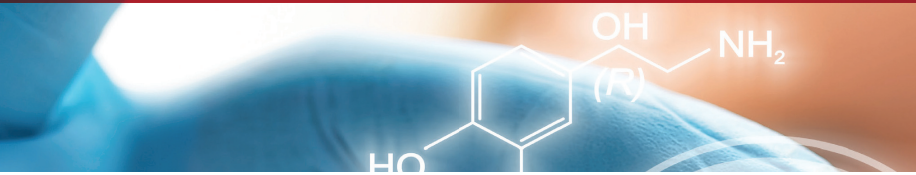


Promoting Medical Products Globally

Handbook of Pharma and MedTech Compliance



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France

Julie Yeni

Interactions Between the Industry and Healthcare Professionals

Within the framework of promoting medicinal products among persons authorized to prescribe or deliver them, it is forbidden to grant, offer or promise a bonus, a pecuniary advantage or a benefit in kind to such persons unless it is of negligible value and relates to the practice of medicine or of pharmacy. This principle, which is codified in Article L. 5122-10 of the French Public Health Code (FPHC), results from Directive n° 92/28/EEC concerning advertising for medicinal products and is included in Article 94 of the Community medicines code.¹

The French legal framework also contains a legal provision that regulates the relationships between healthcare professionals and the pharmaceutical industry in the provisions of the Law of 27 January 1993,² which were codified in Article L. 4113-6 of the FPHC (the “**Anti-Gift Law**” or “**Article L. 4113-6**”).

Article L. 4113-6 of the FPHC complements the provisions of Article L. 4113-8 of the FPHC, which state, in essence, that healthcare professionals are prohibited from receiving, in any form whatsoever, directly or indirectly, interests or rebates whether proportional to the number of units prescribed or sold, whether it be a question of medicinal products or of devices of any nature.

¹ Directive 2001/83/EC of the European Parliament and Council, dated 6 November 2001, as modified, creating a community code relating to medical products for human use, JOCE 1L 311 dated 28 November 2001 (formerly Article 9 of Directive 92/28/EEC of the Council dated 31 March 1992, concerning advertising for medicinal products for human use), originally implemented in France by Law n° 94-43 dated 18 January 1994, relating to public health and social protection, JORF dated 19 January 1994.

² Law n° 93-121 dated 27 January 1993 JORF dated 30 January 1993.

A circular dated 9 July 1993³ spelled out the content of Article L. 4113-6 of the FPHC, stating that this article has to be interpreted in the light of Directive 92/28/EEC, that is, the provisions relating to the promotion of medicines.

The approach of the provisions on the promotion of medicinal product and that of the Anti-Gift Law were, however, distinct. Indeed, where the provisions on promotion forbade pharmaceutical companies from giving benefits to certain healthcare professionals, the Anti-Gift Law forbade healthcare professionals from receiving these benefits from pharmaceutical companies.

The law of 4 March 2002 (the “**Patients’ Rights Act**”)⁴ modified the provisions of the Anti-Gift Law. Henceforth, the provisions of Article L. 4113-6 also forbid certain health product companies from procuring advantages to certain healthcare professionals.

The Patients’ Rights Law also introduced a principle for transparency, codified in Article L. 4113-13 of the FPHC, providing for the following obligation for healthcare professionals:

“The members of the medical profession who have connections with business and establishments manufacturing or marketing health products or counselling organisations involved with these products are required to make such connections known to the public if they make statements on such products in public or in the written or audio-visual press.”

Non-compliance with this obligation gives rise to disciplinary sanctions by the relevant professional body for the healthcare professional. According to Article L. 4113-13 of the FPHC, the public shall be informed, through the press or mass or digital media, of any interest that a healthcare professional may have with certain health

³ Circular dated 9 July 1993, relating to the enforcement of Article L. 365-1 of the FPHC (currently article L. 4113-6), JORF dated 6 August 1993.

⁴ Law n° 2002-303 dated 4 March 2002, relating to patients’ rights and quality of the health system, JORF dated 5 March 2002.



product companies as part of the presentation of such healthcare professional during public events, university education courses, training activities or therapeutic education programs.

The question of promoting health products by way of relationships between healthcare professionals and the health products industry must be dealt with, in the first place, from the viewpoint of an analysis of the Anti-Gift Law (i.e., Article L. 4113-6 of the FPHC). This analysis should be supplemented, if appropriate, by a reference to regulations concerning promotion of medicinal products.

Hence, these relationships are governed by a general principle of prohibition of any advantages granted to healthcare professionals. However, this principle is subject to exceptions spelled out in the Article L. 4113-6 of the FPHC in the context of promotional or exclusively scientific events or research activities, thereby allowing the health products industry to continue its role in these sectors. Article L. 4113-6 of the FPHC *in fine* also specifies that its particular rules do not apply to the notion of “normal working relations” nor prohibit financing of continuous medical training. The prohibition is also mitigated by certain rules concerning promotion. Finally, noncompliance with the rules governing the advantages granted to healthcare professionals triggers the application of criminal and disciplinary sanctions.

Transparency in interactions between the health products industry and healthcare professionals has been intensified with the Law of 29 December 2011, which has modified the Anti-Gift Law and reinforced the powers of the French National Agency for Medicines and Health Products Safety (ANSM), as well as reorganizing its services, including the changing of its name (the “**Bertrand Law**”).⁵

The transparency rules contained in the Bertrand Law are codified in Article L. 1453-1 of the FPHC, requiring certain health product

⁵ Law n° 2011-2012 of 29 December 2011, for the reinforcement of the safety of medicinal products and health products, JORF 30 December 2011. The ANSM was previously called French Authority for the Safety of Health Products (AFSSAPS).

companies to disclose to the public the existence of all agreements entered into with certain healthcare professionals and other health sector actors, as well as any advantages granted to such healthcare professionals and other health sector actors (the “**French Sunshine Act**”).

These transparency provisions have been specified by an implementing decree of 21 May 2013,⁶ which notably spells out the nature of information that must be disclosed and fixes a monetary threshold, beyond which benefits must be disclosed (the “**Decree**”). The French Sunshine Act has also been clarified by an interpretative circular of the General Directorate of Health of the Ministry of Health dated 21 May 2013 (the “**Circular**”).⁷ Finally, French Sunshine Act disclosures are now posted on a single public website that was created by virtue of an order of 3 December 2013, and placed under the supervision of the Minister of Health (the “**Order**”).⁸

A recent law, No. 2016-41 of 26 January 2016 (the “**2016 Law**”), has introduced a number of changes to the French Sunshine Act, it being however noted that the entry into force of certain provisions is pending publication of a decree as at today. The 2016 Law also empowers the French government to expand and strengthen the provisions of the Anti-Gift Law. The related governmental orders have not been adopted as at today.⁹

⁶ Decree n° 2013-414 dated 21 May 2013, on transparency of advantages granted by companies producing or marketing health products for human use.

⁷ Circular n° DGS/PF2/2013/224 dated 29 May 2013, on the application of Article 2 of Law N° 2011-2012 of 29 December 2011, for the reinforcement of the safety of medicinal products and health products.

⁸ Order of 3 December 2013, related to conditions of functioning of the single public website mentioned in article R 1453-4 of the FPHC.

⁹ These changes are addressed in sections “Expected changes to the Anti-Gift Law” and “Transparency: The French Sunshine Act.”



