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The healthcare industry under scrutiny and forced to be more transparent

The so-called Médiator® case[1] has fostered in France an unprecedented climate of suspicion towards the healthcare system and significantly tarnished the image of the medicinal product industry and healthcare companies in general.

Fully aware of the shockwave caused by this case, the French legislator adopted a law to restore public confidence in the French health security system, which imposed new constraints and obligations on healthcare companies that are expected to operate more transparently.

The Law of December 29, 2011[2] (the "2011-2012 Law") is based on a central pillar, i.e. transparency, which is considered as a prerequisite for the prevention of conflicts of interests that have devastating effects in public's mind.

Hence, the creation of a single public declaration of interests[3] according to which each member of commissions, administrative authorities and health bodies must disclose the ties he/she has had with the companies, institutions or bodies operating in the same industry "*during the five years*" preceding the date he/she took up their position. Members who do not comply wit this requirement shall face financial penalties and other sanctions.

The second flagship measure introduced by the 2011-2012 Law is aimed at forcing healthcare companies into more transparency by imposing on them the obligation to publicly disclose any and all agreements entered into with health professionals, patient associations, foundations, specialized media, learned societies, consulting organizations and businesses.

The 2011-2012 Law also contains provisions that improve the transmission of information to consumers and further regulate the advertising of medical devices.

For the sake of clarity and readability, this article will exclusively focus on the obligation imposed on healthcare companies to disclose the agreements entered into with healthcare professionals. Undoubtedly, we will have the opportunity in future articles to address the other measures introduced by 2011-2012 Law in order to restore public confidence in the French healthcare system.

For the record, it should be noted that agreements between healthcare companies and healthcare professionals must already be submitted to the council of the relevant professional board for examination.

Such councils ensure that the independence and impartiality of the healthcare professionals (who are authorized to prescribe the products listed in Article L.5311-1[4] of the French Public Health Code, the "FPHC") will not be compromised by the financial benefits that could be offered to them by healthcare companies **(I).** The 2011-2012 Law further strengthens the control of such agreements as healthcare companies are now required to publicly disclose such agreements. If they fail to do so, they face criminal penalties **(II).**

Agreements between healthcare companies and members of medical professions already subject to control

Since the adoption of the so-called "anti-gift" Law[5], agreements between healthcare companies and healthcare professionals are subject to a strict control mechanism set up by the legislator and implemented by the councils of the relevant professional boards.

As such, Article L.4113-6 §1 of the FPHC establishes a general principle of prohibition of in-kind or in-cash benefits granted *"in any form whatsoever, directly or indirectly"* by healthcare companies (laboratories, industrials) to members of the medical professions[6].

There are, however, two exceptions to this general principle: (i) the benefits granted in the framework of research activities and (ii) the hospitality offered at promotional or scientific events, insofar as they are set forth in a written agreement to be previously submitted for examination to the national council of the relevant professional board[7].

To be approved, the amount of the benefits granted in connection with research activities and the offered hospitality should be justified and proportionate.

Benefits that appear unjustified (with regards to both the activity to which they relate and their amount) should be considered as "prohibited" within the meaning of Article L.4113-6 §1 of the FPHC. Sanctions likely to be imposed on the members of the medical professions who received the benefits and on the companies that granted such benefits are – at least in theory – quite severe.

Specifically, pursuant to Article L.4163-2 §1 of the FPHC, members of the medical professions who have

received “prohibited” benefits are liable to a 75,000 Euros fine, a two-year prison sentence and, in addition, a temporary ban (10 years) from practicing their profession. The corporate officers of an healthcare company that has granted “prohibited” benefits are liable to the aforementioned fine and the company itself – if its criminal liability as legal entity is established in the conditions set forth in Article 121-2 of the French Criminal Code – is liable to a fine up to 375,000 Euros (plus the risk of being banned from managing or being excluded from public procurements for 5 years or even definitively)[8].

It is therefore highly recommended to seek the advice of a lawyer or specialized in-house counsel for the drafting of such agreements, even before submitting them to the national council of the relevant professional board, to make sure their content is fully lawful.

