

Implementation of the French Sunshine Act: one year on

The last two years have been marked by unprecedented scrutiny of financial relationships between manufacturers and healthcare professionals. Both the US and France have imposed sweeping reporting and disclosure requirements in an effort to provide transparency and enable the public to make informed treatment decisions and assess possible conflicts of interest. That being said, a review of the highlights of the two Sunshine Acts demonstrates that transparency is not necessarily the same on one side of the Atlantic as the other. One year after the implementation of the French Sunshine Act, Daniel Kadar of Reed Smith looks back at how compliance has and continues to be a real challenge for global manufacturers.

References to the US Sunshine Act are useful because they show that even if the aims are close, the French and the US regulators used very different means to get there.

Take the actors. Under the new law, US manufacturers will primarily be reporting payments and transfers of value to physicians and teaching hospitals, along with physician ownership information.

In contrast, manufacturers concerned by the French Sunshine Act are any company that manufactures or markets products regulated by the Medicines Agency ('ANM'), including, but not limited to, drugs, biological products, medical devices, devices for in vitro diagnosis, cosmetic products, tattooing products, and biocide products, etc.

It also concerns any company that operates in France providing

associated services in connection with one of these products, such as technical services to use any product or communication or advertising to promote one of these products, and also any company acting on behalf of a company that manufactures or markets such products.

In addition, whereas in the US the list of Health Care Professionals ('HCPs') is relatively short, the transparency obligations that are set forth in France concern a much broader list of

professionals: beneficiaries of agreements concluded or benefits granted by healthcare companies that are affected by the French Sunshine Act are not only all healthcare professionals in the US sense, but also associations of HCPs, medical students, associations of medical students, associations of health system users, clinics and hospitals, foundations, medical societies and advisory societies, and companies operating in the health products sectors, including publishing companies, broadcasters, publishers of public online communications services, publishers of prescription and drug delivery assistance software, and legal entities providing training sessions for covered HCPs.

And if that wasn't enough, it is important to note that even the definition of HCPs differs from the US law, as the French Sunshine Act includes all kinds of healthcare professionals such as physicians, pharmacists, and dentists but also childcare assistants, ambulance staff, medical laboratory technicians and many more.

What must be disclosed?

This is another point where the two sets of regulation differ. For any agreement entered into with HCPs, medical students, associations, and companies must, under the French regulation,

disclose the following:

- The name and address, as well as (i) registration number, qualification and specialty for individual HCPs, (ii) educational establishment and professional number for medical students, (iii) names, and registered office for companies;

- The date of the contract;

- The purpose of the contract without violation of the confidentiality of commercial and industrial information;

- However - and this makes a huge difference with the US regulation - no amount is to be disclosed.

For benefits provided to HCPs, medical students, and legal persons, companies must disclose:

- The name and address, as well as (i) registration number, qualification and specialty for individual HCPs, (ii) educational establishment and professional number for medical students, (iii) names, and registered office for companies of both the recipient of the benefits and the company;

- The value of the benefits (including taxes) rounded to the nearest euro, the date on which the benefits were granted, and the nature of each benefit (threshold: €10 incl. VAT); and

- The period during which the benefits were provided (the first or second half of the year).

What needs to be highlighted here is that there is an important contradiction between the disclosure of the amount of every benefit above €10 whereas there is no need to disclose the amount granted to a HCP under a speaker agreement.

Consequently, the information provided to the public is relatively limited. Companies need to disclose the cost of a coffee with a croissant, whereas they do not need to disclose the amount granted under a specific contract.

Literature has raised the argument that revealing the amount granted through a speaker contract or a research contract on top of an invitation to a dinner would make more sense to highlight the links of interest between a pharmaceutical company and a healthcare professional. The French regulator has - to date - not followed that path. Therefore, and contrary to the US, the transparency obligations do not contain indirect means that would allow for the collecting of information for a possible legal action against manufacturers. The aim of this set of regulations is therefore only to inform the public of existing contractual links without providing any detail.

How to disclose?

This has been a tricky question in France over the past two years. As of today, and now it is opened, a unique web portal set up by the French Government is now receiving the transparency disclosures. This portal offers three possibilities for the disclosure and transfer of data: a script can be filled in online; a specific formatted document can be transferred directly to the website; and automatic sending through a web service can also be set up.

Benefits must be disclosed on the French Government website twice a year:

- Those granted between January to the end of June must be disclosed before 1 August and will be released on the French public website on 1 October.
- Those granted between July to

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the end of December must be disclosed before 1 February of the following year and will be released on 1 April.

What about contracts?

Contrary to benefits, contracts must be submitted within two weeks after the signature of the said contract. As a result, two regimes coexist, which does not ease compliance. The regulator seems to be re-evaluating this calendar in order to set forth a unified disclosure schedule.

Data protection

This is another particularity under French law: the French regulator has specifically addressed the data protection issue (in particular the protection of the HCP's data). The balance between transparency obligations and data protection is really interesting: First of all, no notification of the data collection and processing is required by the French Data Protection Agency, the CNIL. This is quite an exception to the existing regime and can only be explained by the fact that disclosure of the information is mandatory: it would not make sense to notify the collection and processing of personal data that the law obliges a company to collect and process. However, as soon as the data are transferred outside of the EU, a notification will be required in order to make sure that such a transfer is made in compliance with data protection rules. Here, the US is particularly targeted as EU and French regulation does not consider that the US has an 'adequate level' of protection.

On top of that, HCPs must be notified by the company that they will disclose their related data on the French state portal for transparency purposes. The regulation deprives data owners from the right to have their data removed, that said under the French regulation the data can be changed.

Penalties

Manufacturers face a fine of up to €45,000 as well as additional sanctions such as the publication of the judicial decision relating to the conviction and in particular the prohibition of the manufacture, package and import of any health product.

Conclusion

The French Sunshine Act represents a cumbersome process for companies to disclose data, with two different schedules depending on whether agreements or benefits have to be disclosed.

So far, the data collected for the first semester of 2014 are as follows: 779,207 benefits; 323,985 agreements; 1,103,192 new data entries; and 77% of the declarations are related to drugs. More than 1,130 companies are registered on the state portal.

However, this process has at least one advantage: it eases dramatically the monitoring of HCC/FCPA/UKBA compliance as literally everything spent has to be monitored.

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