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Client Alert

FDA & Life Sciences Practice Group

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French National Councils and Companies Publicly Disclose Information About Interactions with French Health Care Professionals for the First Time as Required by the French Sunshine Act

On October 1, 2013, seven national councils representing French health care professionals posted on their publicly accessible websites information submitted by affected enterprises (*i.e.*, companies) that produce or market medications, medical devices, biomaterials, and other therapeutic and cosmetic products about benefits granted to and agreements concluded with French health care professionals, as required by Article L. 1453.1 of the French Public Health Code (PHC).

The disclosure obligation is imposed by Article 2 of *Law No. 2011-2012 Regarding the Reinforcement of the Safety of Medicinal and Health Products* (known as the "Bertrand Act" or "French Sunshine Act")[1] as implemented by *Decree no. 2013-414 Concerning the Transparency of Benefits Granted by Enterprises Producing or Marketing Sanitary and Cosmetic Products Intended for Human Use* ("Implementing Decree").

In addition to requiring that information about benefits and agreements be publicly available on the websites of the French national councils, the Implementing Decree requires each affected enterprise to publicly post the information on its website, or on a website common to several enterprises. As of October 1, 2013, over 100 manufacturers of pharmaceuticals and medical devices have publicly disclosed the required information on their websites.

Procedural History

The French Parliament adopted the French Sunshine Act on December 29, 2011. The French Sunshine Act establishes general disclosure requirements for enterprises (companies) producing or marketing products including, drugs and medical devices, or providing services associated with these products. The disclosure requirements apply to interactions with French health care professionals and entities on or after January 1, 2012.

The French Sunshine Act required the adoption of an implementing decree specifying the nature of the information subject to the disclosure obligations and providing details about the manner of publication by August 1, 2012. An implementing decree in France is comparable to

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agency-issued implementing regulations in the United States. On May 21, 2013, after several months of delay, due to French presidential and parliamentary elections and intense debates between health professionals, the French Government adopted a final version of the Implementing Decree. The Implementing Decree clarifies which recipients are within the scope of the French Sunshine Act and specifies the data elements that must be reported for benefits to and agreements with health care professional recipients.

Following publication of the Implementing Decree, and only days before the first reports were to be submitted to the national councils, the French Ministry of Social Affairs and Health issued *Circular no. 2013- of May 29, 2013 concerning the application of Article 2 of Law no. 2011-2012 of December 29, 2011 Regarding the Reinforcement of the Safety of Medicinal and Health Products* (the "Circular") on May 29, 2013. The Circular, which is similar to an agency-issued guidance document in the United States, has no official regulatory authority but provides context and detail about certain aspects of the reporting and disclosure obligations set forth in the PHC. The Circular explains what information must be made public and imposes data privacy protection measures on the entity responsible for compiling and publicly posting the information submitted by affected enterprises.

The French Minister for Social Affairs and Health is required by the Implementing Decree to adopt an order establishing a "responsible authority" that will be tasked with compiling all of the submitted data and subsequently publishing the information on a single website in French. Until the Minister adopts this order, the relevant information about agreements and benefits must be submitted to the relevant official councils of health care professionals for posting on their websites. In addition, the information must be posted on the website of the enterprise or on a website common to several enterprises. As of October 1, 2013, the Minister of Social Affairs and Health had not yet adopted the required order. This order is likely to be adopted during the first half of 2014.

Over the summer, the French National Medical Council, which is similar to the American Medical Association (AMA) in the United States, and the National Council of Pharmacists released guidance about the standard reporting form that enterprises should use when disclosing information about interactions with French health care professionals and entities. At this time, there is no commonly accepted reporting format or procedure among the seven relevant national councils but discussions are on-going with industry associations.

Overview of Requirements

The disclosure obligations of the PHC apply broadly to enterprises "producing or marketing sanitary or cosmetic products intended for human use" and enterprises "providing services associated with these products." Products intended for sanitary use by humans include, medications, biomaterials, medical devices, and "additional therapeutic products."

The law generally requires enterprises, as explained above, to make public (1) all direct or indirect **benefits equal or greater to €10** in cash or in kind that are provided to and (2) all **agreements** with healthcare professionals, associations of health professionals, medical students and associations representing them, patient associations, hospitals, and healthcare institutions. With respect to benefits granted to these individuals and entities, enterprises are required to publicly disclose the recipient's identity; the value of the benefit (taxes included), rounded to the closest Euro; the nature and date of each benefit; and the half-year period during which the benefit was granted. The information related to agreements that enterprises must publicly disclose includes the identities of the parties to the

agreement; the date the agreement was signed; the purpose of the agreement; and, if the agreement is related to the organization of an event, the program of that event.

