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"SUNSHINE ACT" IN EUROPE: STRENGTHENING OF TRANSPARENCY OBLIGATIONS FOR THE PHARMACEUTICAL AND MEDICAL DEVICE SECTORS

In Belgium, due to the new Sunshine Act, almost all advantages and benefits granted to physicians in 2017 must be disclosed by pharmaceutical and medical device companies before the 31st of May 2018.

During the summer 2017, two Royal Decrees (dated 14th of June and 31st of July) finally led to the entry into force of the « **Belgium Sunshine Act** » (Belgian Law of 18 December 2016, concerning various health-related matters).

This law was named with reference to the "Physician Payments Sunshine Act" adopted by the USA in 2010, that provides for transparency in the relationship between physicians and pharmaceutical companies with respect to payments and other transfers of value, and physician ownership or investment interests in manufacturers.

Similarly, Belgium recently adopted its own Sunshine Act, introducing new transparency obligations applying to the pharmaceutical and medical device industries. Until that time, transparency rules were issued by ethic codes of conduct or guidelines, only binding on member companies, on a voluntary basis. The Belgium Sunshine Act has made these commitments mandatory for all companies acting in the Belgium healthcare sector (and in particular, pharmaceutical and medical device companies, regardless of their legal status and the way they are financed).

Such companies must disclose to the Federal Agency for Medicines and Health Products ("FAMHP") all pecuniary advantages or benefits in kind granted, directly or indirectly, to all healthcare professionals, healthcare organizations and patient associations having their principal activity or registered office in Belgium. Therefore, any transfer of value in money or in kind, although subject to exceptions, must now be notified to the FAMHP.

Belgium is henceforth part of the limited circle of the European countries with a full set of transparency rules, among others like Denmark, France, Portugal or Slovakia.

As it was the case in France − first European country to adopt a "Sunshine Act" with the French Law "Bertrand" in 2011, implemented in 2013 and completed by the recent Law "Touraine" in 2016 −, Belgium has adopted a **broad transparency system**, regarding both the actors concerned and the way of publication of information, namely a unique transparency website accessible by the public.

However, differences may be noted, specifically regarding the types of transfers of value that are subject to the disclosure obligation. Whereas Belgium expressly provides for an exemption for meals and drinks offered in the context of scientific events that are of an exclusively scientific nature, advantages and benefits of "negligible value", economic margins and price discounts as well as free samples, France only provides for derogations concerning benefits in kind or in cash of less than 10 €.

Conversely, some European countries still do not provide for legally binding transparency rules, as this is the case for Germany, where the rare obligations to be fulfilled in certain cases, applicable to the pharmaceutical sector, do not concern the medical device sector.

Other countries, like the United Kingdom, provide for transparency rules only binding on certain limited healthcare professionals, that are members of the National Health Sector organizations. On the other hand, the private sector healthcare professionals are not subject to any legally binding transparency obligations – neither are the companies. The only transparency rules applying to the latest are issued by healthcare industry associations and are not mandatory. As an example of these non-binding rules, the last version (May 2017) of the Association of British Healthcare Industries' Code of Ethical Business Practice provides that from 1st January 2018, member companies will be required to gather the data regarding the educational grants provided to healthcare organizations with a view to publicly disclosing them from 1st January 2019. In practice, such rules are often observed on a voluntary basis by pharmaceutical and medical device companies, which are not members of the ABHI Code.

In practice, it is important for a company to assess whether it is supposed to apply the rules in force in the country where the physician or organization is located. As a result, for foreign companies wishing to interact with a physician or organization in a given country, due to the above assessment issue and to the differences between national laws, the exact regime and formalities to be complied with could be difficult to anticipate. In this respect, a specialized legal advice is highly recommendable.

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