



Fair Market Value, Transparency, Declaration of interests – an external lawyer perspective

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Content

- Transparency
- Fair Market Value
- Conflict of interests

Transparency

■ Privacy

Personal and private data concerning HCPs and medical students will be disclosed i.e. financial information.

In France draft decree provides that the legal entity has to specify the bracket of the cumulated amount received by an HCP or medical student within the last six months

Transparency

■ Data protection

Companies will have to collect and store various personal data on HCPs. For the purpose of the declaration:

- Companies shall check with national data protection agencies if there are any specific formalities to be complied with
- Companies shall check whether need to inform the concerned persons (i.e. right for the HCP to modify his information – what if the HCP disagrees on amount received?)

In France for instance the data protection authority (CNIL) said that it will render its decision on the transparency law upon publication of the decree.

Transparency

■ Confidentiality

Any declaration of interests which is made public has an impact of confidentiality undertakings

How can companies comply with this requirement and their confidentiality undertakings?

In France, companies will have to disclose the subject of the agreement, date of execution etc. However, draft decree provides that declaration shall be in compliance with secrets protected by the law e.g. trade secrets.

Companies may also consider including a clause providing for confidentiality of the agreement except if disclosure requirements whether legal or set forth by a code of practice...

Transparency

■ Impact of group structures on modalities of declaration

When a company has different separated business lines, does it have to disclose relations with HCPs even if with it relates to products which do not fall within the scope of the declaration of transparency ?

In France, as long as the legal entity manufactures/sells a product that falls within the competence of the ANSM (the French medical agency) it will have to disclose this relationship. What matters is the legal entity not the business line.

If different entities of the same group fall within the scope of the law, can a parent company make one consolidated declaration?

No, each entity will have to make a declaration – On top of that, a declaration could be made for the group but this is not mandatory.

Fair Market Value

■ Need for determination of Fair Market Value

Principle of Equivalence: Compensation should be appropriately tied to the services provided by healthcare professionals (HCPs);

Implementation of principle of equivalence: setting up internal guidelines – indeed, pre-defined values for typical interactions reduce the risk of overpayments / hidden benefits

Fair Market Value

■ Examples of criteria for determination of Fair Market Value

Hourly or daily rates

Enhancing factors: e.g. qualification experience and reputation of the physician; ancillary tasks etc. Criteria not to be too detailed to keep flexibility in order to be able to justify exceptions

Benchmark studies: need supporting data to consider a region as a whole; how much HCPs are paid for their main activity etc.

Conflict of interests

■ Confidentiality

Agreement with an HCP who has to make a declaration of interest – will have to disclose the subject of cooperation with the company (e.g. name of product) – what if this information by itself is confidential ?

Examples of information that French experts may have to disclose: date, remuneration, name of product, subject of the study, type of clinical trial (monocenter or multicenter)



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