This recommendation is now more appropriate than ever, given the recent legislative evolution that further increases the burden of liability of healthcare companies concerning the content of agreements entered into with members of the medical professions and the mandatory disclosure thereof.

The 2011-2012 Law further strengthens the control of agreements entered into between healthcare companies and members of medical professions

The 2011-2012 Law imposes three series of rules that force contracting healthcare companies and healthcare professionals to be more vigilant on the terms and conditions of the concluded agreements.

a) The scope of prohibition is extended to other healthcare actors

The principle of prohibition of benefits now extends to associations of healthcare professionals (including learned societies) and healthcare students (new Article L.4113-6 § 1 of the FPHC)[9].

This extension caused quite a stir among health professionals and associations whose very existence is threatened as a great part of their budget comes from grants and subsidies from companies operating in the healthcare industry.

Their concern is all the more justified as it seems that they do not benefit from the exemptions provided for under Article L.4113-6 §2 and §3 of the FPHC dealing with research activities and hospitality. The wording of these two paragraphs remained indeed unchanged.

The LEEM (French Pharmaceutical Companies Association) expressed its concerns and indicated that “*extending the scope of the prohibition of benefits to associations, without providing for correlative exemptions for research activities and hospitality (…) results, strictly speaking, in a ban on all activities with associations of healthcare professionals*”.

It is hard to believe that the legislator – however keen he may be to prevent conflicts of interests – intended to

deprive many scientific associations of resources, with the risks of seeing these associations disappear one by one.

A letter of January 25, 2012 from the General Health Directorate ("GHD") seems to reveal a belated awareness of the consequences that could be associated with an extension of the scope of the prohibition to associations (without providing for correlative exemptions). The GHD indicated that "*the intention of the legislator is that students (…), members of the medical professions and associations representing them all be treated in the same way, as regards both the principle of prohibition, the available exemptions and transparency requirements*".

As such, in a circular letter[10] dated January 26, 2012, the LEEM concluded: *"(…) the LEEM obtained from the GHD a letter specifying that they [the associations] will in fact benefit from the same exemptions as the health professionals. There was apparently a mere omission and there will be an "administrative tolerance" on this specific issue"*. It thus should be still possible to enter with scientific associations into agreements for research activities and hospitality.

It remains to be seen whether and how the implementing decree (not yet published to date) will soften the provisions of the 2011-2012 Law or remedy this omission.

b) Obligation to submit any and all agreements to the competent council of the relevant professional board

Until now, it was a customary practice – at least, this is what we use to recommend – to submit all agreements (and not only those dealing solely with research and hospitality benefits) to the council of the relevant professional board for opinion[11].

This is now an express legal obligation introduced in Article L.4113-6§4 of the FPHC by the 2011-2012 Law[12]: all agreements whatsoever that have been entered into between healthcare companies and healthcare professionals must be submitted for opinion to the council of the relevant professional board (local or national council, depending on the scope of the agreement).

As per the above Article, it is up to the healthcare company to submit the relevant agreement to the competent council and to inform it of the effective implementation of such agreement (which will enlighten the relevant council on the consideration given to its opinion, especially when it issues a negative opinion!).

c) Obligation to disclose the agreements

Since 2010 and until now, companies had the obligation to file each year with the French

Health Authority ("FHA") the list of patient associations they supported as well as the amount of aids of any nature whatsoever granted to such associations over the past year (Article L.1114-1 of the FPHC).

In the wake of the US *Sunshine Act*, the 2011-2012 Law now imposes the obligation to disclose the agreements entered into between healthcare companies and healthcare professionals.

As such, pursuant to Article L.1453-1 of the FPHC, companies that manufacture or market the products listed in Article L.5311-1 of the FPHC (cf. footnote 3) as well as those "*that provide services associated with these products*" must disclose any and all agreements entered into with healthcare professionals, association of healthcare professionals, healthcare students, patient associations, healthcare facilities, foundations, specialized press bodies, companies providing software concerning the drafting and delivery of medical prescriptions as well as companies involved in the initial training of healthcare professionals.

In addition, this disclosure obligation applies to all benefits in-kind or pecuniary benefits granted by healthcare companies to healthcare professionals insofar as such benefits are equal to or exceed a threshold to be fixed by decree.

