Sunshine spreading across the Atlantic and over Europe

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Abstract

The quest for transparency in the relationships between life sciences companies and healthcare professionals is quickly becoming a global movement. Reporting requirements for financial interactions have been prevalent in the United States for many years, but the movement is spreading throughout the world to places like Japan, Australia, and Europe. In France, the government passed a law that imposes burdensome reporting requirements. Industry groups across Europe, most notably the European Federation of Pharmaceutical Industries and Associations, are acting aggressively to try to forestall more government laws by adopting industry-developed disclosure systems. These activities will affect many different segments of the European healthcare system.

Keywords: Pharmaceutical companies, Medical device companies, Regulatory compliance, French Sunshine Act, European Federation of Pharmaceutical Industries and Associations, Financial transparency

The trend towards transparency in the relationships between life sciences companies and healthcare professionals (HCPs) is quickly accelerating on a global basis. For many years, the focus of life sciences transparency has been on the United States because of state-level reporting requirements. That focus has only been heightened by the federal government's release of final regulations implementing the Sunshine Act provisions of the Patient Protection and Affordable Care Act, which requires federal-level reporting in 2014. However, the transparency movement is not confined to the United States. It is spreading quickly throughout the world, including Europe.

As this trend extends into Europe, it is accompanied by a debate about how to achieve the goals of transparency. On one hand, supporters of legislation argue that government-imposed disclosure requirements will increase transparency while lowering healthcare costs and reducing corruption. Advocates of this approach point to France's version of a Sunshine Act as a model for additional legislation. On the other hand, supporters of self-regulation contend that an industry-created reporting system holds greater potential for uniformity across borders and will result in a more efficient transparency system. The most important development for this approach is the June 2013 adoption by the European Federation of Pharmaceutical Industries and Associations (EFPIA) of the *EFPIA Code on Disclosure of Transfers of Value From Pharmaceutical Companies to Healthcare Professionals and Healthcare Organisations* (Disclosure Code).[1]

It is imperative for all those involved in the European healthcare industry, including medical writers, to be aware of these governmental laws and industry codes, because they will have a significant, wide-ranging impact on many professions.

Legislative approach

In December 2011, France enacted *LOI n 2011–2012 du 29 décembre 2011 relative au renforcement de la sécurité sanitaire du médicament et des produits de santé* (French Act).[2] The French Act requires pharmaceutical and medical device companies to publicly disclose agreements they have with HCPs and benefits provided to HCPs and various entities. Under the French Act, the details of those requirements were to be included in a decree that was to be in effect by 1 August 2012. Although draft decrees were circulated in 2012, the final decree was not issued until 21 May 2013.[3] The French Ministry of Health and Social Affairs also published a Circular, dated 29 May 2013, that provides guidance about the final decree.[4]

The final decree imposes two main types of disclosure requirements on life sciences companies: (1) all agreements, except for commercial sales agreements of goods and services, that they have with defined individuals and entities; and (2) certain benefits given to those individuals and entities. The list of covered recipients includes:

- Healthcare professionals (e.g. physicians, nurses, but the disclosure requirements do not

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apply to the reporting company's own employees);
- Associations of HCPs and associations of HCP students;
- Students for relevant occupations;
- User associations of the health system (public or private);
- Health facilities;
- Foundations, learned societies, and consulting companies or organisations in the health sector;
- Publishing companies: press, radio, television, and on-line media;
- Publishers of prescription and dispensing software; and
- Legal entities contributing to the initial training of HCPs.

According to the Circular, the inclusion of the 'publishing companies' category reflects the government's intention to focus on and extend the reporting obligation to the scientific and medical press, as well as the specialist press intended for HCPs.

For agreements, companies must disclose the following information:

- The identity of the parties to the agreement:
  - For HCPs: name, professional address, qualifications, title, specialty, and registration number with the relevant professional board.
  - For healthcare students: name and educational institution.
  - For legal entities, like associations, health institutions, etc.: name, corporate purpose, and registered address.
- The date the agreement was signed.
- The subject matter of the agreement (which should be phrased in a manner to protect confidential and trade secret information).
- If the agreement involves a promotional or scientific event, the program of the event.

