La Kanzlei

# Sunshine Act in France: declaration obligations for health actors

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As a result of the so-called mediator scandal in France, which shed light on the relations between pharmaceutical companies and health care institutions, the French legislator has adopted measures concerning the transparency for conflicts of interest between companies producing or marketing health and beauty products and certain health care professionals.

The so-called "Sunshine Laws", which were adopted in the United States with a view to increasing the transparency of decisions taken by public authorities, were considered to be both pioneering and exemplary.

With his draft law, the former French Minister of Health, Bertrand, thus intended to clarify the relationship between the health system and industry. In this respect, the law on strengthening the health safety of medicines and health products of 29 December 2011 followed three approaches: the transparency for conflicts of interest, the reorganisation of the French Agency for the Health Safety of Health Products (so-called "Afssaps"), which became the National Agency for the Safety of Medicines and Health Products (so-called "ANSM"), and the control of medicines.

Decree no. 2013-414 of 21 May 2013[1] lays down the modalities of "transparency" and "public information" on the relations (advantages granted or agreements concluded) between companies producing or marketing health and beauty products and certain health care professionals. The decree of 22 March 2017[2] establishes the framework for the website ("**Base Transparence Santé**") on which declarations of potential conflicts of interest are to be made.

Article L. 1453-1 of the French Public Health Code (Code de la santé publique, "CSP") requires companies in France that manufacture or brand products for health or cosmetic purposes to publish the conflicts of interest that they may have with health care actors on a public website, the "Transparence Santé" database.

The Ministry of Health's communication of 29 May 2017 defines the information that must be disclosed, in particular:

- The **beneficiaries concerned** by the obligation to declare;
- the **types of benefits and rewards** that have been granted and that fall within the scope of the obligation to declare;
- the **amount of the advantages granted** (subject to a minimum amount of EUR 10).

The **companies and persons concerned** are, on the one hand:

- pharmaceutical companies (pharmaceutical laboratories or other companies that manufacture or market products for health and cosmetic purposes);
- Companies providing services related to these products.

**Attention should be paid to:**

According to the communication of the Ministry of Health of 29 May 2017[3], foreign companies must also comply with the regulations applicable to French companies and thus also comply with this obligation of declaration. Once foreign companies have signed agreements with French healthcare actors or granted them benefits or rewards, they must declare the information required by the law in the "Transparence Santé" database.

**Are considered as contracting parties or beneficiaries:**

- healthcare professionals, associations or federations bringing those healthcare professionals together;
- students preparing for these professions and associations or federations of those students;
- nursing institutions;
- foundations, scientific societies (so-called "sociétés savantes") and consultancy firms or institutions operating in the field of health products for human use;
- Press publishers, publishers of radio or television services and publishers of on-line communication services for the public;
- publishers of software for prescription or distribution;
- associations of users of the health system;
- legal entities providing or participating in the initial training of health professionals.

The following potential **conflicts of interest** are covered by this publication requirement, if they involve a minimum amount of EUR 10:

- **Agreements** between companies and health care professionals (so-called "conventions"): This concerns agreements that involve obligations for both parties. These include, for example, participation in a congress as a speaker (professional's obligation), with the company providing transport and accommodation (company's obligation).
- **Advantages** (so-called "avantage"): all services that are allocated or paid by a company to a health professional without any return (donation of equipment, meals, transport, accommodation, etc.).

- **Remunerations** (so-called "rémunérations"): the amount paid by companies to a health professional (health professionals or legal entity) in return for carrying out a work or service.

**Registration periods:**

Agreements, benefits and reimbursements must be declared within the deadlines set out below (see art. R. 1453-5 CSP):

- For agreements concluded and benefits and remuneration allocated or paid during the first half of the calendar year, i.e. from 1 January of year N to 30 June of year N, the declaration must be made on the "transparence santé" website no later than 1 September of year N.
- For agreements concluded and benefits and allowances allocated or paid during the second half of the calendar year, from 1 July of year N to 31 December of year N, the declaration on the "transparence santé" website shall be made no later than 1 March of year N+1.

**Sanctions:**

Pursuant to article L.1454-3 CSP, a fine of up to 45,000 EUR may be imposed on companies which knowingly fail to publish this information.

**Publication period**

The provided data are published for a period of 5 years. An exception is made for agreements concluded for more than 5 years. The data remain archived on the "Transparence Santé" database for a 10-year period from the last modification.

**To be noted in the registration:**

- Companies that are registered in the database must always submit a so-called Kbis (data provided by the French company register). For foreign companies, registration without Kbis is possible. In this case, the FAQ provides that for the purpose of registration (instead of the Kbis) the company receives registration data that it should apply for beforehand.
- Within groups of companies it is possible to centralise such declarations so that the parent company can submit declarations for its branches.

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[1] Decree No 2013-414 of 21 May 2013 on the transparency of advantages granted by companies manufacturing or marketing health and beauty products for human use, which is intended to apply Law No 2011-2012 of 29 December 2011.

[2] Decree of 22 March 2017, which repeals the decree of 3 December 2013 concerning the operating conditions of the public website "Base Transparence Santé".

[3] Information note No DGS/PP2/2017/180 of 29 May 2017 on the transparency of advantages granted by companies manufacturing or marketing products for human health and cosmetic purposes.

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