General Principle of Prohibition of Advantages Granted by the Industry to Healthcare Professionals

The principle is formulated in Article L. 4113-6 of the FPHC, paragraph 1, which provides that:

“The members of the medical professions mentioned in the this book (i.e. book I of the fourth part of the FPHC relating to healthcare professionals), as well as students preparing a diploma to practice the medical professions mentioned in the fourth part of the FPHC, and associations representing such healthcare professionals and/or students, are prohibited from receiving pecuniary advantages or benefits in kind, in any form whatsoever, directly or indirectly, provided by companies that provide services, manufacture or market products reimbursed by the mandatory social security regimes. These companies are also prohibited from offering or procuring such advantages.”

In addition to prohibiting the receipt of advantages for healthcare professionals, this article also prohibits the targeted health sector companies from offering or procuring such advantages to healthcare professionals, subject to Article L. 4113-6 of the FPHC.

Definition of Advantage

Definition

The scope of Article L. 4113-6 of the FPHC is broad. In effect, it targets pecuniary advantages or benefits in kind, in any form whatsoever, given directly or indirectly. However, it does not provide for a legal definition of the notion of advantage.

Prohibited advantages must be understood as being any advantage paid or allocated to healthcare professionals without any reciprocal benefit on their part (such as in the form of scientific collaboration or expertise), or when the said reciprocity is out of proportion to what is allocated or paid. Consequently, this means that unjustified compensation must be considered as an illegal advantage.

This was the case for surgeons who were remunerated for the performance of a study that did not involve any research effort, and the results of which were limited to a very simple synthesis of comments on the surgeons' monitoring of patients. In this case, the surgeons were remunerated an average of EUR220 per patient, whereas this kind of study is, in practice, generally paid EUR75 per patient (the surgeons were eventually sentenced to a EUR2,875 fine).¹⁰

Pecuniary Advantages or Benefits in Kind

The prohibition covers both pecuniary advantages and benefits in kind.

For example, trips for leisure, invitations to cultural and sporting events, gifts in the form of equipment or objects, and putting items at disposal are considered benefits in kind. The payment of an amount of money, particularly in the form of a commission or payment by the company of professional expenses on the professional's behalf (e.g., expenses of renting of real properties or equipment), constitute pecuniary advantages in the meaning of Article L. 4113-6 of the FPHC.

A physician was fined EUR1,220 for having taken advantage of a fixed-price tourism package in addition to the costs related to his business trip in Cuba.¹¹

Moreover, the circular of 9 July 1993, specifies that it makes no difference whether the advantages in question are related solely to products or services not reimbursed by social security organizations, as long as the company that provides such advantages markets other products or provides other services that are reimbursed by social security organizations.

¹⁰ Court of Appeal of Montpellier, 3rd correctional chamber, 3 December 1998, case No. 1538.

¹¹ TGI of Brest, 16 February 1999, case No. 464/99.



Direct or Indirect Advantages

Finally, the advantages may be granted directly or indirectly. This detail is important as it extends the application of the principle of prohibition to advantages given to third parties when said advantages benefit a healthcare professional individually in the end. In such a case, the third parties are intermediaries, for instance, when physicians' associations receive gifts from health product companies. The funds given to such associations may or may not benefit the physician, whether or not he is a member of the association that receives such funds. Such an indirect advantage could only be granted in compliance with prohibition and procedure set out in the Article L. 4113-6 of the FPHC.

The Court of Appeal of Angers spelled out the notion of indirect advantage in a decision issued on 25 March 1999, in which a physician who was simultaneously the president and chief executive officer of a company that owned a 60 percent stake at a clinic, was fined EUR3,050. The physician held 23 percent of the shares of the company, which in turn meant that he was 60 percent owner of the clinic. The physician, as president and chief executive officer, had accepted various items from various medical device manufacturers (e.g., video operating equipment) with a total value of around EUR56,400. The Court of Appeal of Angers considered that the free supply of equipment by the manufacturer was reciprocated by the purchase of other products marketed by that manufacturer and hence was to be characterized as a prohibited advantage under Article L. 4113-6 of the FPHC. Thus, the Court of Appeal of Angers ruled that said article was applicable to that case since: *“the advantage granted to a company through which physicians practice in common their art, constitutes an indirect advantage that is of such nature as to lead them to choose equipment, not strictly in the light of its medical characteristics, but also because of the advantage that they may*

derive from the sales terms of the said equipment, not only as users of the goods obtained, but also as partners.”¹²

Moreover, the available precedents suggest that the concept of indirect advantage is even wider. In its ruling of 26 November 1998, the Court of Appeal of Montpellier¹³ recalled the position of the controlling authority, the French Authority for Consumption, Unfair Competition and Fraud Affairs (the *Direction Générale de la Concurrence, de la Consommation et de la Répression des Fraudes* or **DGCCRF**), that Article L. 4113-6 of the FPHC “*does not require in order for the offence to be constituted that the benefits in kind or cash in any form whatsoever, cause the perception of an income in the form of higher fees for the doctors benefitting from the advantage.*” In this case, a manufacturer of medical devices had made a medical device available for free to a private clinic for the duration of a clinical study. The Court of Appeal of Montpellier held that making the medical device available constituted a benefit in kind, although it was not established that it allowed the defendant-doctors to generate higher personal income and although they were not shareholders of the clinic. The Court of Appeal of Montpellier did not, however, condemn the defendants, considering that the device was effectively used to carry out the clinical study, which had not been used to conceal an illegal advantage, and that the contract by which the medical device was made available was terminated by the doctors promptly after they had been made aware of the negative opinion of the National Board of Physicians’ Association (**CNOM**).

Healthcare Professionals Targeted by the Prohibition

Article L. 4113-6 of the FPHC refers to the members of the medical professions identified in the “Present Book.” The book is Book I of the fourth part of the FPHC relating to the healthcare professions. The book covers the category of the medical professions, which includes physicians, midwives and dental surgeons.

¹² Court of Appeal of Angers, correctional chamber, 25 March 1999, case No. 245.

¹³ Court of Appeal of Montpellier, 3rd correctional chamber, 26 November 1998, case No. 1518.



Pharmacists,¹⁴ nurses,¹⁵ masseur-physiotherapists,¹⁶ speech therapists, orthoptists,¹⁷ and chiropodists-podiatrists¹⁸ are also subject to the prohibition principle by reference to the Article L. 41136 of the FPHC. Incidentally, the courts have already applied Article L. 4113-6 of the FPHC by sentencing a nurse to pay a fine of EUR3,050 for having received EUR1,070 from a pharmaceutical company in order to purchase medical equipment for herself.¹⁹

The Patients' Rights Act extended the scope of the application of the prohibition on receiving advantages, particularly to members of consulting committees advising ministers in charge of health and social security and to persons who occasionally participate in the work of these committees. Members of the transparency commission (*commission de la transparence*), who are responsible for giving a prior opinion on the inscription of a medicine on the list of reimbursable medications, are especially targeted here.

Finally, the Bertrand Law modified Article L. 4113-6 of the FPHC, including in the scope of this article students preparing to practice any of the medical professions mentioned in the fourth part of the FPHC, as well as associations representing healthcare professionals and health sector students in these sectors.

Companies Targeted by the Prohibition

Article L. 4113-6 of the FPHC deals with the advantages granted by companies “providing services or manufacturing or marketing products reimbursed by the mandatory social security regimes.”

¹⁴ Article L. 4221-17 of the FPHC.

¹⁵ Article L. 4311-28 of the FPHC.

¹⁶ Article L. 4321-19 of the FPHC.

¹⁷ Article L. 4343-1 of the FPHC.