For benefits, companies must disclose each of the benefits that they provide, whether direct or indirect, in kind or in cash, to the aforementioned recipients if the benefits are equal to or exceed ten euros, inclusive of VAT. When disclosing benefits, companies must identify the recipient and the recipient's personal information in the same manner as for agreements (e.g. name, address, title); the amount, date, and nature of each benefit; and the time period (either the first six months of a year or the latter six months) during which the benefit was received. The Circular expanded upon the definition of benefits, explaining that in-kind benefits include gifts, donations of equipment, invitations, hospitality expenses, or payment for trips, as well as commissions, discounts, rebates, or repayment of expenses.

All of this information about benefits and agreements will eventually be disclosed, in French, on a to-be-established public website. A public authority will create and operate the website, and the information will be available for a period of 5 years.

As to timing, companies must report the required information for agreements to the public authority within fifteen days of the signing of the agreement. For benefits, however, the requisite information must be submitted bi-annually: by August 1 for benefits provided from January to June, and by February 1 for benefits provided from July through December of the preceding year. Once the website is operational, the information about benefits provided and agreements made during the first part of a calendar year will be made public by October 1 of that year, and benefits provided and agreements made during the second part of a year will be published by April 1 of the following year.

Because the public website is not yet operational, the decree established an interim reporting process. The decree provides that by 1 June 2013 (ten days after the decree was issued), companies were to submit all reportable benefits and agreements from calendar year 2012 to the appropriate national council of the healthcare professionals association (e.g. National French Medical Association). Companies were then to submit the required information for agreements and benefits covering the first six months of 2013 to the appropriate national council by August 1. All of this information covering both 2012 and the first six months of 2013 was then to be published by 1 October 2013, in two different locations: the website of the reporting company, and the website of the relevant French national council. The next reports are due on 1 February 2014, to cover agreements and benefits for the last six months of 2013.

A number of significant questions remain unanswered, for example, whether the reporting obligation applies only to companies based in France or also to those based outside of France but that do business in France or otherwise interact with French HCPs. Regardless, the act and its implementing decree will have an immediate and enormous impact on transparency reporting in France.

The French experience may also serve as a model for other European countries that are pursuing, or considering, a legislative approach to transparency. For example, Denmark currently has some limited reporting requirements, whereby pharmaceutical companies must identify relationships they have with HCPs, but they do not have to provide

financial transparency information like that required in France. However, the current Danish scheme is expected to be changed by new legislation in 2013. This legislation is expected to apply to both pharmaceutical and medical device companies. Under the anticipated legislative scheme, it is HCPs – not the life sciences companies – who will have the primary obligation to report their financial interactions with industry. Other European countries with existing financial transparency reporting requirements include Portugal, Slovakia, and Estonia, though their current requirements are not as extensive as the French system.

Self-regulatory approach

In contrast to, and, in direct response to, the legislative approach taken by some European governments, EFPIA has been proactive in seeking to implement an industry-driven approach to transparency across Europe. It is important to note that while EFPIA has been aggressive in adopting its Disclosure Code, the medical device industry has not been as active. Unlike EFPIA, which is the representative body of the European pharmaceutical industry, Eucomed, which represents the medical device industry in Europe, has not adopted reporting requirements and has not made any public announcements that it has plans to implement a similar system.

EFPIA's members include 40 pharmaceutical companies and the national industry associations of 33 countries. Before the adoption of its Disclosure Code in June 2013, EFPIA had two relevant codes: (1) EFPIA Code on the Promotion of Prescription-Only Medicines to, and Interactions With, Healthcare Professionals;[5] and (2) EFPIA Code of Practice on Relationships between the Pharmaceutical Industry and Patient Organisations.[6] These Codes, like the Disclosure Code, apply to EFPIA member companies, their subsidiaries, and any companies affiliated with EFPIA member companies or their subsidiaries, and they establish minimum standards that national organisations must have in their own national codes.

The EFPIA Code on Interactions with Healthcare Professionals does not contain reporting or disclosure requirements, but encourages companies to make publicly available information about donations, grants, or benefits in kind made to institutions, organisations, or associations comprised healthcare professionals or that provide healthcare or conduct research. The EFPIA Code on Relationships with Patient Organisations contains reporting requirements about support provided to patient organisations. The disclosure requirements apply to activities commenced as of or ongoing on 1 January 2012, and the first reports were required to be made public by the end of the first quarter of 2013.