An agreement is excluded when it qualifies as a commercial agreement under French law. Agreements governing the purchase of goods and services **from the enterprise** are therefore excluded from the scope of disclosure obligations. Agreements related to research activities and clinical trials are not exempt from the disclosure obligations, unless they qualify as commercial agreements. As outlined in the Circular, enterprises are not required to disclose work contracts and a health care professional is subject to the French Sunshine Act when acting in his or her capacity as a health care consumer.

Key Compliance Dates

Information related to interactions that occurred in 2012 and during the first half of 2013 were due to the relevant national councils by **June 1, 2013** and **August 1, 2013**, respectively, and were published by the seven relevant councils by **October 1, 2013**. In addition, it appears that a significant number of affected enterprises published this information on their websites by October 1, 2013.

Information relating to benefits granted and agreements concluded during the first half of a calendar year must be reported by August 1 on an annual basis, and will be publicly disclosed annually by October 1. Information concerning benefits granted and agreements concluded during the second half of a calendar year must be reported by the following February 1 and will be publicly disclosed by April 1. Following the adoption of the ministerial order referred to above, enterprises will be required to disclose information about agreements within 15 days of signing, on a rolling basis.

Information Published by National Councils and Affected Enterprises

As required by the PHC, on October 1, 2013, seven national councils publicly disclosed information submitted by affected enterprises.[2] Each of the seven councils has posted disclaimer language on its website indicating that the council is not required to ensure the accuracy and completeness of the data submitted, but rather is only obligated to publish the information in a timely manner. The councils encourage health care professionals to contact the affected enterprise directly with any disputes or questions about disclosed information.

In a number of cases, it appears that information provided by affected enterprises to the relevant councils was not provided in a format that allowed it to be entered into the council's template. The National Medical Council, for example, provides two separate data sets: one from enterprises that submitted usable data, and a set of information from enterprises where the data did not conform to the council's template and standards. Similarly, the Council of Dentists states on its website that due to the tight deadlines for submitting data, only one enterprise sent data that conformed to the Council's format.

Each affected enterprise was required to publicly disclose the required information on its own website, or on a website common to several enterprises, by October 1, 2013. It appears that several enterprises did publicly disclose this information; many enterprises included the information on a webpage devoted to transparency on their France-specific website.

Challenges Under the French Sunshine Act

There are many questions related to the French Sunshine Act that are open for debate. The French Minister of Social Affairs and Health has yet to adopt an order establishing a responsible authority to compile and publicly disclose the information submitted by affected enterprises. When the responsible authority is announced, that entity will likely develop a standard template for disclosure and may issue further guidance interpreting the requirements of the French Sunshine Act. If and when that occurs, the current interpretations and methodologies of a manufacturer subject to the French Sunshine Act may be subject to change.

Life sciences manufacturers may face an additional challenge in determining whether they may be within the scope of the French Sunshine Act. As the law is drafted, it appears that enterprises that produce or market medications, biomaterials, medical devices, and other therapeutic products, or enterprises that provide services associated with those products, may be within the scope of the disclosure requirements. Neither the PHC nor the Circular appear to reference the place of incorporation of the enterprises concerned or the place of manufacture or distribution of the products covered. According to the guidance of French Health authorities, a key issue appears to be whether the enterprise contracts with or provides benefits to listed individuals and entities who "practice their activity on the French territory."

The French Sunshine Act will have several implications on life sciences manufacturers doing business in France and interacting with French health care professionals. The full impact of the French Sunshine Act on the life sciences industry remains to be seen.

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We will continue to monitor the implementation of the French Sunshine Act and will provide more information about this issue as warranted. In the meantime, please contact us if you have any questions or comments regarding the requirements or implications of the law.

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This alert provides a general summary of recent legal developments. It is not intended to be and should not be relied upon as legal advice.

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[1] Articles L.1453-1, D. 1453-1 and R. 1453-2 to 9 of the French Public Health Code.

[2] The publicly disclosed information can be accessed at: **http://www.sunshine-act.ordre.medecin.fr/** (National Medical Council); **http://sunshine.ordre-sages-femmes.fr/** (Council of Midwives); **http://transparence.ordre.pharmacien.fr/transparence-fo-view/search** (National Council of Pharmacists); **http://www.ordre-chirurgiens-dentistes.fr/chirurgiens-dentistes/transparence-liens-entrepriseschirurgiens-dentistes.html** (Council of Dentists); **http://conventions-avantages.ordremk.fr/** (Council of Physiotherapists); **http://www.onpp.fr/transparence-liens-d_interets.html** (National Council of Chiropodists); and **http://transparence-infirmier.cnoi.fr/** (National Council of Nurses).