¹⁸ Article L. 4322-12 of the FPHC.

¹⁹ Tribunal de Grande Instance of Albi, judgment dated 27 May 1999, quoted by T. Pléan, “*La loi anti-cadeaux, premiers éléments de jurisprudence*” *Contracts, Competition, Consumptions*, n° 116, July-August 2000.

Companies Subject to the Principle of Prohibition

Companies that manufacture or market, directly or indirectly, at least one reimbursed product or provide such services are obviously targeted here.

Article L. 4113-6 of the FPHC is also echoed in the rules relating to advertising for medicinal products. Article L. 5122-10 of the FPHC *in fine*²⁰ provides as follows:

“Within the framework of promotion of medicinal products among persons authorised to prescribe or to deliver them, it is forbidden to grant, offer or promise, to such persons a bonus, a pecuniary advantage or a benefit in kind to such persons unless it is of negligible value and relates to the practice of medicine or of pharmacy.”

The prohibition, expressed here for pharmaceutical companies (to the exclusion of medical device manufacturers), does not distinguish between companies marketing reimbursed medicinal products and companies marketing only medicinal products that are not reimbursable.

Finally, it should be noted that the tolerance of advantages of negligible value set out in the above article is no longer applied by the pharmaceutical industry. Indeed, the applicable industry guidelines adopted by the French association of pharmaceutical manufacturers (LEEM) adopt a general prohibition of any gifts in line with the approach of the European Federation of Pharmaceutical Industries and Associations (EFPIA) code regarding interactions with healthcare professionals.²¹

²⁰ Article L. 5122-10 of the FPHC implements Article 9 of directive 92/28/EEC (Article 94 of the Community code on medical products).

²¹ EFPIA Code of Practice on the promotion of prescription-only medicines to, and interactions with, healthcare professionals (amended following Statutory General Assembly approval of 6 June 2014).



Intermediaries

The notion of indirect advantage, as construed by the Court of Appeal of Angers and the Court of Appeal of Montpellier, covers not only situations where the advantage would be reversed to the healthcare professional by a third party (whether a third party association, service provider or a parent company) but also where the advantage would otherwise indirectly benefit the healthcare professional involved in the activity of such a third party (whether the healthcare professional is a shareholder or not).

The Exceptions to the Prohibition Principle

The principle of prohibition of advantages granted to healthcare professionals by companies manufacturing or marketing products reimbursed by the mandatory social security regimes is subject to certain exceptions.

The Exceptions Provided for by Article L. 4113-6 of the FPHC

Two exceptions are explicitly provided for in Article L. 4113-6 of the FPHC: one for advantages extended in application of research or scientific evaluation agreements entered into between manufacturers and healthcare professionals and the other for hospitality extended to such persons in the context of exclusively professional and scientific or promotional events. These two exceptions are admissible only if the procedure referred to in Article L. 4113-6 of the FPHC is complied with. This procedure requires in particular requesting a prior opinion from the competent professional associations.

It should also be noted that Article L. 4113-6 of the FPHC, as modified by the Bertrand Law, now expressly states that all agreements entered into between the targeted healthcare professionals and companies are submitted to the appropriate professional association for a prior opinion, thereby expressly authorizing such agreements that in any case were already entered into between the healthcare professionals and the health sector companies. The

previous drafting indeed did not set forth exceptions or procedures, other than for research and scientific agreements.

Finally, Article L. 4113-6 *in fine* of the FPHC specifies that advantages granted in the context of normal working relations do not require entering into an agreement and does not prohibit financing of continuous medical training.

Agreements entered into Between Healthcare Professionals and Companies and relating to Research or Scientific Evaluation Activities

Article L. 4113-6 of the FPHC, paragraph 2, provides as follows:

“However, the foregoing paragraph [principle of prohibition of advantages] does not apply to the advantages provided for in agreements entered into between the members of the said medical professions and companies provided that the said agreements have the explicit object and real purpose of research or of scientific evaluation activities, if before their implementation they are submitted for an opinion to the departmental board of the relevant professional association, and duly notified, when the research activities are carried out, even in part, in a health establishment, to the person in charge of such establishment, and as long as the remuneration is not calculated in a way that is proportional to the number of services or products that are prescribed, marketed or provided. It [principle of prohibition of advantages] does not apply either to advantages provided for in agreements entered into between companies and students preparing a diploma to practice a healthcare profession [...] if the purpose of such agreements relates to research activities in the framework of the preparation of a diploma.”

This relates to research agreements with investigators in the framework of clinical trials, as well as agreements dealing with non-interventional studies such as epidemiological studies, pharmacovigilance studies, surveys, or even tests of medical equipment.



Interventional and Non-Interventional Clinical Trials

With respect to the interventional and non-interventional clinical trial agreements, all stages in research are covered.

In order to be compliant with the Article L. 4113-6 of the FPHC, the agreements relating to research and scientific evaluation activities must provide for a remuneration that is in proportion with the assignment and work load of the healthcare professional. Work load is measured by the number of observations made in connection with the trial, the extent of the professional's assignment for each of his/her observations, and the other obligations that might result from carrying out the trial in question. When investigators conducting research are remunerated each time a patient is included in research, the CNOM requires that the research protocols or the related agreements must determine the maximum number of patients to be included for the purpose of the research. In the absence of such a limit, the CNOM considers that investigators are incentivized to include the greatest number of patients in the research only to increase their remuneration. Such situation would affect their independence.

It must be noted here that Article 15 of the Code of medical ethics states similarly that *“the physician may take part in biomedical research on persons only under the conditions laid down under the law. He must make sure of the regular nature and of the relevance of such research as well as of the objectivity of its conclusions.”*²²

Article L. 4113-6 of the FPHC provides that agreements relating to research or scientific evaluation must, when the concerned activity is conducted within a health establishment, be notified to the director of such establishment.

²² Codified in Article R. 4127-15 of the FPHC.

Hospitality Offered for Promotional Events or for Events of a Strictly Professional and Scientific Nature

Article L. 4113-6 of the FPHC, paragraph 3 provides as follows:

“It [the principle of prohibition] also does not apply to the hospitality offered, directly or indirectly in the context of promotional events or exclusively professional and scientific events when it is set forth under an agreement entered into between the company and the healthcare professional and is submitted for opinion to the departmental board of the competent professional association before its implementation, and as long as said hospitality is of a reasonable level, remains of secondary importance in comparison with the principal objective of the meeting, and is not extended to persons other than the professionals directly concerned. The same applies to students preparing a diploma to practice a healthcare profession (...), for hospitality offered, directly or indirectly, in the context of scientific events to which they participate if such hospitality is of reasonable level and limited to the scientific purpose of the event.”

The principle of prohibition therefore does not prevent the health products industry from contributing to the financing of meetings, seminars or conferences aimed at, notably, updating knowledge, research or practices in given scientific domains nor from contributing financially to healthcare professionals’ participation to such meetings, seminars or conferences. Nor should it prevent companies from launching continuing medical training actions, also expressly authorized by Article L. 4113-6 of the FPHC.

Promotional Meetings Organized by Companies

Healthcare professionals may be invited to take part in promotional meetings organized by companies, particularly in connection with the launch of a new product. The promotional nature of such meetings triggers the application of the rules governing advertising for health products and, more particularly, may entail intervention by the



commission responsible within ANSM for checking on advertising and information on proper use of health products.

Introduction of the products must be objective, limited to scientific presentation, and guided by the goal of promoting their proper use.

