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France: An unrecognized transparency pioneer?

» There is a lot of talk about the new French anti-corruption law and whether it will have a positive impact on France's current inadequate enforcement of its anti-corruption laws.

» Meanwhile, France is undergoing a "petite revolution" in relation to the transparency of the relationships between the healthcare industry and healthcare professionals.

» The country is in the process of imposing a regime of pre-authorization for certain types of interactions with healthcare providers.

» We are also expecting regulations setting maximum amounts for advantages, and by type of advantages (e.g., meals, hotels, compensation).

» Finally, the country is moving toward full-transparency mode for those interactions through more stringent rules of public disclosure.

There is a lot of talk about France's new anti-corruption law dated 9 December 2016 (Sapin II Law), including a lot of questions. However, it all boils down to one key question: is it going to work? Is France finally going to join the ranks of countries seriously enforcing their anti-corruption laws?

Fellouse-Guenkel

You can read a lot of articles inside and outside of France referring to how French companies might not be ready, despite the sophistication of the pre-existing French anti-corruption legislative arsenal. Whether the Sapin II Law will have a positive impact on the locally driven fight against corruption is yet to be seen and could take several years to play out.

The purpose of this article is not to explore the intricacies of the Sapin II Law but rather to highlight the ongoing revolution in French healthcare compliance: France is aiming toward total transparency in regard to the interactions between the healthcare industry and healthcare professionals.

In December 2011, France adopted the first transparency law, called "Bertrand Law," in the wake of a major healthcare scandal (the Mediator Scandal). Interpreting the law was challenging, however, and the pace it imposed on companies for its implementation was simply brutal.

In a nutshell, the key milestones and events are summarized below:

- December 2011: adoption of the Bertrand Law, requiring a large array of healthcare-related companies to publicly disclose all advantages given to, and contracts entered into, with an even wider array of healthcare professionals. However, the how, the what, and the when of that public disclosure was pretty much left up in the air.

- Effective date of the new requirement: 1 January 2012, subject to the adoption of subsequent complementary and interpretative regulations.
- On 21 May 2013 (yes, 18 months after the Bertrand Law was implemented!), the main application decree was adopted and informed healthcare companies that on 1 June 2013, companies needed to disclose on their websites, and on the websites of the relevant professional medical boards, all advantages over 10€ given to, and contracts entered into, with healthcare providers licensed in France **since 1 January 2012** (yes, going retroactively by 18 months as the decree could not technically overcome the legislatively imposed effective date of the obligation).
- Finally, a public website was created, and companies got into the rhythm of making the necessary disclosures, and that, it seemed, was that.

On the positive side, we had a website (though largely unknown to the French population) in France where you could see how often your GP eats lunch with the pharmaceutical or medical device industry. You could also see what contracts they have in place with the healthcare industry.

However, you were unable to determine how much was paid by the company to the doctor under the contract. Companies were not compelled to disclose that aspect of the contract. This meant that although you would know the price of the breakfast offered to Dr. Duchemin by *Laboratoire La Science* to discuss their new consulting agreement, you would not know how much was paid under that contract.

Now, one could have thought that was sufficient improvement by the so-called low anti-corruption French standards and that progress would stop there. However, with these clear inadequacies, France's lawmakers decided to turn up the heat even further, with tougher requirements now set to be imposed.

On 26 January 2016, as per the requirements of the French Conseil d'Etat, who chastised the government for the lack of transparency of the initial system, a new law "on the modernization of the healthcare system" pushed for full transparency of the interactions between the industry and the healthcare providers.

In terms of the main changes, this means the following:

I. On the transparency system whereby agreements and advantages over 10€ are being publicly disclosed on the transparence.sante.gouv.fr website: Both the **amount** of the contracts and the **remuneration** paid to each healthcare provider (which could mean two new entries for companies to implement in their reporting systems) will now have to be disclosed as of 1 September 2017.

II. On what is usually called the "anti-gift law," which provides a general principle of prohibition of any advantage given to most healthcare providers:

   A. Extension of the scope of the general principle of prohibition of advantages.
   The new law entails a drastic widening of the scope of the pre-existing general principle of prohibition of advantages to French healthcare providers, and in particular:
   - Extension of the principle of prohibition of advantages to healthcare companies, even if their drug or medical device is not reimbursed by the French social security, whereas up until

now the "anti-gift law" applied only to companies having at least one reimbursed product.
- A clearer extension of the prohibition to associations of healthcare providers.
- Extension of the prohibition of any advantages to public officials in the healthcare-related public bodies.

B. Narrower definition of the acceptable exceptions to that general principle of prohibition of advantages, thus giving less room for interpretation (e.g., it would seem that the overall exception to the general principle of the prohibition for "normal work relationships" is now gone).
C. The upcoming definition by the law of what "reasonable hospitality amounts" are. The amounts to be clearly defined should (hopefully!) come as no surprise to French healthcare compliance practitioners. Historically, the French Medical and Pharmaceutical boards unofficially defined acceptable amounts for hospitality and compensation, and it is expected that these new official limits will align with those amounts.
D. A shift from what has been up to now an unclear and constantly changing system of declaration of interactions with healthcare providers to the French healthcare professional boards: the new process will require a simple declaration for interactions below a certain amount and a comprehensive prior authorization for interactions above said amounts.

In conclusion, France is endeavouring to go well beyond just "paper transparency." In fact, it's going for a fully fledged and much more robust system of transparency with a clear goal in mind: to assist its citizens in knowing about links between their healthcare providers and the industry. Of course, the "Sunshine Act à la *française,*" whilst offering significant improvements, is still imperfect and will have its limits even after all the outstanding pieces of legislation have been adopted. Nonetheless, I believe that these developments help shed a different light on how France can fight corruption. ✳

1. https://www.transparence.sante.gouv.fr

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