It should be noted that non-compliance with this new legal obligation is punished by a 45,000 Euros fine[13], it being specified that the infringing individual may also be subject to additional penalties under Article L.1454-4 of the FPHC[14].

Pursuant to Article L.1454-3 of the FPHC, legal entities whose criminal liability is established (Article L.1454-5 of the FPHC) are subject to a fine up to 225,000 Euros (plus possible standard ancillary sanctions) if they do not comply with the disclosure obligation.

On the date hereof, the – long-awaited – Implementing Decree has not yet been published: the terms and conditions of disclosure, the authorities to which such disclosure must be made and the nature of the information to be disclosed thus remain unknown.

Yet, and this is precisely the problem, Article 41II of the 2011-2012 Law stipulates that: *"these provisions shall apply, as from the date of publication of the Decree implementing Article L. 1453-1 and on August 1, 2012 at the latest, to all agreements implemented or entered into and to all benefits granted and remunerations paid as from January 1, 2012".*

This means that, if the Implementing Decree is not shortly published – which is still the case on the date hereof – companies should nonetheless comply with the disclosure requirements set forth in Article L.1453-1 as at August 1, 2012 (whereas, in the absence of a decree, uncertainty remains as to the practical terms and conditions of disclosure).

In our opinion and pursuant to the general principle that penalties must have a proper legal basis, it is unlikely that companies that failed to comply with the disclosure requirement set forth in Article L.1453-1 of the FPHC as at August 1, 2012, will be convicted and sanctioned.

However, we can only strongly recommend that all companies affected by this reform of healthcare regulations start preparing the list of agreements entered into with healthcare professionals so that they can complete the

disclosure formalities as soon as the Implementing Decree is published.

Generally speaking, this new disclosure obligation will undoubtedly lead companies to implement an internal reorganization (in terms of staff and IT tools) to manage such disclosure formalities that will generate additional work.

Lastly, an upstream control of the agreements seems essential: as transparency is now systematically required, an agreement with unlawful content will no longer go unnoticed…

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[1] Officially marketed for use in diabetes, the Mediator – manufactured by the French pharmaceutical company *Laboratoires Servier* – was also widely prescribed as weight loss drug. It remained on the market for years despite a succession of warnings over its side- effects, including the fact that it caused heart valve disorders. It was finally withdrawn in late 2009. *Laboratoires Servier* and its founder, Mr. Jacque Servier, were indicted for fraud and aggravated deception in September 2011.

[2] Law n°2011-2012 of December 29, 2011 for the improvement of medicinal and heath product safety.

[3] Article L.1451-1 of the French Public Health Code.

[4] Are covered by Article L.5311-1 II of the FPHC:

1. medicinal products, including pesticides, acaricides and anti-parasitic drugs intended for human use, extemporaneous (magistral), hospital and officinal preparations, narcotic and psychotropic substances as well as other poisonous substances used in medicine, essential oils and medicinal plants and raw materials for pharmaceutical use;
2. Contraceptives and contragestives;
3. Biomaterials and medical devices;
4. In vitro diagnostic devices;
5. Labile blood products;
6. Organs, tissues, cells and products of human or animal origin, including those from surgical operations;
7. Cellular products for therapeutic use;
8. Breast milk collected, classified prepared and stored by breast milk banks;
9. Products used for lens care and application;
10. (Repealed)
11. Processes and equipment used for disinfecting premises and vehicles in the circumstances listed in Article L. 3114-1 (of the FPHC);
12. Therapeutic products;
13. (Repealed)
14. Non-corrective ocular lens;

15. Cosmetics;
16. micro-organisms and toxins listed in Article L. 5139-1 ;
17. Tattoo products;
18. Software that are not medical devices and that are used by medical biology laboratories for the management of medical biology examinations and for the validation, interpretation and appropriate communications and record-keeping of the results;
19. Devices not strictly used for medical purposes and used by medical biology laboratories to perform medial biology examinations.

[5] Law n° 93-121 of January 27, 1993 on various social measures. Article 47 of this Law introduced the general principle of prohibitions of in-kind or in-cash benefits granted to members of the medical professions by private sector companies.

