux@hunton.com

D. Kyle Sampson
ksampson@hunton.com