Payment of travel and meal expenses and, if the case arises, of lodging for the invited professionals must comply with the same conditions as those that apply to scientific seminars and conferences, as specified hereinafter.

Hospitality Offered in Connection with Third Parties' Meetings, Seminars or Conferences

This assistance generally takes the form of payment of registration expenses for the event, as well as meals, lodging or transportation. It is acceptable, subject to observance of the rules governing the said exception.

The hospitality must be of a reasonable level. Invitations offered to healthcare professionals must not be ostentatious and must simply enable such persons to attend meetings of interest to them, under normal conditions. Moreover, companies may not cover the expenses of the accompanying spouse or family of the invited healthcare professional. If the professional would like to be accompanied by someone close to him/her, he/she must pay for the additional cost. The Court of Appeal of Pau, in a decision issued on 10 June 1998, sentenced a physician who had been invited by a pharmaceutical company to a conference in San Francisco and who had accepted a downgrade of his airline ticket to allow his spouse to accompany him without increasing the expenses paid by the company. In ruling on the appeal lodged by the physician against said decision, the *Cour de Cassation* confirmed the decision, stating that even if the hospitality offered to a physician in connection with events of a professional or scientific nature is not covered, under certain conditions, by the prohibition laid down in Article L. 4113-6 of the FPHC, “*it may not be extended to persons other than the professionals directly*

concerned.”²³ (Reference can also be made to the Tribunal of Grasse judgment dated 26 February 1999, in which a physician was sentenced to a fine of EUR2,290 for having taken advantage of a tourism trip in the West Indies, accompanied by his wife and children²⁴; and the Tribunal of Clermont-Ferrand judgment dated 15 March 2010, in which a pharmaceutical company was sentenced to a fine of EUR20,000.²⁵)

In a decision of the Tribunal of Nanterre of 21 February 2014, a pharmaceutical company was fined EUR100,000 and was made to publish the judgment in scientific journals and at its premises, for violation of Article L. 4113-6 of the FPHC. This referred to a case where a substantial part of the professional events that were to take place in Padova were cancelled and replaced by an overnight stay in Venice, including a closing evening. Additionally, expenses of spouses and additional expenses that had not been disclosed to the competent professional association were covered.²⁶

All services that are not related to the planned meeting must be excluded from the scope of the exception (particularly cultural, tourist or sports activities), and the entertainment proposed as a complement to the event must be paid for by the healthcare professional.

Topics addressed at such meetings must correspond to the practical interest of the invited healthcare professional. The scope of the exception does not cover meetings or seminars for which the agenda or the program is imprecise or contains common and unimportant subjects.

²³ Court of Appeal of Pau, 10 June 1998, and Cass. Crim. 7 December 1999, quoted by T. Pléan, “*La loi anti-cadeaux, premiers éléments de jurisprudence*”, *Agreements, Competition, Consumptions*, n° 116, July-August 2000.

²⁴ TGI of Grasse, 26 February 1999, case No. 99/895.

²⁵ TGI of Clermont-Ferrand, Criminal Section, 15 March 2010.

²⁶ Correctional Tribunal of Nanterre, 15th chamber, dated 21 February 2014, No. 09042045469.



Meals accompanying the events must remain incidental and necessary. A dinner organized in a restaurant to allow healthcare professionals to listen to a lecture on scientific or professional topics would fall under the scope of the principle of prohibition if the time devoted to the meal exceeded the time devoted to the lecture.

Lodging offered by a company for seminars or conferences must, similarly, be necessary and incidental. If it is permissible for the company to organize a seminar or a conference in a pleasant place, leisure activities must remain secondary. The CNOM specifies, as an indication, that free time must not exceed one-third of the total time of the event. It also notes that the expenses resulting from leisure-time activities must be paid for by the healthcare professionals, in addition to the expenses due to an extension of the stay beyond the time of the scientific program of the event. Such approach has been confirmed by case law. A healthcare professional was sentenced to pay a fine of EUR720 for having stayed in Marbella on the occasion of a scientific seminar, with the time spent for purposes other than the seminar having exceeded one-third of the total duration of the stay in Marbella.²⁷

Travel expenses may also be paid by the company. The amount of said expenses must remain reasonable, particularly when the event takes place abroad. However, the reasonable level of these expenses shall be analyzed on a case-by-case basis, particularly with respect to reserving air tickets, in light of negotiations between the company and the travel agencies with which they deal (e.g., any price reduction for reservation booked far in advance of the event date and group rates) and of the duration of the flight (e.g., tickets in tourist class are advisable, business class should be justified only for very long flights).

Finally, the guidelines jointly adopted in 2007 by the LEEM, the French association of medical devices manufacturers (**SNITEM**) and

²⁷ Court of Appeal of Rennes, 3rd correctional chamber, 21 July 1998, case No. 1249/98.

CNOM²⁸ contain provisions regarding hospitality and, regarding LEEM members, refer to the EFPIA code regarding interactions with healthcare professionals.²⁹ With regard to the venue of a meeting, the main principle of Article 10 of the EFPIA code provides that hospitality offered for events organized abroad must be justified by logistic organization or the international nature of the event, and that venues that are reputed for their entertainment facilities should be avoided. This article has been transposed in the LEEM Code for professional ethics in Article 1.10.³⁰ The Code of Ethical Business Practice adopted by the European association representing the medical technology industry (**EUCOMED**) further states that sales and promotional meetings should, as a general rule, occur at, or close to, the healthcare professional's place of business. Also the Anti-Gift Law guidance documents of SNITEM and LEEM recall that organizing a meeting abroad must be duly justified.³¹

Submission Procedure for Prior Opinion of Professional Associations

Pursuant to Article L. 4113-6 of the FPHC, for the purpose of benefiting from the exception to the general principle of prohibition on advantages, the proposed research or scientific evaluation agreement or the proposed invitation to a scientific event must be submitted ahead of time to the appropriate professional association. As previously set out, Article L. 4113-6 of the FPHC, as modified by the French Sunshine Act, now expressly states that all agreements entered into between the targeted healthcare professionals and

²⁸ Document for the interpretation and implementation of FPHC Article L. 4113-6, 21 June 2007, jointly adopted by LEEM, SNITEM and CNOM.

²⁹ Art. 10 of the EFPIA Code of Practice on the promotion of prescription-only medicines to, and interactions with, healthcare professionals (Amended following Statutory General Assembly approval of 6 June 2014).

³⁰ Professional ethics provisions adopted by the LEEM and applicable as of 1 September 2015.

³¹ Questions and Answers document (*Article L. 4113-6 du Code de la Santé Publique. Questions et Réponses. FAQ*) of LEEM updated as at September 2014 and questions and answers document of SNITEM (*Relations professionnels de santé et industries. Foire aux Questions. Cadre légal français et recommandations*) updated as at September 2011.



companies are submitted to the competent professional associations for a prior opinion. The submission for prior opinion is incumbent upon the health products company, which must request an opinion.

The professional associations of medical professions (namely, physicians, midwives and dental surgeons), as well as the professional board of pharmacists, nurses, masseur-physiotherapists and chiropodists-podiatrists, are already organized for the examination of the requests for prior opinion submitted by companies.

However, there is currently no professional association of speech therapists or orthoptists that has been implemented in France within the meaning of Article L. 4113-6 of the FPHC. Nonetheless, it is recommended to observe the other criteria developed under this article, as these healthcare professionals remain subject to the prohibition principle. Therefore, it is necessary to draw up a written agreement, avoid extending advantages that would exceed the generally accepted quantum and type, and to keep all necessary documentation related to this agreement and the advantages, as they may be required by any relevant authority in respect with Article L. 4113-6 of the FPHC.