EFPIA, however, revolutionized its approach to transparency at its 2013 Annual Meeting when it adopted the Disclosure Code. With the Disclosure Code, EFPIA for the first time is requiring individual-level HCP reporting. Specifically, the Disclosure Code requires companies to publicly report, in 2016, their 2015 financial relations with HCPs and healthcare organisations. The Disclosure Code provides that company disclosures must be made on an annual basis, with each reporting period covering a full calendar year. Companies are required to make their disclosure within six months following the end of the reporting period.

The Disclosure Code requires companies to disclose in one of two ways: (1) on their own website; or (2) on a central platform, which could be developed by the national member association or local public authority. The disclosures themselves must be made in the local language, though companies are encouraged to also make the disclosures in English if that is not the local language.

To assist companies with their disclosure obligations, EFPIA adopted a multi-coloured, multi-column XL spreadsheet template that offers a structure for how all the information should be reported. Companies must report, on the individual level, their transfers of value provided to HCPs (members of the medical, dental, pharmacy, or nursing professions) and healthcare organisations in the following categories:

- Donations and grants (for healthcare organisations only);
- Contributions to costs related to events (registration fees; travel and accommodation, to the extent permissible;
- For organisations only, sponsorship agreements to manage an event ('events' are defined to include all promotional, scientific, or professional meetings, congresses, conferences, symposia and other similar events, like advisory board meetings); and
- Fees for service and consultancy.

The Disclosure Code defines transfers of value to include direct and indirect transfers, whether in cash, in kind, or otherwise. Significantly, transfers of value do not include gifts of medical utility, meals and drinks, medical samples, and money provided by a company to a HCP as part of an ordinary purchase and sale of a medicinal product.

Companies must also report, for the same categories outlined above, the aggregate amounts they spend during the reporting period. Moreover, companies are required to report, on an aggregate basis, their research and development transfers of value to HCPs and healthcare organisations, which includes support relating to the planning or conduct of (1) non-clinical studies, as defined in OECD Principles on Good Laboratory Practice; (2) clinical trials, as defined in the governing directive of the European Commission; and (3) non-interventional studies pursuant to EFPIA's HCP Code.

The Disclosure Code requires formal transposition of these new requirements into the national codes of EFPIA's member associations by 31 December 2013. Member associations are expected to incorporate the Disclosure Code's provisions into their own national codes in full, except when EFPIA's provisions conflict with governing national law. In such instances, e.g. France, EFPIA will permit deviations from the Disclosure Code, but only to the extent needed for compliance with the controlling national legislation.

While EFPIA's activities may have the most significant long-term consequences for transparency within the European pharmaceutical industry, several countries already have experience with transparency reporting. For example, the code of the Netherlands industry group required its members to report in 2013 on amounts spent in support of healthcare practitioners – on an individual level – in 2012. Similarly, members of the British industry group disclosed their relationships with HCPs for the first time in 2013 for 2012 data but, unlike their Dutch counterparts, they only had to report at the aggregate level. As members of EFPIA, however, the Dutch and British industry associations are bound to incorporate EFPIA's disclosure provisions into their codes by the end of 2013.

Impact of transparency laws on medical writers

Many sectors of the life sciences industry in Europe will be tracking whether more governments adopt transparency laws or whether they will defer action and wait to see how EFPIA's approach is implemented across the continent. One such group will be medical writers, as these types of transparency measures could have a direct impact on their activities. In that regard, France's law explicitly covers agreements made with and benefits provided to publishing companies in the healthcare field. The nature and extent of the impact of the French law on medical writers cannot be predicted at this time, but it will start to become apparent as pharmaceutical and medical device companies grapple with their reporting obligations and recipients react to the public reporting of their financial dealings. Medical writers would also be well advised to monitor whether additional European countries, be it in the form of legislation or self-regulation, require the public disclosure of their financial relationship with life sciences companies and, if it is required, how such public disclosure affects the underlying relationship.

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