

Client Alert

June 2013

UPDATE: French Ministry of Health Provides Guidance On Recent ‘Sunshine’ Provisions

As discussed in our [previous Alert](#), the French government has imposed Sunshine-like obligations on the pharmaceutical industry. Article 2 of Law No 2011-2012 of 29 December 2011 on the Strengthening of Health Protection for Medicinal and Health Products (“*loi relative au renforcement de la sécurité sanitaire du médicament et des produits de santé*” or “*Loi Bertrand*”) inserted Articles L. 1453-1 in the French Code of Public Health (“*Code de la santé publique*” or “CSP”). Article L. 1453-1 is the French “Sunshine” Act; it imposes the public disclosure of transfers of value from certain companies to certain actors of the health care sector. Article 2 of the *Loi Bertrand* also amended Article L. 4113-6 CSP, which generally prohibits any transfer of value from certain companies to certain actors of the health care sector.

On 21 May 2013, Article L. 1453-1 was implemented by Decree No 2013-414.. This week, the Ministry of Health published [an interpretative guideline to the new rules, Circulaire No DGS/PF2/2013/221](#) (the “Circular”). The Circular in essence interprets new Article L. 1453-1 CSP and the extension of the scope of application of Article L. 4113-6 CSP. We highlight the key points of the Circular below.

Article L. 1453-1 CSP

Specification of the following concepts:

- Health care professionals.
- Services associated to health and cosmetic products.
- Benefits.

Confirmation that:

- Fees paid to health care professionals or institutions for their services should not be disclosed.
- Benefits given in relation to purchase agreements should not be disclosed.
- Multiple reporting by different companies of an agreement with, or a benefit to, the same health care professional or institution should be avoided (so companies should get organised and collect the relevant information internally and from contractors).
- Companies should disclose direct and indirect benefits or agreements (and so should inquire about potential indirect beneficiaries).
- No specific format or presentation is required when reporting the relevant information.
- The obligation applies to agreements with, and benefits to, health care professionals practising in France.

No discussion on the application of the obligation to companies located outside France. The draft Circular specified that the public disclosure obligation did not apply to non-French companies, but this specification has been removed from the final version. The guideline from *Les Entreprises du*

Médicament (“LEEM”), the French trade association of pharmaceutical companies, anticipated that Article L. 1453-1 would not apply to non-French companies, but that guideline was issued before the adoption of the Circular. On the other hand, the guideline from the *Syndicat National de l’Industrie des Technologies Médicales* (SNITEM), the French trade association of medical devices companies, which was issued after the adoption of the Circular, clarifies that the disclosure obligation does apply to non-French companies.

Article L. 4113-6 CSP

Specification of the following:

- The concept of “association of health care professionals”. The associations fall into the scope of Article L. 4113-6 CSP if they represent or defend the interests of a category of professionals. The concept therefore depends on the purpose of the association, and the following associations are not concerned by the general prohibition:
 - Recognised public interest associations that comprise several categories of professionals and whose purpose is of general interest rather than the specific interests of its members.
 - Associations that comprise health care professionals and whose purpose is to conduct (or participate in) health research or medical training.
 - “*Sociétés savantes*”, i.e., associations whose purpose is, for a specific area, to improve knowledge and encourage the training and research in that area.
- A transfer of value to an association that in turn makes a transfer of value to a health care professional is an indirect transfer of value to a health care professional.

Confirmation that the scope of application of Article L. 1453-1 CSP is broader than the scope of application of Article 4113-6 CSP. For the application of Article L. 1453-1 CSP:

- Reimbursement of the product(s) by social security is not relevant.
- The concept of health care professionals is broader (for example, dieticians).

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