

The French Sunshine Act continues to be a challenge

Daniel Kadar, Partner at Reed Smith, analyses the legal instability surrounding the French Sunshine Act, which has been brought into sharp focus by the recent ruling of the French Supreme Administrative Court, which on 24 February significantly expanded the scope of the law. Daniel discusses the latest developments, alongside the erratic evolution of the law, which has the potential to negatively impact the healthcare industry in France.

Still a work in progress

The so-called French Sunshine Act (Law No. 2011-2012 of 29 December 2011) is unfortunately still to be seen as a work in progress that requires clarification on an ongoing basis. The chronology of the evolution of the regulation is quite erratic in that respect.

The general rule for 'companies which produce or market health products or which provide services associated with such products' to disclose 'the agreements concluded with and the benefits in cash or in kind granted directly or indirectly to French healthcare professionals [hereinafter 'HCP']' was enshrined in law and came into force on 1 January 2012. However, the implementing rules of the disclosure obligations were left to the interpretation of a decree (Decree No. 2013-414 of 21 May 2013), which was adopted 17 months later and set forth full retroactivity back to January 2012. A governmental circular (Circular No. DGS/PF2/2013/224 of 29 May 2013) was also issued at the same time to clarify the applicable regulation. A Ministerial Order - Arrêté - (Arrêté of 3 December 2013) was then adopted six months after these interpretative

texts, and foresaw the implementation of a unique transparency portal, which went live in June 2014. Then, in late 2014, an opinion from the French Directorate General of Health (Direction Générale de la Santé, 'DGS') reinterpreted the territoriality of the law stated in the French Sunshine Act, by extending the disclosure obligations to companies headquartered abroad - even if they do not produce or market health products in France - which contract with a French HCP. This represented a significant change by increasing the types of companies that are subject to disclosure obligations. As a result, this new interpretation now contradicts a literal lecture of the text of the regulation.

The proliferation of interpretative texts does not only create legal insecurity and instability surrounding the regime, but it also adds additional complexity due to the retroactive effects of the new requirements associated with the changes in interpretation.

The Supreme Administrative Court's decision

This period of legal instability does not seem to have come to an end yet: on 24 February 2015, a decision of the French Supreme Administrative Court (Conseil d'Etat) significantly expanded the scope of the law.

This important decision was issued after a French association standing for independent medical training and information, free of any interest other than human health ('FORMINDEP') and the French National Medical Council ('CNOM') challenged the legality of the implementing decree of 21 May 2013 and its governmental circular of 29 May 2013:

● The Conseil d'Etat annulled the provision of the implementing decree under which companies

which manufacture or market non-corrective contact lenses, cosmetic and tattoo products are not subject to the same disclosure obligations that apply to companies which manufacture or market medicinal products. As a result, reporting obligations should be aligned for both industries.

● Most importantly, the Conseil d'Etat also annulled the provision of the circular under which remuneration specified in agreements with HCPs are not treated as benefits and are therefore not disclosed. Such a view results from a restrictive interpretation in the circular of the French Sunshine Act, which provides that 'all benefit in cash or in kind' must be disclosed and therefore healthcare companies will need to disclose the remuneration paid to HCPs.

One could argue that there was no consistency in disclosing on the one hand the information concerning the price of a meal or air ticket granted to an HCP traveling to a conference organised by a healthcare company, but not disclosing on the other hand the fees for services paid by the company to the same HCP for their participation in a conference or for consulting services.

The reason that it was accepted in the first place that companies should not have to disclose the remuneration of HCPs was related to the aim of ensuring business secrecy and confidentiality. The new requirement related to the disclosure of HCPs' remuneration should therefore provide the public with a 'true picture' of the links between healthcare companies and the French HCPs.

Implementation of the new requirements

That being said, the core difficulty of the French Sunshine Act's regime is that these interpretations

of the law, being an indirect change of the regulation, should be immediately applicable. However, the date of application of the new requirements is still a major practical issue that needs to be addressed, as the Court's decision does not clarify when the changes in the implementation of the French Sunshine Act will apply.

A restrictive interpretation would be that the new decision that the provision foreseeing no disclosure of the remuneration paid in the framework of agreements with HCPs being considered null and void, should be repaired as of the beginning of the coming into force of the law, i.e. as of 1 January 2012, which would mean corrections over the last three years. A more conservative approach would be to consider that no retroactivity is foreseen and therefore, the reporting obligations could start as of 1 January 2015 in order to have a full year of reporting.

The complexity of the implementation of such indirect changes should not be underestimated as these are key for the industry: the abovementioned transparency decree of 21 May 2013 can in that regard be valued as one of the worst examples of retroactive implementation. The text imposed retroactively the disclosure of data back to 1 January 2012. On top of that, such requirement was supposed to be implemented by the industry within a week, on 1 June 2013.

The only possible way to circumvent such a rigid framework was to allow some flexibility in its implementation, which is what happened. However, whilst flexibility is welcome, the downside is that there is no clear guidance as to the length of such an 'adaptation phase' and the tolerance in that respect. So again legal uncertainty is created, in particular for international companies that are

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required to navigate through this challenging environment and who may not be that familiar with the French legislative 'adaptation' process.

These unstable times may continue as another round of changes to the French Sunshine Act are currently under discussion: the issue of territoriality could be revisited after the aforementioned opinion of the DGS, as well as the periodicity of disclosure reporting - it makes no sense to have benefits disclosed every six months whilst agreements have to be disclosed 15 days after their signature.

Further concerns

Besides the legal instability described above, initial trends can be identified concerning the consequences of the implementation of the transparency regulation. Two trends at least can be identified:

First, with regard to the interpretation of the Conseil d'Etat, the French sunshine regime seems now to be aligned with the US sunshine system in terms of the value of the contract. Does this have any consequences for product liability and litigation?

In that respect, the terms of the debate are different in France, as (a) class actions have for now a limited scope - however, things are about to change as a bill for the extension of class actions to health related claims is currently being discussed at the French National Assembly, and (b) the liability is based on the defectiveness of the product rather than the negligence of the manufacturer. However, the crossing of such transparency data, which will now be publicly available, with potential defectiveness concerns could potentially lead to an increase of separate liability/tort claims against HCPs, and perhaps even criminal claims. Just recently, a French

investigatory newspaper examined the transparency filings and found that 75% of the approval committee for two vaccines were bound by a consulting agreement to the vaccine manufacturers.

This particular point will certainly be closely monitored in terms of insurance coverage alongside broader 'reputational screening' of HCPs if their links to industry could be valued as too close.

Another trend of the disclosure of 'links of interest,' as they are called in France, between HCPs and the healthcare industry, is that no HCP having been in a contractual relationship with the industry for a period of less than five years can be associated in any form whatsoever with the evaluation of a drug or medical device by the French Agency for Drug Safety and Health Products ('ANSM'). As a consequence, practitioners who are helping to improve drugs and medical devices cannot be part of this process although it would be very helpful. This situation could also more directly affect the industry if French HCPs consider that they should be less involved in the improvement of drugs and medical devices because of reputational and insurance concerns now that all payments made to them are to be disclosed. Should this happen, it would be questionable as to whether all this helps the patient in terms of research and development.

The French transparency requirements, along with other transparency requirements like the US Sunshine Act, should not only be scrutinised for compliance purposes but also raise important questions in regards to liability that also need to be addressed.

Daniel Kadar Partner
Reed Smith, Paris
dkadar@reedsmith.com