

## Publication of a new decree related to the law n°2011-2012 of 29 December 2011 improving the safety of medicines and health products ("Transparency law")

The long-awaited decree was issued on 21 May 2013 (the "Decree"). The Decree enables the implementation of the Transparency Law.

A circular which will provide complete terms and conditions of application of the Decree should also be published soon.

**According to the Transparency law, any company manufacturing or selling health products for human use or providing any related services ("Healthcare companies") is required to disclose all the agreements it enters into as well as any benefit granted, in kind or in cash, directly or indirectly.**

**The disclosure requirement is applicable to the agreements concluded with the following nine categories of persons:**

- HCPs (e.g. physicians, nurses, pharmacists, veterinarians, etc.);
- Associations of HCPs;
- Healthcare students and associations of healthcare students;
- Associations of users of the healthcare system (e.g. patients associations);
- Hospitals (public or private);
- Foundations and societies (*sociétés savantes*) or organisms involved in the sector of health products supported by the French health fund;
- Publishing companies : Press, radio, television and online media;
- Editors of prescription and dispensing software;

- Legal entities providing or taking part to the initial training (*formation initiale*) of HCPs.

In addition, any company manufacturing or selling cosmetic products, non-corrective ocular lenses, tattooing products or providing any related services, is required to disclose all agreements with the above listed categories relating to assessment work of safety, vigilance or biomedical research it enters into as well as any benefit granted in kind or in cash, directly or indirectly.

The disclosure requirement does not apply to agreements governed by Articles L. 441-3 and L. 441-7 of the French Commercial Code (e.g. annual commercial negotiation) which apply to the purchase of goods or services to the above nine categories of persons.

### 1. Threshold

Article D. 1453-1 of the French Public Health Code (FPHC) provides that each benefit must be disclosed when the amount **is higher than or equal to ten (10) euros all taxes included.**

## Key issues

- Threshold for the disclosure is ten Euros;
- The information must be sent to the relevant medical board no later than 1 June 2013 in relation to agreements and benefits related to 2012;
- The first disclosure will be made on 1 October 2013 and will concern agreements and benefits related to 2012 and the first six months of 2013;
- The disclosure will be published on a single public website, in French language. However the relevant *arrêté* has not been published yet. An intermediary system is put in place in the meantime.

## 2. Information related to agreements

The amounts specified in the agreements are disclosed.

The following contractual information must be disclosed by Healthcare companies: (a) identity of the parties, (b) date of signature, (c) purpose and (d) when applicable the program of the event.

### (a) Identity of the parties:

Regarding the quality of the beneficiary, Healthcare companies must disclose the following information:

- (i) For a HCP: name, first name, quality and if applicable, qualification, title, specialty, personal identifiers in the shared directory of health professionals and professional address;
  - (ii) For a student: name, first name, study institution and, if applicable, personal identifiers in the shared directory of health professionals;
  - (iii) For a legal entity: name, purpose and registered address.
- (b) Date of signature of the agreement;
  - (c) Purpose of the agreement must be drafted in compliance with the rules protecting business secrets including industrial and commercial secrets;
  - (d) Program of the event if the agreement is concluded for a promotional event or for events having exclusively professional and scientific purposes (this requirement does not apply to companies

which manufacturer or sell cosmetic products, non-corrective ocular lenses, tattooing products).

## 3. Information related to benefits

The following information must be disclosed by Healthcare companies:

- (a) Identity of the parties according to the same modalities mentioned above;
- (b) The amount, all taxes included, must be rounded to the nearest euro;
- (c) Date of each benefit;
- (d) Nature of the benefit received by the beneficiary during the preceding 6-month period;
- (e) The six month period during which the benefits have been granted.

## 4. Temporary modalities of disclosure

Until publication of an *arrêté* not yet published, the information must be disclosed on the relevant medical board's website if the agreement or benefit concerns HCPs, healthcare students or the associations of HCPs and of healthcare students.

The information will also have to be disclosed on the company's website or on a website common to several Healthcare companies (but available from each company's website). Thus, a trade association representing Healthcare companies is entitled to disclose the information on behalf of its members (e.g. LEEM).

The relevant information must be made available on the websites, in French language, within a dedicated section, identifiable and free of charge.

Until publication of the *arrêté*, Healthcare companies will have to send to the relevant medical board

the information relating to agreements or benefits granted during the first six months of the ongoing civil year no later than 1 August and during the second six months no later than 1 February of the year after.

Healthcare companies, trade associations representing Healthcare companies and the relevant medical boards will have to disclose the information relating to agreements and benefits on the relevant website granted during the first six months of the ongoing civil year no later than 1 October and during the second six months no later than 1 April of the year after.

So far the transitional provisions mentioned above concern the agreements concluded and the benefits granted during the period starting on 1 January 2012 until 31 December 2012 as well as the first six months of 2013.

For 2012, the information must be sent by Healthcare companies to the relevant medical board no later than 1 June 2013.

The first disclosure on the relevant websites will be made by Healthcare companies (or trade associations representing Healthcare companies) and the relevant medical boards no later than 1 October 2013.

## 5. Future modalities of disclosure

Declarations will be published on a single public website in French language. The information is transmitted directly to the relevant website's authority. An *arrêté* will specify the operating conditions of this public website.

Healthcare companies will send the above mentioned information to the relevant website's authority:

- no later than fifteen days after the date of signature of the agreement;
- no later than 1 August for benefits granted during the first six months of the ongoing civil year, and no later than 1 February of the year after for benefits granted during the second six months of the ongoing civil year.

The relevant website's authority has to publish this information respectively no later than 1 October of the ongoing civil year and no later than 1 April of the year after.

The public must have access to this information for a period of at least five (5) years from the date of its publication.

#### 6. Data Retention

The relevant website's authority has to take technical measures to ensure the integrity of the public website on which the information is disclosed, and to ensure safety and protection of exclusively identifying data (*données directement identifiantes*) against indexing by search engines.

Healthcare companies will have to inform the relevant persons of the

collection and of the publication of their data. They must retain data collected for divulgation purpose for a period of ten (10) years from the date of the last modification of the data.

#### NEXT STEP

A circular is expected to be adopted soon in order to provide, in particular, further details on the territoriality, the various categories of persons concerned by the disclosure, or the notion of advantage as well as other legal requirements.

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