

Healthcare & Life Sciences - France

Remaining Sunshine Regulations finally adopted

Contributed by **Hogan Lovells International LLP**

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Introduction

Decree 2013-414, implementing the French Sunshine Regulations, was published in the *Official Journal* on May 22 2013.⁽¹⁾ The Sunshine Regulations were introduced into French law pursuant to the Bertrand Law (December 29 2011) and oblige enterprises working in the health sector to publish details of benefits granted to and agreements entered into with various players in the health sector, including healthcare professionals.

A government circular is due to be adopted shortly by the State Health Department in order to regulate the interpretation of the various concepts contained in the decree by the administration.

Which companies are affected?

The decree covers enterprises that produce or market health products, or that provide services connected to these products. There is some uncertainty as to the scope of this latter concept. The French administration's interpretation of this issue should be set out in the circular, which should also clarify how to handle overlapping cases in which the same information might be published by different players.

A previous draft of the circular specified that only enterprises established in France would be subject to the Sunshine Regulations. However, this has yet to be confirmed.

What information must be published?

Principles

The following information must be published:

- information on agreements that are entered into with stakeholders listed in Article L1453-1 of the Public Health Code (commercial agreements for the purchase of goods or services, as well as the *convention unique* entered into between suppliers and distributors, need not be published); and
- benefits in cash or in kind granted directly or indirectly to these same stakeholders, when such benefit is €10 or more, inclusive of taxes. This concept should cover benefits granted without consideration (eg, grants, gifts or hospitality). The concept of 'benefit' should be defined further in the circular.

The stakeholders referred to above and listed in Article L1453-1 of the Public Health Code include healthcare professionals, healthcare professionals' associations, healthcare students, health institutions, foundations and societies, press agencies and publishers of online communication to the public. The various categories listed in the regulations are potentially far reaching and details on this matter are expected to be included in the circular. Concerned stakeholders should be only those established in France, and the circular should confirm the administration's interpretation of this aspect.

Information published for both agreements and benefits

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The following information on the identity of the parties must be published for both agreements and benefits:

- Healthcare professionals – name, professional address, qualifications, title, speciality, professional board or Collective Database of Health Professionals registration number;
- Healthcare students – name, educational institution and, if applicable, Collective Database of Health Professionals registration number; and
- Legal entities (health institution, associations, companies) – name, corporate purpose and registered address.

Information published only for agreements

The following information must be published for agreements:

- the date of signature;
- the purpose of the agreement (which can be described in a way that ensures that trade secrets are protected); and
- if the subject matter of the agreement relates to an event, the programme for such event.

Information published only for benefits

The following information must be published for benefits:

- the amount of each benefit (including tax and rounded up to the nearest euro);
- the date and nature of each benefit granted to the beneficiary; and
- the calendar semester in which the benefit was granted.

The decree specifies that the benefits mentioned in agreements must also be published as 'benefits'. This covers, for instance, reimbursement of expenses incurred by a contracting party (eg, meal, transport and accommodation costs). Requiring the publication of such amounts as benefits seems to be inconsistent with the principle that a benefit is granted without consideration.

How will publication take place?

The information will be published in French on a unique public website. This website will be set up by the authorities and the authority responsible for this website will be the recipient of the information to be disclosed. The conditions for the functioning of the website will be determined by ministerial decree.

Until the website is set up, information will be published:

- on the website of the relevant French national professional body (eg, the *Conseil National de l'Ordre des Médecins* for physicians), if the agreement or benefit relates to a healthcare professional, student or association; and
- on the enterprise's website, a common website shared by several enterprises or the website of the professional trade union of which the enterprise is a member (in the latter two cases, the website must be identifiable from the enterprise's website or by any other means if such website does not exist). Enterprises are free to decide how they want to present the information. The website must integrate technical measures ensuring its integrity and the safety of the information disclosed, and prohibiting the re-indexing of directly identifying data. Setting up the website will require compliance with data protection regulations (eg, declaration obligations and compliance with data subjects' access rights).

When must information be transmitted and published?

Timetable for transmission of information

The enterprise must transmit the information to the authority that is responsible for the unique website according to the following timetable:

- for an agreement – within 15 days of signature of the agreement; enterprises must put in place periodic data transmissions for agreements; and
- for a benefit:
 - granted between January 1 and June 30 – transmission must occur on August 1 of the same year at the latest; and
 - granted between July 1 and December 31 – transmission must occur on February 1 of the following year at the latest.

Dates of publication of information

The authority that is responsible for the unique website will publish the information on agreements and benefits as follows:

- an agreement concluded or a benefit granted between January 1 and June 30 – publication occurs on October 1 of same year at the latest; and
- an agreement concluded or a benefit granted between July 1 and December 31 – publication occurs on April 1 of the following year at the latest.

Transitional provisions

The first publication under the decree will cover agreements concluded and benefits granted between January 1 2012 and June 30 2013.

In 2013 the following planning must be carried out in regard to the transmission and publication of the information:

- By June 1 2013 at the latest – transmission to the relevant French national professional body (as applicable) of the information relating to agreements concluded and benefits granted in 2012. As this date is so close to publication of the decree, many enterprises are likely to find it hard to comply with this obligation.
- By August 1 2013 at the latest – transmission to the relevant French national professional body (as applicable) of the information relating to agreements concluded and benefits granted during the first calendar semester of 2013.
- By October 1 2013 at the latest – first publication (by professional bodies and enterprise websites) of the information relating to agreements concluded and benefits granted between January 1 2012 and June 30 2013.

After 2013, if the unique website has not yet been set up, information on agreements and benefits must be transmitted to the relevant French national professional body (as applicable) by August 1 and February 1 of each year at the latest. Publications will need to take place on October 1 and April 1 of each year at the latest.

How long will information be accessible and stored?

The information relating to agreements and benefits will remain accessible to the public for five years once it is online, and will be kept by the authority that is responsible for the unique website for 10 years following the last modification of the information.

What penalties apply in case of non-compliance?

Infringement of the Sunshine Regulations may result in criminal penalties (fines of up to €45,000 for an individual and up to €225,000 for a company, as well as other penalties such as publication of the penalties and a prohibition on manufacturing products) where the offender deliberately omitted to publish the relevant information. The risk of such penalties requires a case-by-case analysis, due in particular to the specific context in which the applicable legal provisions have been adopted.

Other details

The decree provides further details on the changes made by the Bertrand Law to French anti-benefits regulations:

- The time periods given to professional bodies to provide their opinion on the agreements submitted to them under Article L4113-6 of the Public Health Code are:
 - two months for scientific research or evaluation agreements; and
 - one month for all other agreements.
- The enterprise must inform the relevant professional body of the implementation of agreements submitted to it within one month.

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Endnotes

(1) Available at

www.legifrance.gouv.fr/affichTexte.do?cidTexte=JORFTEXT000027434029&fastPos=1&fastReqId=633856616&categorieLien=id&oldAction=rect

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