[6] This prohibition needs to be combined with that set forth in Article L.5122-10 of the FPHC: "*Where medicinal products are being promoted to persons qualified to prescribe or supply them, no gifts, pecuniary advantages or benefits in kind may be supplied, offered or promised to such persons, unless they are inexpensive and relevant to the practice of medicine or pharmacy*".

[7] It is also necessary to previously check and, as the case may be, obtain the authorization of the healthcare facility to which the physician is attached, if such physician practices, as his/her main occupation and on a full-time basis, in a public hospital (Article 4 of Decree n°2007-568).

[8] Article L.4163-2 of the FPHC : "*Members of the medical professions mentioned in the present Book, healthcare students falling within the scope of the fourth part of this Code as well as associations or groups representing them who directly or indirectly receive benefits in-kind or pecuniary benefits, in any form whatsoever, from companies supplying services or manufacturing or marketing products the cost of which is reimbursed by compulsory social insurance schemes shall be liable to two-year prison sentence and a fine of 75,000 Euros.*
In the event of a person being sentenced, the courts may also temporarily ban that person from practicing the profession for a period of ten years in addition to the main penalty.
However, these provisions shall not apply to the benefits mentioned in the second and third paragraphs of Article L.4113-6.
Companies referred to above that propose or provide the benefits mentioned in the first paragraph above to members of the medical professions mentioned in this Book shall be liable to the penalties set forth in the first paragraph hereof.
Legal entities convicted, in the conditions set forth in the French Criminal code, of the offense defined in this Article shall be liable, in addition to the fine as per Article 131-88 of the French Criminal Code, to the penalties provided for in Article 131-39 §2 to §5 and §9 of said Code."

[9] Article L.4113-6 of the FPHC : "*It is prohibited, for healthcare students falling within the scope of the fourth part of this Code and for the members of the medical professions mentioned in this Book, as well as for associations representing them, to receive in-kind or pecuniary benefits, in any form whatsoever, directly or*

indirectly, from companies supplying services or manufacturing or marketing products the cost of which is reimbursed by compulsory social insurance schemes. It is also prohibited for such companies to propose or supply such benefits".

[10] Circular letter n°12-0059 issued by the LEEM on January 26, 2012 in relation to the Law n°2011-2012 of December 29, 2011

[11] Article R. 4127-83 of the FPHC, referring to Article L.4113-9 of said Code, stipulates that any agreement between a physician and, notably, a company, must be expressed in writing and submitted for opinion to the local council of the relevant professional board.

[12] Article L.4113-6 §4 of the FPHC: *"Any and all agreements entered into between members of the medical professions or healthcare students falling within the scope of this Code and the aforementioned companies must, before being implemented, be submitted for opinion to the local council of the relevant professional board or, when their scope of application is inter-departmenalt or national, to the national council of the relevant professional board".*

[13] Article 1453-1 of the FPHC : *"companies producing or marketing products listed in Article L. 5311-1 or supplying associated services which knowingly omit to disclose the existence of agreements mentioned in Article L. 1453-1, entered into with persons, associations, facilities, societies, bodies and entities mentioned in §1 to §7 of said Article, as well as the benefits mentioned in II of said Article that they supply, shall be liable to a 45,000 Euros fine".*

[14] Article L.1454-4 of the FPHC : *"for the offenses listed in this chapter, individuals are also liable to the following sanctions, in addition to the main penalty;*

1. *the diffusion of the conviction and of one or several release(s) informing the public of this conviction, in the conditions provided for in Article 131-35 of the French Criminal Code;*
2. *the posting of the conviction, in the conditions, and subject to the penalties provided for in said Article 131-35 of the French Criminal Code;*
3. *the loss of civic rights, in the conditions set forth in Article 131-26 of the French Criminal Code;*
4. *the prohibition to hold a public office or to exercise a commercial or industrial activity, in the conditions set forth in Article 131-27 of the French Criminal Code;*
5. *the prohibition to manufacture, package, import and put on the market the products listed in Article L. 5311-1 of this Code during a maximum period of five years".*

specific needs.

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