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Client Alert

FDA and Life Sciences

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European Federation of Pharmaceutical Industries and Associations (EFPIA) Launches New Financial Relations Disclosure Code

Member Organizations Will Have Tracking and Reporting Obligations for Certain "Transfers of Value" to HCPs and HCOs

On July 2, 2013, the European Federation of Pharmaceutical Industries and Associations (EFPIA or "the Federation") officially announced its newly-approved and highly anticipated Disclosure Code (the "Code"). The Code creates obligations for EFPIA member companies, and companies that are members of an EFPIA member association, to track and report certain transfers of value to health care professionals (HCPs) and health care organizations (HCOs). Tracking must begin in 2015, for mandatory reporting in 2016.

Background

EFPIA members include pharmaceutical industry associations in over thirty European nations and nearly forty individual pharmaceutical manufacturers. Through these two membership channels, EFPIA's polices and codes apply to roughly 1,900 pharmaceutical manufacturers. Due to its broad membership, EFPIA is able to exert significant influence over European pharmaceutical codes and, consequently, pharmaceutical manufacturers operating in Europe.

EFPIA recognized the need for uniform disclosure requirements across Europe, especially as it observed the passage of the U.S.'s Patient Protection and Affordable Care Act in March 2010, and the federal Physician Payments Sunshine Act contained therein. Absent a uniform law, each European nation could develop a splintered set of transparency laws requiring manufacturers to track and report different transfers of value in each country. In response to this concern, EFPIA worked with its members and other stakeholders to develop the Code of Practice, as part of its larger Transparency Initiative.

Tracking Requirements

EFPIA member associations are required to transpose into their national code by December 31, 2013, tracking and disclosure requirements that are no less rigorous than those contained in the new Code. EFPIA expects the resulting national codes to be generally the same, but also recognizes that there may be slight differences -- to the extent necessary to comply with national law or regulation only -- around

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such issues as the reporting of food and beverage spend. For example, the Code states that, during the transposition process, each member association must set a threshold for what constitutes a "modest meal." Meals that do not have a monetary value exceeding this threshold are not required to be tracked and/or reported. Likewise, the disclosure language (*e.g.*, German, English, Spanish, etc.) may vary to conform with that prescribed in national codes, as may member association sanctions.

Starting January 1, 2015, each manufacturer subject to the Code (which includes both EFPIA manufacturer members and members of EFPIA association members) will be required to track transfers of value related to human prescription drugs, at three distinct levels. These are the aggregate level, the named individual HCO level, and the named individual HCP level. These levels of tracking must occur for the following types of relationships/transfers of value, whether made directly or indirectly:

Aggregate (where information, for legal reasons, cannot be disclosed on an individual basis, and for the categories below)

- Research & Development: Transfers of value to HCPs/HCOs related to the planning and conduct of:
  - Non-clinical studies (as defined in the Organization for Economic Cooperation and Development (OECD) Principles of Good Laboratory Practice)
  - Clinical trials (as defined in Directive 2001/20/EC)
  - Non-interventional studies that are prospective in nature and that involve the collection of patient data from or on behalf of individual, or groups of HCPs, specifically for the study

Individual HCO

- Donations & Grants to HCOs
- Contribution to costs of events
  - Sponsorship agreements with HCOs and third parties appointed by HCOs to manage an event
  - Registration fees
  - Travel & accommodation
- Fee-for-service & consultancy
  - Fees
  - Related expenses agreed in the fees for service or consultancy contract

Individual HCP

- Contribution to costs of events
  - Registration fees
  - Travel & accommodation
- Fees for service & consultancy
  - Fees
  - Related expenses agreed in the fees for service or consultancy contract

A standardized reporting model template is provided on the EFPIA website (http://www.efpia.eu).

Disclosure Requirements

Data collected for transfers of value occurring in year 2015 must be disclosed, as yearly totals, within 6 months of that year's end (*i.e.*, by the end of June 2016). The disclosures may appear on each company's website (or on a common website, e.g., a national government or national member association website, if one exists) and must be accompanied by a document stating the methodologies used in preparing the disclosure. The methodologies requirement appears to be similar to the voluntary inclusion of an "assumptions document" under the Physician Payments Sunshine Act mentioned above.

EFPIA has not given an indication of whether it intends to aggregate the date from companies reporting under the Code. However, without a central repository for the disclosures, we believe that it is unlikely the Federation will take such steps.

Finally, please note that several minor amendments also were made to EFPIA's HCP Code, to reflect its general prohibition on gifts, as well as its exceptions for items below the nationally-set threshold for "meals and drinks" and for inexpensive items of medical utility (not offsetting the routine business practices of the recipient) aimed at the education of HCPs and patient care.

For more detailed coverage of international marketing and disclosure compliance issues, click here to access information about King & Spalding's International Marketing and Disclosure Compliance Group, a subscription-based membership group that receives access to a growing on-line repository of transparency requirement-related materials. These include national transparency laws and codes and industry code source materials – generally with translations; analyses of marketing, promotion, and advertising laws and industry codes of conduct; regular email updates regarding new developments, as well as detailed conference calls and PowerPoint presentations on such developments; comparison charts of country and industry trade group requirements and related tools, and; a members-only website --, as well as access to King & Spalding professionals working on international pharma matters.

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