Request for Advice by the Company

Article L. 4113-6, paragraph 4 of the FPHC provides as follows:

“All the agreements between members of medical professions or students and companies [agreements and invitations to meetings, seminars or conferences] are, before their application, submitted for opinion to the departmental board of the healthcare professional concerned or, if their scope is national or covers more than one department, to the national board of the competent professional association. A decree determines the methods of submission of these agreements as well as the time periods in which the professional associations must issue their opinion. If the latter give a negative opinion, the company must forward this opinion to the healthcare professionals, before the implementation of the agreement. If there is

no response from the association within the applicable time period, the opinion is deemed favorable. The company must inform the competent professional association when the agreement is implemented.”

The abovementioned decree was adopted in 2007, codified in Article R. 4113-104 and following of the FPHC, as modified.³² Article R. 4113-107 of the FPHC provides for a period of two months for research or scientific evaluation agreements and for a period of one month for all other agreements. In case of urgency, a unique period of three weeks applies, but the condition of urgency for this accelerated procedure is strictly assessed.³³ If the file submitted to the professional association is not complete, the professional association notifies the company without delay, in which case the clock stops until the submission of a complete file.³⁴ However, as far as hospitality agreements are concerned, CNOM has agreed with LEEM and SNITEM that the modification of the list of invited physicians after the submission of the file does not suspend the one-month period.³⁵

When the request for an opinion concerns a research or scientific evaluation agreement, the company must submit a dossier containing the following:

- Draft agreement identifying the company (name and registered office)
- Amount and terms allowing to determine the compensation and, if applicable, the nature of the advantages that may be granted to the healthcare professional
- Names of the healthcare professionals concerned, with their profession, specialty and professional address

³² Decree No. 2007-454 of 25 March 2007, as modified.

³³ Article R. 4113-107 of the FPHC.

³⁴ Article R. 4113-106 of the FPHC.

³⁵ Document for the interpretation and implementation of Article L. 4113-6, 21 of the FPHC June 2007, jointly adopted by LEEM, SNITEM and CNOM.



- Document of data collection relating to the research or scientific assessment activities
- Summary of the research or assessment protocol in French

If the request for an opinion concerns the hospitality offered to a professional on the occasion of a scientific or promotional event, the dossier presented by the company shall include the following:

- Draft agreement identifying the inviting company (name and registered office)³⁶
- Nature and amount of each service or if appropriate as well as the list of the various services supported on the occasion of the event considered (the nature of the paid services on the occasion of the event in question and the amount of the accommodation, food and registration fees)
- Contemplated detailed program of the event
- List of the members of medical professions to whom the invitation was sent, with their respective professions, specialties and professional addresses³⁷

Finally, it should be noted that this notification procedure is aimed at obtaining a simple prior opinion from the competent professional association. Such opinion does not bind the company requesting it. Hence, in case of a negative opinion, the company can still decide to perform the research agreement or to maintain its hospitality to the scientific event. Such a decision shall be made by the company after having considered each situation on a case-by-case basis. However, under article L. 4113-6 of the FPHC, it is obliged to notify the negative opinion to the healthcare professionals concerned.

³⁶ The invitation to the event is accepted as an agreement by CNOM, but not by the professional association of pharmacists, the CNOP.

³⁷ Article R. 4113-105 of the FPHC.

Moreover, the controlling authorities, including the DGCCRF, could conclude that the advantages extended are in violation of Article L. 4113-6 of the FPHC, regardless of a favorable opinion. Indeed, although DGCCRF often follows the opinions of the relevant professional association, it is not bound by such opinions. However, it should be noted that the DGCCRF may not adopt sanctions itself, as regards to the Article L. 4113-6 of the FPHC, but may decide to refer any matters of noncompliance to the French Public Prosecutor. The French Public Prosecutor then decides whether to prosecute the case before the competent French criminal courts with neither the prosecutor, nor the courts being bound by the opinion of the professional association.

Additionally, compliance with Article L. 4113-6 of the FPHC is subject to the review by the courts. In relation to the hospitality offered to physicians for a conference, a decision dated 29 June 1999 by the Court of Appeal of Paris ruled that the opinion issued by the professional association was strictly advisory.³⁸

Finally, the companies are required to notify the professional association of such implementation of each agreement within one month following the implementation of agreements they enter into with a targeted healthcare professional.

Communication of the Agreements by the Professionals

Pursuant to Article L. 4113-9 of the FPHC, physicians, midwives, dental surgeons and nurses³⁹ must communicate to their departmental professional board of their professional association the agreements relating to the practice of their professions, as well as the agreements assuring them of the use of equipment or premises if they do not own the equipment they use or the premises where they practice their profession.

³⁸ Court of Appeal of Paris, 11th correctional chamber, A, 29 June 1999, case No. 98/03995.

³⁹ This obligation is set out for nurses by reference in Article L. 4311-28 of the FPHC.



This communication must take place one month after the signing of the agreement at the latest so as to enable the relevant association to ascertain compliance with the principles of morality, probity and dedication that are essential to the practice of the profession.

Failure or refusal to communicate agreements constitutes a disciplinary fault that may be sanctioned by the relevant professional association.

The verification is for professional ethical purposes. The departmental board of the competent professional association shall ensure that the concerned healthcare professional does not expose himself/herself to any alienation of his/her professional independence, and that the opinion issued, if any, is also merely advisory.

Normal Working Relations

Article L. 4113-6, in fine, of the FPHC provides that:

“The provisions of this article do not require entering into an agreement for normal work relations (...)”.

The notion of normal working relations is not defined by statute or regulation and has led to various interpretations. In practice, these normal relationships are very limited (e.g., lunch or a cup of coffee following a working session).

Practices Authorized by Regulations on Promotion

Like Article L. 4113-6 of the FPHC, which applies mostly to healthcare professionals, regulations on the promotion of medicinal products explicitly authorize pharmaceutical companies to provide such healthcare professionals with free medical product samples and to offer them advantages of negligible value. The possibility of offering advantages of negligible value is incorporated into the provisions of the FPHC, which relate to promotion for pharmaceutical establishments, and those provisions also allow pharmaceutical companies to make gifts to encourage research or training of

healthcare professionals. In practice, the tolerance for advantages of negligible value also applies to medical device companies. Moreover, the applicable industry guidelines of the pharmaceutical industry adopted by the LEEM go beyond the prohibitions and limits set out by the French law, adopting a general prohibition of any gifts in line with the approach of the EFPIA code regarding interactions with healthcare professionals,⁴⁰ as explained in more detail in the section relating to advantages of negligible value.

Delivery of Free Samples

Article L. 5122-10 of the FPHC authorizes the supply of free samples to “*persons authorised to prescribe or to deliver drugs within the framework of hospital pharmacies at their request.*”

This means that pharmaceutical companies may give free samples to hospital physicians and to hospital pharmacists only, to the exclusion of any other member of the medical or paramedical professions.

The delivery of free samples may occur only at the request of the physicians or of the hospital pharmacists. Hence, pharmaceutical companies may not spontaneously make such deliveries since the initiative is not theirs.

Furthermore, Article L. 5122-10 of the FPHC prohibits such deliveries on facilities accessible to the public during medical or pharmaceutical conferences.

