The new EFPIA code on disclosure of transfers of value: a meaningful path to transparency?

Vincenzo Salvatore, Hae-Won Min Liao and *Catherine Starks* discuss the new code.

The European Federation of Pharmaceutical Industries and Associations issued on 24 June a new code on the disclosure of transfers of value from pharmaceutical companies to healthcare professionals (HCPs) and healthcare organizations (HCOs) in response to an increasing demand for transparency in the interactions between the parties discussed in the code.

The code applies to EFPIA member companies and national pharmaceutical member associations. The first reporting period will be the 2015 calendar year. Disclosures must be made by June 2016 on a member company's website or other publicly available platform.

The code adds to a patchwork of transparency requirements imposed on pharmaceutical manufacturers by various laws and regulations, such as the Physician Payment Sunshine Act in the US. However, while the code supplements domestic laws, it is not a source of binding rules, and enforcement will be left to national member associations, which lack the enforcement tools that state authorities can rely upon. Thus, whether the code can achieve its intended objective of increased transparency will depend on the extent to which member associations adopt and flesh out the code's requirements.

At a high level, the code requires pharmaceutical companies to report certain "transfers of value" provided to HCPs and HCOs who primarily practise in Europe.

Specifically, the code states:

each Member Company shall document and disclose Transfers of Value it makes, directly or indirectly, to or for the benefit of a Recipient.

The term "transfers of value" means, in part:

[d]irect and indirect transfers of value, whether in cash, in kind or otherwise, made, whether for promotional purposes or otherwise, in connection with the development and sale of prescription-only Medicinal Products exclusively for human use.

Generally, member companies must report transfers of value only to the extent that they fall within specified categories. For transfers of value provided to HCOs and/or HCPs, member companies must report fees for service along with contributions to costs related to promotional, scientific, or professional events organized or sponsored by or on behalf of a company. Donations and grants, which may not be provided to individual HCPs, may nonetheless be provided to HCOs and must be reported pursuant to the code. Importantly, the code excludes a number of transfers of value from the reporting obligation, including those that:

(1) are solely related to over-the-counter medicines;
(2) are part of ordinary-course purchase and sales of medicinal products with HCPs; or
(3) do not fall within the categories identified by the code.

In general, transfers of value may be aggregated on a category basis provided that an itemized disclosure is available upon request to the recipient and relevant authorities. Notably, however, itemized disclosure is not required for research and development payments nor for payments that cannot be disclosed on an individual basis for legal reasons.

Member associations must transpose the provisions of the code into their national codes in full, except where there is a conflict with national law or regulation. Also, member associations must establish procedures for receiving, processing and adjudicating complaints (which may be lodged with a member association or with EFPIA) and designate a national body to handle such complaints. Importantly, the code does not specify the exact sanctions to impose for violation of the code's requirements, but, instead, states:

Sanctions should be proportionate to the nature of the infringement, have a deterrent effect, and take account of repeated offences of similar nature or patterns of different offences. A combination of publication and fines will generally be considered to be the most effective sanction; however, each Member Association may use any other appropriate sanction to enforce its code.

Member associations must also provide to the EFPIA code committee an annual report that summarizes efforts undertaken to implement, develop, and enforce the code within the applicable year. The committee will monitor member associations' adoption of national codes, but otherwise, the code does not call for a central body to monitor or enforce compliance nor does it require member associations to establish analogous enforcement or monitoring bodies at the national level.

In the absence of national law, considerable discretion is assigned to member associations with respect to the sanctions that they adopt, as well as the scope of their procedural requirements for adjudicating allegations of noncompliance. There is an open question of how far a member association will implement the code's requirements, and the answer may depend on the constituency of, and resources available to, an individual member association. While the EFPIA code committee conducts a certain level of monitoring, the adoption of the code's provisions lies in the hands of member associations.

At the member company level, depending on the sanctions and other provisions adopted by the governing member association, the cost of compliance with the code could outweigh the benefits, especially in light of costly efforts currently undertaken by many pharmaceutical companies to comply with other emerging transparency laws, which already incorporate specific penalties for noncompliance. For example, the US Physician Payment Sunshine Act includes civil monetary penalties as much as $100,000 per payment that is not fully and accurately reported. Even there, however, the maximum annual penalty is only $1 million, and no sanction has yet been imposed because the first annual reports are not due until 31 March 2014.

Even if a member association does not adopt significant sanctions, there is the threat of reputational damage if a member company is found to be non-compliant with the code, particularly because the code states that sanctions should incorporate both fines and publication. However, whether these reputational risks present incentive enough to compel compliance is an open question. Furthermore, because the code does not call for central monitoring or enforcement bodies, it is unclear whether even significant sanctions, reputational or otherwise, can motivate manufacturers to comply with yet another set of transparency requirements if no one is, in fact, watching.

In short, in its current form, the code provides a voluntary framework that must be further developed by member associations at the national level to complement national legislation and fill legislative gaps. Success of this initiative will greatly depend on the ability of member associations to transpose the code into national codes of practice before the 2015 reporting target and ensure a consistent approach, accurate monitoring, and adequate enforcement of the revised rules governing all transfers of value between the pharmaceutical industry and healthcare professionals.

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