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Here Comes The Sunshine Act — This Time, In Europe

Law360, New York (June 25, 2013, 1:12 PM ET) -- When it comes to mandating transparency in the relationships between life sciences companies and health care professionals, it appears that Europe will not be outdone by the United States. Although compliance professionals at global pharmaceutical and medical device companies lately have been fixated on the recently released final regulations implementing the Sunshine Act provisions of the Patient Protection and Affordable Care Act, a U.S.-centric approach will fail to address the growing demands of European transparency regulations.

The trend toward greater transparency imposed by governments has accelerated over the past nine months, with France, Portugal, Denmark and Slovakia leading the way in Europe.

On May 21, 2013, the French government issued its long-awaited decree to implement its Sunshine Act, which was passed on Dec. 29, 2011. The French decree requires pharmaceutical and medical device companies to report agreements they have with health care professionals, as well as benefits they provide to them. Several aspects of the decree are controversial, especially in terms of the low thresholds for reporting and the onerous burdens that the reporting requirements impose on life sciences companies.

The final decree imposes two main types of disclosure requirements on pharmaceutical and medical device companies: all agreements, except for commercial sales agreements of goods and services, that they have with certain categories of individuals and entities and certain benefits given to those individuals and entities.

Specifically, companies must disclose the existence of agreements with and benefits provided to the following:

- Health care professionals (e.g., physicians, nurses, etc., but the disclosure requirements do not apply to health care professionals who are employed by the reporting company)
- Associations of health care professionals and associations of students for relevant occupations
- Students for relevant occupations

- User associations of the health system (public or private)
- Health facilities
- Foundations, learned societies and consulting companies or organizations in the health sector
- Publishing companies: press, radio, television and online media
- Editors of prescription and dispensing software
- Legal entities contributing to the initial training of health care professionals

There are some similarities, but also some significant differences, between the information that companies must reveal about agreements with the aforementioned recipients and the benefits they provide to them. For agreements, companies must reveal the following:

- The identity of the parties to the agreement:
    - For health care professionals: name, professional address, qualifications, title, specialty and registration number with the relevant professional board
    - For health care 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 can be phrased in such a way as to protect confidential and trade secret information)
- If the agreement involves a promotional or scientific event, the program of the event

As to benefits, companies must disclose all 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 €10, inclusive of value-added tax. Benefits worth less than €10 do not have to be disclosed.

In 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, etc.); the amount of each benefit; the 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.

All of this information about agreements and benefits will eventually be disclosed, in French, on a to-be-established public website. The website will be created and operated by a public authority, and the information will be available for a period of five years.

Companies must report the pertinent information for agreements to the public authority within 15 days of the signing of the agreement. In contrast, for benefits, the relevant information must only be submitted biannually: by Aug. 1 for benefits provided from January through June of a calendar year and by Feb. 1 for benefits provided from July through December of the preceding calendar year.

Once the public website is operational, the information about benefits provided and agreements made during the first part of a calendar year will be made public by Oct. 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 provides for a different reporting scheme until the website is ready. Specifically, the decree provides that by June 1, 2013 (10 days after the decree was issued), companies were to submit all reportable benefits provided and agreements made during calendar year 2012 to the appropriate national council of the health care professionals association (e.g., National French Medical Association).

Companies are to provide the reportable information for agreements made and benefits provided during the first six months of 2013 to the appropriate national council by Aug. 1, 2013. All of this information covering both 2012 and the first six months of 2013 is then to be published by Oct. 1, 2013, on two separate websites: the website of the reporting company (or a common website shared by several companies for that purpose) and the website of the relevant French national council.

Although the decree provides important details about the French transparency system and imposes significant reporting requirements on life sciences companies, several important issues remain unclear or ambiguous. For example, the decree requires that the value of benefits be disclosed but does not impose a similar requirement for agreements. This distinction between reporting the value of one type of interaction but not a different type of interaction may be addressed, and the inconsistency reconciled, in a future decree or in further guidance from the government.

Moreover, it is unclear if the decree applies only to companies established in France or more broadly to companies that are doing business in France or are otherwise interacting with French health care professionals. The precise definition of “benefits” and the operational details of the public website, among other matters, are expected to be clarified by additional decrees or guidance.

Thus, the life sciences industry will once again be waiting for further clarification while simultaneously having to proceed with its reporting obligations in France. As it monitors any such developments, the life sciences industry will also be closely watching to see if any health care professionals or organizations challenge the decree, which could lead to further delay or complications for the industry.