With respect to the samples themselves, it should be emphasized that delivery of samples of medicinal products containing substances classified as psychotropic drugs or narcotics, or to which all or part of the regulations concerning narcotics apply, is prohibited. When delivery thereof is authorized, these samples must be identical to the medicinal products concerned and bear the indication “free sample.”

⁴⁰ EFPIA Code of Practice on the promotion of prescription-only medicines to, and interactions with, healthcare professionals (amended following Statutory General Assembly approval of 6 June 2014).



Article R. 5122-17 of the FPHC incorporates these rules, spelling them out as follows:

- Each supply of free samples must be in response to a dated and signed written request from the beneficiary.
- For each medicinal product, only a limited number of samples may be provided, with a limit of four per year and per beneficiary, determined in consideration with the nature of the medicinal product and of the need for the prescriber to familiarize himself/herself with it; each sample must be in the smallest packaging marketed.
- When a medicinal product is subject to limited prescription conditions, the samples may be delivered only to hospital pharmacists and to prescribers authorized to write a prescription.
- Each pharmaceutical company providing samples must set up tracking procedures for checking such deliveries and monitoring the samples.
- Each sample must be accompanied by a summary of the characteristics of the product.
- Article L. 5122-17 of the FPHC provides that samples must be delivered in reply to written requests from physicians only. As a result, the charter relating to the promotion of medicines by medical representatives through canvassing or prospection as signed between LEEM and the Economic Committee of Health Products (*Comité Economique des Produits de Santé* or **CEPS**) specifies that medical representatives may not deliver samples.⁴¹

⁴¹ Information charter for canvassing or prospection for medicines promotion as signed between LEEM and the CEPS dated 15 October 2014, in Part III - Deontology - Article 2-d.

It must also be highlighted that Article R. 5122-17 of the FPHC was amended in 2012⁴² and now provides that free samples are only authorized during the first two years following the effective commercialization in France:

- of a medicinal product covered by a first registration or marketing authorization; or
- of a medicinal product already covered by a registration or a marketing authorization but with a new dosage or a new pharmaceutical form if the related registration or marketing authorization has been extended accordingly.

Free samples are also authorized during the two years following a change in the prescription status of the medicinal product.

Advantages of Negligible Value

The possibility for health product companies to provide healthcare professionals with advantages of negligible value is not provided for in Article L. 4113-6 of the FPHC.

As far as pharmaceutical companies are concerned, the provisions of Article L. 5122-10 *in fine* of the FPHC concerning promotion for medicinal products and R. 5124-65 of the FPHC concerning advertising for pharmaceutical companies state that it is forbidden to grant, offer or promise to healthcare professionals any offer of bonuses, objects, products or material benefits, procured directly or indirectly, of any kind whatsoever, unless they are of negligible value and, as required by Article 94-1 of the Community Code on Medicinal Products,⁴³ relate to the practice of the medical or the pharmaceutical profession.

⁴² Article 10 of the decree No. 2012-741 of 9 May 2012, regarding regulations on advertising for medicinal products for human use, JORF of 10 May 2012.

⁴³ Directive 2001/83/EC of the European Parliament and of the Council of 6 November 2001, on the Community code relating to medicinal products for human use, OJEU L-311/67 of 28 November 2001, as modified.



This tolerance, however, is no longer applied by the companies that are members of LEEM. Indeed, the LEEM code for professional ethics has transposed the provisions of the EFPIA code relating to interactions with healthcare professionals,⁴⁴ which sets out that no gifts or pecuniary advantages (in cash or benefit in kind) can be supplied, offered or promised to a healthcare professional.

However, under Article 9 of the EFPIA code, and also transposed by the LEEM code, the following items do not fall within the prohibition of gifts and may be granted to the healthcare professionals:

- Informational or educational materials, provided that such materials are inexpensive, directly related to the practice of medicine or pharmacy, and of direct benefit to the care of patients
- Items of medical utility, provided that such items are inexpensive, aimed directly at the education of healthcare professionals and patient care, and do not offset costs that would be normally borne by healthcare professionals in their routine business practices

Although the provision of the abovementioned Article L. 5122-10 *in fine* of the FPHC provisions are limited in scope to pharmaceutical companies, it is admitted in practice that medical device manufacturers can grant advantages of negligible value. In order to be allowed under this tolerance, gifts to healthcare professionals (whether provided directly or indirectly) must be:

- directly related to the practice of medicine or pharmacy; and
- of negligible value, that is, up to EUR30, exclusive of VAT, per healthcare professional per year.

⁴⁴ EFPIA Code of practice on the promotion of prescription-only medicines to, and interactions with, healthcare professionals (amended following Statutory General Assembly approval of 6 June 2014) and Professional ethics provisions adopted by the LEEM and applicable as of 1 September 2015.

Grants by Pharmaceutical Companies

Finally, among the rules governing advertising for pharmaceutical establishments, Article R. 5124-66 of the FPHC authorizes pharmaceutical companies to make grants, subject to compliance with the following three conditions:

- The recipient of the grant must be a legal entity. Any donation to an individual healthcare professional would be subject to the prohibition of advantages provided for in Article L. 4113-6 of the FPHC.
- The grant must only aim at encouraging research or medical education, and Article R. 5124-66 of the FPHC provides that the grant must not have the actual purpose of providing a healthcare professional with an individual advantage.
- The grant must be formalized in a written agreement and must be declared in advance to the Regional Health Agency (**ARS**) of the region where the beneficiary entity has its registered office.

The declaration must include the following information:

- The designation of the donor, as well as of the nature of its activity and address
- The designation of the beneficiary, as well as of the nature of its activity and address
- The nature and amount of the grant
- The purpose of the grant

Although grants are authorized in these circumstances, it is recommended to check each case with scrutiny, particularly if the beneficiary entity is an association of one of the healthcare professionals targeted by the Anti-Gift Law. The notion of indirect advantage, as construed in the precedents, requires pharmaceutical



companies to make sure that their grants do not ultimately benefit a healthcare professional in an individual way and thus become subject to the procedure set forth in Article L. 4113-6 of the FPHC.

In practice, pharmaceutical companies ask the beneficiary entity for a copy of its articles of association to verify the actual corporate purpose of the said entity, with evidence of their declaration with the competent prefecture and of publication of an extract of such declaration in the French official journal. The companies also request a certificate or a contractual clause undertaking to use the grant in accordance with the purpose for which it is given, as well as with the corporate purpose of the beneficiary, and not to use the grant for the benefit of an individual healthcare professional, whether directly or indirectly.

This legal framework is normally applied by medical device manufacturers voluntarily.

Finally, when the Bertrand Law was adopted, it amended Article L. 4113-6 of the FPHC in a way that led to the consideration that grants to all associations of healthcare professionals could be prohibited, given that it included associations representing the targeted healthcare professionals in the prohibition principle. However, it has been further clarified by the interpretative Circular⁴⁵ that the only associations targeted by Article L. 4113-6 of the FPHC are those associations in charge of the defense of the sectorial interests of healthcare professionals (e.g., trade-unions, “*syndicats*”).

However, healthcare professionals belonging to an association not targeted by the Article L. 4113-6 of the FPHC remain subject to this article. Advantages granted to such healthcare professionals via association would be considered as an indirect advantage and require complying with the prohibition and procedure for exceptions set out in Article L. 4113-6 of the FPHC.

⁴⁵ Circular No. DGS/PF2/2013/224 dated 29 May 2013, on the application of Article 2 of Law No. 2011-2012 of 29 December 2011, for the reinforcement of the safety of medicinal products and health products.

