

Healthcare & Life Sciences - France

New transparency requirements imposed on foreign companies

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Introduction

The Sunshine Regulations were introduced into French law pursuant to the Bertrand Law (December 29 2011) and completed by Decree 2013-414 (May 22 2013). These texts also affected the anti-benefits regulations introduced by Law 93-121 (January 27 1993).

The new rules require the public disclosure of information concerning agreements concluded between healthcare companies and individuals (eg, healthcare professionals) or entities (eg, patient organisations) active in the French health sector, and direct and indirect benefits provided by the companies to such individuals or entities.

The industry expected an interpretative circular from the administration to clarify various aspects of the newly introduced Sunshine Regulations. This circular, which was published on June 12 2013,⁽¹⁾ provides details on the Health Department's interpretation of the sunshine and anti-benefits regulations.

Although the circular provides some useful information regarding the application of certain aspects of the regulations, the interpretative document remains silent on many other aspects

Impact on companies established abroad

The public disclosure requirement introduced by the Sunshine Regulations is imposed on companies which manufacture or market health (or cosmetic) products, including medicinal products and medical devices, or which provide services linked to those products.

An initial draft of the circular (issued in September 2012) limited the scope of this public disclosure requirement to companies established in France, but the final version of the circular contains no such limitation. However, the circular clearly provides that the transparency obligation relates to agreements concluded with and direct or indirect benefits granted to stakeholders carrying out activities in France.

At present, none of the various texts applicable (in particular, Articles L1453-1 and L5311-1 of the Public Health Code) provide for an explicit limitation of this public disclosure requirement to French companies or companies established in France.

The obligation to publish is subject to criminal penalties. French criminal law is generally applicable to any offence perpetrated in France. This principle applies regardless of the nationality of the perpetrator. A company that breaches French criminal law may be subject to criminal penalties irrespective of whether it is established in France.

An offence is deemed to have been perpetrated in France if one of its composite elements is located in France. The offence at issue here relates to the fact that one company intentionally omitted to publish information. In order to locate the offence (where the location is not immediately obvious), case law considers that such an offence should be located where the omission has consequences and where the omitted action (ie, the declaration for publication purposes) should have been performed.

Regarding the failure to disclose publicly information concerning agreements

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concluded between healthcare companies and individuals or entities active in the French health sector and direct and indirect benefits provided by the companies to such individuals or entities, it could be argued that the offence could be located in France. Consequently, in the absence of any text explicitly limiting the scope of the public disclosure requirement to French companies, this obligation may apply to both French and foreign legal entities. In other words, a company is likely to be subject to the public disclosure requirement, regardless of its structure and connection(s) with France, if

- it:
 - manufactures the products referred to in Article L5311-1 of the Public Health Code which are then sold in France;
 - markets such products in France (eg, medicinal products and medical devices companies selling products into France from abroad); or
 - provides services (eg, a clinical research organisation) linked to such products on behalf of the companies mentioned above; and
- it enters into a relationship with one of the stakeholders listed in Article L1453-1 of the Public Health Code which practises its activities in France.

This analysis can be further fine tuned depending on the circumstances. It could also evolve on the basis of the application of the new provisions by the authorities and the interpretation provided by the courts in relation to these provisions. In the meantime, the risk of criminal penalties can best be mitigated by considering the publication obligation to apply to non-French companies until further notice.

Other issues

'Multi-product' companies

For companies producing or marketing various types of product, the public disclosure requirement applies only in relation to activities relating to the products mentioned in Article L5311-1 of the Public Health Code.

Avoiding publishing same information twice

There may be circumstances where both a company producing or marketing products falling within the scope of the Sunshine Regulations and a service provider acting for such company are legally subject to the publication obligation for the same type of information (eg, a benefit granted by a clinical research organisation to a healthcare professional may also be a benefit granted indirectly by the producer or marketer which appointed the clinical research organisation to work with such healthcare professional).

The circular provides that in such case, the two companies must organise themselves to make only one publication.

Clarifications regarding stakeholders and agreements concerned by public disclosure requirement

The circular includes clarifications regarding each type of stakeholder listed in Article L1453-1 of the Public Health Code. As an illustration, the circular provides that advisers which are part of regulated professions are not considered to fall within the category of advisers and consultancies listed in Article L1453-1, Section I(6) of the code.

The circular also provides details on the agreements that are subject to the publication obligations. Employment agreements are expressly excluded from the scope of application of the new public disclosure requirement.

Penalties in case of non-compliance

The infringement of the Sunshine Regulations may expose companies to fines up to €45,000, and to other penalties such as publication of the findings or a prohibition on manufacturing products.

Benefits granted to healthcare professionals associations

The circular clarifies the question of whether a healthcare professionals association can be funded via grants. The circular provides that healthcare professionals associations which are not intended to represent and defend the professional interests of healthcare professionals can receive grants (eg, if the purpose of the association is the conduct of research or medical training activities).

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Endnotes

(1) Available at http://circulaires.legifrance.gouv.fr/pdf/2013/06/cir_37074.pdf.

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