The French decree will have an immediate, direct and enormous impact on transparency reporting in France, but it may also serve as a model for other countries that are pursuing, or considering, a legislative approach to transparency. In that regard, it is possible that governments in other countries will enact laws that are at least as strict as, or similar to, the French system as they will not want to be viewed as “soft” on industry. Therefore, the recent issuance of the French decree could serve as a seminal moment in the European, as well as global, transparency movement.

Portugal entered the transparency fray earlier this year but took a different tack. With the publication of Decree-Law n. 20/2013 of Feb. 14, which was an amendment to the Medicinal Products Act, Portugal established new reporting requirements for several actors in the health care field.

Under the amendment, pharmaceutical companies must report to Infarmed (the Portuguese National Authority of Medicines and Health Products, which is a government agency accountable to the Ministry of Health) the grant of any financial support provided to patient organizations. Significantly, the amendment also requires patient organizations, scientific associations and health care professionals (including doctors, dentists, pharmacists and nurses) to submit to Infarmed information about subsidies, grants and other financial support that they receive from pharmaceutical companies if such support exceeds €25.

It is too early to evaluate the relative effectiveness of the French and Portuguese approaches to transparency, but it will be interesting to observe how life sciences companies and other key stakeholders react to and comply with these new reporting requirements.

Denmark is somewhat unique in that it currently has government-imposed disclosure requirements, but it is expected to adopt an additional legislative scheme this year. Currently, Danish health care professionals are required to obtain permission from the Danish Health and Medicines Authority before they can establish a relationship or collaborate with a pharmaceutical company.

In turn, pharmaceutical companies must report annually to the Danish agency by Jan. 31 their collaborations with doctors, dentists and pharmacists. Although pharmaceutical companies must provide certain information about the doctors, dentists and pharmacists with whom they have worked (e.g., name, address and dates of collaboration), they are not required to list any information concerning any financial compensation or benefits that were provided to those health care professionals.

The current system, which identifies relationships between industry and professionals but does not provide for any financial transparency, is expected to be modified by new legislation in 2013. This legislation is expected to be applicable to both pharmaceutical companies and medical device companies.

Under the anticipated legislative scheme, it is the health care professionals — not the life sciences companies — who will have the primary reporting obligation. Health care professionals are expected to have to disclose the amount of fees they receive for research (e.g., clinical research); fees for education or speaking; fees for consultancy (e.g., advisory boards); fees for market research; events; and other sponsorships.

Further, it is anticipated that the Danish Health and Medicines Authority will disclose this individual data on its website. The life sciences industry should pay close attention to the legislative process in Denmark as it will determine whether the primary reporting burden will be on the health care professional, as in Portugal, or on industry, as in France.

This recent flurry of transparency legislation builds upon earlier legislative approaches. For example, in September 2011, Slovakia adopted health care professional interaction reporting requirements as part of a broad drug policy reform bill. Under Slovakia's law, companies must submit annually, no later than Jan. 31, a report to the Ministry of Health of the Slovak Republic providing the value of advertising and marketing expenses and nonmonetary benefits provided directly or indirectly to health care professionals. The Ministry must then publish a report of that information on its website.

In addition, the law prohibits companies from directly or indirectly financing, sponsoring or otherwise supporting health care professionals attendance at events, including conferences and seminars, unless the purpose of the events is expert, scientific or educational. Companies that provide support pursuant to that exception must provide to the National Health Information Centre a list of the health care professionals it supports, which is then published online.

Conclusion

The movement toward legislatively mandated transparency in the life sciences industry has gained momentum throughout 2012 and the first six months of 2013, highlighted by the long-awaited issuance of the final Sunshine Act regulations in the United States and the decree implementing the French Sunshine Act.

The French decree, in particular, has generated significant controversy as it not only mandates disclosure of transactions dating back to January 2012 but also imposes aggressive deadlines that will be difficult for industry to satisfy.

In short, the transparency landscape is quickly changing, ever-evolving and unpredictable, as evidenced by what is transpiring in Europe. Companies cannot focus merely on the United States or any other single jurisdiction. The industry must be aware of all developments as the one definite, predictable effect of the transparency movement is that there will be more — not fewer — reporting requirements, leading life sciences companies to devote more time and resources to ensuring compliance and transparency.

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