Expected changes to the Anti-Gift Law

The 2016 Law aims at strengthening the Anti-Gift Law provisions and in this respect, empowers the government to expand and strengthen the provisions of the Anti-Gift Law within a period of one year from its promulgation. Under the 2016 Law, the French government is authorized to proceed with the following modifications of the Anti-Gift Law:

- Extend the scope of companies targeted by the Anti-Gift Law to any person manufacturing or selling health products or providing services relating to such products, regardless of whether or not such products or services are reimbursed by the French Social Security System.
- Extend the scope of individuals targeted by the Anti-Gift Law to cover:
 - any healthcare professionals and students, beyond the current limitative list;
 - any association composed of healthcare professionals and/or students (i.e., not restricted to associations representing their members as currently); and
 - any public officials and agents at state or regional level, as well as public establishments and any administrative authorities developing or participating in the development of a public policy on health or on social security, or having health policing powers, and individuals providing assistance to boards, commissions, committees and working groups working with the said administrations or authorities in this respect.
- Redefine the exemptions to the prohibition to receive or offer benefits and the related regime of authorization, which could



evolve from a non-binding advice to a binding required authorization.

- Specify the benefits excluded from the scope of the Anti-Gift Law and clarify the conditions under which they may be granted.
- Harmonize and develop consistency between provisions of the criminal code, the public health code and the social security code regarding criminal and/or administrative sanctions relating to noncompliance with Anti-Gift Law provisions.
- Adapt the prerogatives of the authorities responsible for controlling the compliance with Anti- Gift Law.

As of this date, no more official specific guidance has been issued as to the strengthening of the Anti-Gift Law provisions or any specific changes that could be contemplated.

Transparency: The French Sunshine Act

The French Sunshine Act,⁴⁶ as modified by the 2016 Law, provides for a new transparency regime requiring the targeted health product companies to disclose:

- the existence of agreements entered into with certain healthcare professionals and other health sector actors; and
- the advantages they grant to these same individuals and entities, as specified in its implementing Decree.⁴⁷

These provisions are further explained in the interpretative Circular of the Ministry for Health.⁴⁸

⁴⁶ Law No. 2011-2012 of 29 December 2011, for the reinforcement of the safety of medicinal products and health products, JORF 30 December 2011, as modified.

⁴⁷ Decree No. 2013-414 of 21 May 2013 on transparency of advantages granted by companies producing or marketing health products for human use.

Pursuant to a new disclosure obligation resulting from the 2016 Law, remuneration also paid to the targeted recipients must be disclosed. The effective entry into force of the obligation to disclose remuneration is pending publication of a decree that will set out a disclosure threshold and modalities (the “**New Decree**”).

The French Sunshine Act also broadens the regime for the declarations of interests for the experts involved in the various decision-making processes regarding health products in France.⁴⁹

Disclosure Obligation Incumbent on Health Sector Companies

The new transparency regime, as modified by the 2016 Law, is codified under Article L. 1453-1 of the FPHC, as follows:

“I - Enterprises manufacturing or marketing products mentioned under II of article L. 5311-1 or providing services related to such products are required to disclose on the single public website, precise subject matter, the date, the direct and ultimate beneficiaries, and the amounts of agreements they enter into with:

1. *Healthcare professionals referred to in the 4th part of this code,*
2. *Associations of healthcare professionals,*
3. *Students studying to become healthcare professional referred to in the 4th part of this code, and their representative organisations and associations;*
4. *Associations of health system users;*
5. *Health establishments referred to in the 6th part of this code⁵⁰;*

⁴⁸ Circular No. DGS/PF2/2013/224 dated 29 May 2013, on the application of Article 2 of Law No. 2011-2012 of 29 December 2011, for the reinforcement of the safety of medicinal products and health products.

⁴⁹ New Articles L. 1451-1 *et seq.* of the FPHC.



6. *Academies, foundations, learned societies and advisory companies or bodies operating in the health products and/or services sector mentioned in the first sub-paragraph;*
7. *Legal persons in the sectors of press publishing broadcasting of radio or television services and publishing online communications services to the public;*
8. *Publishers of product prescription and delivery aid software;*
9. *Legal entities providing initial and continuing training for the healthcare professionals mentioned under 1° or participating to such training.*

I-bis. Enterprises manufacturing or marketing products mentioned under II of Article L. 5311-1 or providing services related to such products are required to disclose beyond a threshold set by decree on the website mentioned in I of this Article, remuneration paid to natural or legal persons in the context of agreements mentioned in I.

II - The same obligation applies, beyond a threshold set by a decree, to advantages in cash or in kind granted by these same companies, directly or indirectly, to persons, associations, establishments, foundations, companies, organisations and bodies, mentioned in I.

[article II bis not reproduced]

III.-A Decree of the Council of State, (...), sets out the conditions for applying this article, the nature of information to be made public on the single public website, including the precise subject matter and date of the agreements mentioned in I, and the disclosure schedule and terms and updating of the information. (...)"

The French Sunshine Act disclosure obligation therefore captures agreements entered into with certain healthcare professionals and other health sector entities, advantages granted to these same actors

⁵⁰ I.e., in particular both public hospitals and private clinics.

beyond a threshold set by the Decree at EUR10 (including VAT), as well as remuneration paid to these same actors beyond a threshold that will be set by the New Decree, pending publication at the date hereof.

Moreover, as explained here below under the section on “Information to be Disclosed,” the 2016 Law introduced certain changes to the list of information to be disclosed. Such changes will be further specified by the New Decree.

Companies Required to Make Disclosures

Article L. 1453-1 of the FPHC refers to “*companies manufacturing or marketing products that are listed by Article L. 5311-1-II of the FPHC or providing services in connection with such products.*”

The French Sunshine Act is therefore much broader in scope than the Anti-Gift Law (i.e., Article L. 4113-6 of the FPHC). The Anti-Gift Law only covers companies manufacturing or commercializing products that are admitted to reimbursement in France (i.e., pharmaceuticals and medical device manufacturers), whereas the French Sunshine Act refers to Article L. 5311-1 of the FPHC, which draws up a list all the products over which the ANSM is competent, regardless of the reimbursement status of such products.

In this respect, Article L. 5311-1 II of the FPHC specifies that ANSM is competent over health products for human use and cosmetics, and further sets out a non-exhaustive list of products that notably, but without being limited thereto, include pharmaceuticals, medical devices and cosmetics.

Healthcare Professionals and Other Health Sector Actors Targeted by the French Sunshine Act

The notion of healthcare professionals and health sector actions in the framework of the French Sunshine Act is broader in scope than the same notion under the Anti-Gift Law as regards the healthcare professionals.



In addition to the legal persons referred to in the Article L. 1453-1 of the FPHC, as set out above, Article L. 1453-1 of the FPHC refers to all professionals whose practice is regulated by Part IV of the FPHC. This includes physicians, dental surgeons, midwives, nurses, masseur-physiotherapists, occupational therapists and psychometricians, orthoptists and speech therapists, podiatrists, technicians of medical imaging centers and of biological analysis laboratories, specialists for hearing aid prosthesis, opticians, specialists of prosthesis for disabled persons, dieticians, assistants for patients care, assistants for children care, paramedics (ambulance personnel), pharmacists, and assistants who assist pharmacists within pharmacies in town or hospitals' pharmacies.

