

E-ALERT | Health Care

May 23, 2013

SUNSHINE OBLIGATIONS FOR THE HEALTHCARE INDUSTRY APPLY

On May 22nd the French government published the long awaited Decree (the Decree is available [here](#)) that implements, and makes enforceable, the Sunshine Act adopted in December 2011 (see our E-Alert on the Sunshine Act by clicking [here](#)). The Sunshine Act imposes disclosure requirements on companies manufacturing or marketing pharmaceuticals, medical devices, and cosmetics in France. The Act was adopted as a consequence of the Mediator scandal in France. Mediator – a medicine authorized for the treatment of diabetes – had been widely prescribed as an appetite suppressant and allegedly caused 500 to 2000 deaths. The LEEM (the French pharmaceutical companies' association) already criticized the “heaviness” of the new sunshine obligations and the unrealistic deadlines, especially the obligation to report 2012 data by June 1st.

WHO ARE THE COMPANIES CONCERNED?

Companies that manufacture or market health products or associated services are subject to the publication obligations. The health products concerned are the categories of products that are under the supervision of the French Medicines Agency (ANSM), such as medicines, medical devices, cosmetic products, essential oils, human and animal tissues or cells, contact lenses, tattoo products, etc.

WHAT ACTIVITIES ARE COVERED?

The companies concerned must publish benefits granted and agreements. The information must be published in French.

Benefits

Companies must publish any direct or indirect benefit, in kind or in cash, with a value above 10 Euros, that is granted to a broad range of recipients, including healthcare professionals (e.g. doctors, dentists, pharmacists, nurses, mid-wives), associations of healthcare professionals, healthcare students, patient associations, hospitals, non-profit associations (foundations, societies), providers of medical software, companies providing advice in relation to health products, companies running a press, radio, television or online public communication services, or legal entities providing or participating in the initial training of healthcare professionals. This also includes benefits granted in the context of the performance of services under agreements concluded with these recipients (for example, a flight ticket), but seems to exclude the remuneration granted as a compensation for these services. However, the Ministry of Health is expected to publish an interpretative note where this issue may be clarified.

The companies must publish: (i) the name of the recipient and the company; (ii) the exact amount or value (VAT inclusive), the date and the nature of the benefit; (iii) the civil semester during which the benefit has been granted.

Agreements

Companies must also publish key elements of the agreements concluded with the above listed actors, except for commercial agreements regulated by the French Commercial Code. The

publication must cover: (i) the parties to the agreement (specifying the qualifications of the recipient); (ii) the date of signature of the agreement; (iii) the purpose of the agreement (worded in such a way that it protects business secrets); and (iv) the program of the event, when the agreement relates to a scientific or promotional event.

Companies manufacturing or marketing cosmetic products, contact lenses, and tattoo products must only publish the key elements of clinical trials agreements or agreements related to safety evaluation and vigilance (*i.e.*, not agreements related to hospitality, advisory boards etc.)

WHERE AND WHEN MUST COMPANIES PUBLISH?

Ultimately, the information will have to be made public on a central website operated by a competent authority that will be designated by a Ministerial Order. Regarding agreements, companies will have to transmit the relevant information to the competent authority within 15 days after the conclusion of the agreement. The information regarding benefits will have to be transmitted before August 1st for benefits granted during the first civil semester and before February 1st for benefits granted during the second semester of the preceding year. The competent authority must publish this information before October 1st and April 1st, respectively. The information will remain available during five years after publication by the competent authority.

Before the designation of the competent authority, companies must publish the information on an easily identifiable section of their own website (or a website shared with other companies or via the website of the relevant industry association) and on the website of the relevant national professional council of the recipients (such as the National Council of Doctors - Conseil National de l'Ordre des Médecins). Companies must transmit the relevant information to the relevant national professional organization of the recipients before August 1st for benefits granted and agreements concluded during the first civil semester and before February 1st for benefits granted and agreements concluded during the second semester of the preceding year. The information must be published on the two websites before October 1st and April 1st, respectively.

RETROACTIVITY OF THE PUBLICATION OBLIGATION

The Decree provides that the publication obligation applies retroactively to all benefits granted and agreements concluded since January 1st, 2012. Companies must transmit the information for 2012 to the relevant national professional council before June 1st, 2013. This information must be published on both the national professional organization and company websites before October 1st, 2013.

SANCTIONS

Companies that 'knowingly' violate the transparency obligations may be subject to a criminal fine up to €45,000 and may face ancillary sanctions, such as a ban on participating in public tenders, the suspension of business activities, or the closing of facilities.

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