

Client Alert

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FRANCE - Implementation of 'Sunshine' Provisions for Pharmaceutical, Medical Device, and Cosmetic Companies

After the Netherlands, Slovakia, and the UK, it is now France's turn to impose Sunshine-like obligations on the pharmaceutical industry. Soon, similar obligations will apply to all EU countries, after EFPIA, the European trade association for the pharmaceutical industry, adopts a code of conduct on disclosure of transfers of value between pharmaceutical companies and health care professionals or institutions.

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 and L. 1454-3 to L. 1454-5 in the French Code of Public Health ("*Code de la santé publique*" or "*CSP*"). Article L. 1453-1 is the French 'Sunshine' Act, and Articles L. 1454-3 to L. 1454-5 set out the criminal sanctions.

Article L. 1453-1 focuses on the scope of application of the new obligation on public disclosure (by whom to whom), and the obligation had to be specified in an implementing decree. It is done. After more than 16 months, Decree No 2013-414 on Transparency of Benefits Given by Companies Manufacturing or Marketing Health and Cosmetic Products for Human Use ("*décret relatif à la transparence des avantages accordés par les entreprises produisant ou commercialisant des produits à finalité sanitaire et cosmétique destinés à l'homme*") (the 'Decree') has been adopted.

New Articles R. 1453-1 to 1453-9 detail the information to be disclosed as well as the means and frequency of disclosure. Specific rules apply to non-corrective lenses, cosmetic products, and tattoo products.

The Decree also implements the amendments to Article L. 4113-6 CSP brought by Law No 2011-2012. The law extended the general prohibition of benefits to health care students and associations of health care professionals or students. The exemptions to the prohibition (hospitality and research-related agreements) apply to students, but their application to associations of health care professionals is controversial. The Decree implements the prohibition only for students and student associations, which suggests that the exemptions do not apply to associations of health care professionals.

The Decree applies to agreements entered, and benefits granted, from 1 January 2012. **Companies must provide the information relating to the 2012 agreements and benefits by 1 June 2013 for publication by 1 October 2013.**

Despite the Decree, many aspects of the transparency obligation remain unclear. There will be numerous interpretation problems, such as the applicability to companies based outside France. The Ministry of Health is working on a guideline, but it is unclear when it will be available.

Scope of Application

The transparency obligation applies to (i) any agreements entered by a 'company' with a 'recipient', and (ii) from a certain threshold, any benefits in kind or in cash, provided by a 'company' to a 'recipient'.

Companies — The transparency rules apply to companies that manufacture or market health or cosmetic products or provide services that are associated with those products. Health or cosmetic products are the 19 categories of products that are under the French Medicines Agency's supervision under Article L. 5311-1(II) CSP, regardless of whether they are subject to social security reimbursement. The Decree, however, sets out specific rules for non-corrective lenses, cosmetics, and tattoo products (see below).

Recipients — Covered companies must disclose all the agreements entered with, and benefits given to, nine categories of health care actors, including health care professionals (doctors, veterinarians, dentists, pharmacists, nurses, midwives); associations of health care professionals; health care students; patients associations; hospitals; non-profit associations (foundations, societies); companies providing advice in relation to health products; companies running press, radio, television, or online public communication services; or legal entities providing or participating in the initial training of health care professionals (Art. L. 1453-1 (I) CSP). The Decree does not provide any specification as to the recipients although such a specification would have been helpful. So, do CROs or law firms qualify as companies "providing advice in relation to health products"?

Cut-off date — The Decree applies to agreements entered into, and benefits given, from 1 January 2012. However, specific rules apply until the entry into force of the ordinance that sets out the public website where the information will be published (the 'Transitional Period') (see below).

Conditions of Disclosure and Publication (What? Where? When?)

New Articles R. 1453-2 to R. 1453-9 CSP specify the conditions of disclosure.

Agreements — Any agreement entered into by a company and a recipient is to be disclosed except for the purchase agreements governed by Articles L. 441-3 and L. 441-7 of the Commercial Code.

For each agreement, companies must disclose the identity of each party, the date of signature, the subject matter (taking into account industrial and commercial secrets), and the program of the event in cases of hospitality. The amount paid to the recipient needs not to be revealed. The information must be forwarded, in French, to the Authority (see below) within 15 days of the execution of the agreement.

Benefits — The concept of 'benefit' is not legally defined by Law No 2011-2012, but Article L. 4113-6 CSP can be referenced for guidance. The term is interpreted very broadly to cover any type of payment, goods, or services given, directly or indirectly, without counterpart. Any benefit qualifies for public disclosure, whether or not exempted from the general prohibition set forth in Article L. 4113-6. However, public disclosure is only mandatory for any benefit whose value is equal or above 10 Euros (including VAT), including those given in relation to agreements (such as in cases of hospitality).

For each benefit given during a calendar semester, companies must disclose the identity of the beneficiary; the amount (including VAT), date, and nature of the benefit; and the semester. The information must be forwarded, in French, to the Authority by 1 August for benefits given during the first semester and by 1 February of the following year for benefits given during the second semester.

Publication — The information is published on a single public website to be run by a public authority ('Authority'). An ordinance will be adopted to determine the operation of the website.

The information is updated every six months. The Authority publishes the information related to the agreements entered into, and benefits granted, during the first semester by 1 October, and publishes the information related to the agreements entered into, and benefits granted, during the second semester by 1 April of the following year. The information remains available for a period of five years from publication.

The Authority takes the necessary technical measures (i) to ensure the integrity of the website; (ii) to ensure the safety and protection of directly identifying information against search engines; (iii) to comply with the data privacy rules; and (iv) to retain the personal data for ten years (from last modification).

Transitional Period — Specific rules apply until the adoption of the ordinance that sets up the public website.

Agreements entered into, and benefits given, in 2012: The information must be provided by companies to the relevant National Ethics Boards by 1 June 2013 and published by 1 October 2013.

Agreements entered into, and benefits given, from 2013 to adoption of the ordinance: The information related to the agreements entered into, and benefits granted, during the first semester is disclosed to the National Ethics Boards by 1 August and is published by 1 October. The information related to the agreements entered into, and benefits granted, during the second semester is disclosed by 1 February and published by 1 April of the following year.

The publication is made on the website of the relevant National Ethics Board and on the website of the company (or a website shared by several companies); alternatively, a trade association of companies may publish the information on its website on behalf of its members. The information must be published on dedicated pages of the website and be accessible for free. Companies, trade associations, and National Ethics Boards are subject to the same obligations as the Authority.

Specific Rules for Non-corrective Lenses, Cosmetics, and Tattoo Products

New Articles R. 1453-8 and R. 1453-9 CSP set out specific rules for companies that manufacture or market non-corrective lenses, cosmetics, and tattoo products. The same rules apply to those companies, except that:

- the application of the transparency obligation to agreements is limited to agreements relating to safety assessment, vigilance, or clinical trial; and
- the program of the event in cases of hospitality needs not to be disclosed.

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