Information to be Disclosed

Article L. 1453-1 of the FPHC provides that companies must make the existence of these items available to the public:

- All agreements entered into with the targeted recipients, with the exception of commercial agreements relating to purchase of goods or services from the targeted companies, and agreements governed by Articles L. 441-3 and L. 441-7 of the French Commercial Code concerning the purchase of goods or services between targeted companies and targeted recipients
- All benefits in kind or in cash, directly or indirectly granted, to the targeted recipients, equal to or exceeding EUR10, inclusive of VAT
- Remuneration paid to the targeted recipients (new disclosure obligation resulting from the 2016 Law); the effective entry into force of the obligation to disclose remuneration is pending publication of the New Decree.

Article L. 1453-1 of the FPHC specifies that this obligation applies to agreements that are effective as of 1 January 2012, or which become effective after that date, as well as advantages granted after that date.⁵¹

The information to be disclosed and the disclosure schedule are detailed by the Decree.⁵²

- The 2016 Law, however, introduced some changes to the information to be disclosed. Such changes are set out in CAPITAL LETTERS in the below list. These changes will be further specified by the New Decree and are not yet applicable.
- The Order of 3 December 2013, which promulgated the creation of the single public website on which the French Sunshine Act disclosures are made, also introduced some changes to the information to be disclosed. In application of the Order, the information indicated below by an asterisk would not be mandatory and certain other information would be required to be disclosed.⁵³

Subject to the above, the targeted companies are required to disclose the following information regarding the agreements:

- Identity of the parties
- Declaring entity (identified with a single identifier granted upon registration on the single public website)

⁵¹ Article 41-II of the Law No. 2011-2012 of 29 December 2011, for the reinforcement of the safety of medicinal products and health products, JORF 30 December 2011.

⁵² Decree n° 2013-414 dated 21 May 2013, on transparency of advantages granted by companies producing or marketing health products for human use.

⁵³ However, these changes have not been definitively adopted. According to certain sources of information the New Decree could confirm the changes set forth by the Order and introduce certain other amendments that have been previously contemplated. As at today, the text of the New Decree has however not been made public and such changes might not be included therein.



- Healthcare professionals -- category of beneficiary (healthcare professional), name and surname, profession (e.g., doctor, nurse), title (e.g., Professor, Doctor)*, specialty*, qualification*, the ordinal number or the RPPS and full professional address
- Students -- category of beneficiary (student), name and surname, and identification number (if any)
- Companies -- category of beneficiary (healthcare professional's association, foundation), corporate name, corporate purpose and registered office
- Execution date
- PRECISE subject matter of the agreement
- For promotional and scientific events in addition to the above -- the program of the event*
- DIRECT AND ULTIMATE BENEFICIARIES
- AMOUNT OF THE AGREEMENT

With respect to advantages, the following information must be disclosed under the Decree:

- Identity of the parties (as above)
- Amount of the advantage, including VAT rounded to the nearest euro
- Date and type of the benefit received by each beneficiary
- Half of the year during which the benefits were granted*

Disclosure Schedule

The transparency obligations set out under the Decree provided for two different disclosure schedules:

- A temporary disclosure schedule, applicable until the publication of the Order, setting up the single public website
- A final disclosure schedule applicable as from such date

The Order of 3 December 2013, promulgated the creation of the single public website, and the final disclosure schedule has been applicable since 20 December 2013. In order to make a disclosure under the French Sunshine Act, each targeted company must register on the single public website.

The data required to be disclosed is submitted via the single public website by the targeted companies, as follows:

- Within 15 days from the signature of each agreement
- By 1 August of each year for the advantages granted during the first half of the year
- By 1 February of each year for the advantages granted during the second half of the preceding year

The authority responsible for the single public website then makes public the information related to agreements and advantages granted during the first half year by 1 October of that year and during the second half year by 1 April of the following year. The information remains accessible to the public for a period of five years after they are made available.

The New Decree could also include certain changes to the disclosure schedule of agreements. In particular, according to previously envisaged changes, disclosure schedule of agreements could be aligned with the disclosure schedule applicable to benefits, so that both disclosures would be made twice a year. As at today, the text of



the New Decree has, however, not been made public and previously contemplated changes might not be included therein.

Finally, it should be noted that the processing of healthcare professionals' data in order to comply with the French Sunshine Act (collection and submission of personal data to the single public website) qualifies as processing of personal data and therefore requires compliance with the requirements of the French data protection act.⁵⁴

Sanctions

Noncompliance with the provisions of Article L. 4113-6 of the FPHC may entail the application of disciplinary and criminal sanctions. Moreover, the regulations on promotion are combined with administrative sanctions and may also give rise to criminal proceedings.

First of all, it should be mentioned that the breach of the provisions of Article L. 4113-6 of the FPHC by a company can be considered by a competitor as unfair competition detrimental to its interests and may also lead to litigation between competitors before the commercial courts.⁵⁵

Violation of the Provisions of Article L. 4113-6 of the FPHC

Noncompliance with the principle of prohibition of advantages may be seen as alienation of the independence of the professional who has benefited from the prohibited advantage and thus allows the relevant professional board to apply disciplinary sanctions. Independent of these professional sanctions, Article L. 4113-6 of the FPHC includes criminal sanctions, and disregard thereof may trigger proceedings filed by the Public Prosecutor's office.

⁵⁴ Act No. 78-17 of 6 January 1978, as modified.

⁵⁵ For an enforcement: Court of Appeal of Versailles, 12 ch. 6 May 2003 Pharmacia v. Alcon, case No. 260.

Disciplinary Proceedings

When they are incorporated, the duty of the professional association is to ensure the principles of morality, probity and dedication that are essential to exercise the profession.

Professional associations are authorized to sanction professionals who violate professional regulations or the profession's code of ethics. With respect to the acceptance of an advantage prohibited by Article L. 4113-6 of the FPHC, the following disciplinary sanctions can be enforced against the professional at fault: warning, reprimand, temporary suspension of the right to practice and expulsion from the association.

Criminal Proceedings

The opinion issued by the professional association in application of Article L. 4113-6 of the FPHC is part of a preventive approach. This preliminary procedure does not prevent the triggering of subsequent enquiries.

Pursuant to Article L. 4163-1 of the FPHC, inspecting pharmacists or inspecting physicians, inspectors of the ANSM, agents of the DGCCRF, or even agents of the French Customs Agency (*Direction Générale des Douanes*) or the French Tax Authority (*Direction générale des Impôts*) are authorized to look for and establish infractions of Article L. 4113-6 of the FPHC.⁵⁶

In practice, inquiries are generally carried out by DGCCRF agents. The inspection is conducted during or after execution of the research agreement or the scientific or promotional event, and it focuses on the actual conditions of realization of the operations carried out by the companies. Consequently, companies are advised to keep all documentation establishing the fact that their operation complies with the requirements laid down in Article L. 4113-6 of the FPHC.

⁵⁶ Article L. 4163-1 of the FPHC.



Such inspections may trigger proceedings before the courts. By way of illustration, a pharmaceutical company was sentenced to a fine of EUR20,000 following the organization of various dinners with physicians on the occasion of medical congresses. An inspection report from the DGCCRF had evidenced that the cost per physician for these dinners was not reasonable and exceeded the costs that the company had declared to the CNOM and for which the CNOM had issued a positive opinion.⁵⁷

Article L. 4163-2 of the FPHC essentially provides that if a healthcare professional benefits from an advantage granted by a company in violation of Article L. 4113-6 of the FPHC, such infraction is punishable by imprisonment of two years and a fine of up to EUR75,000, unless the infraction falls within the scope of the exceptions provided for in relation to research agreements and hospitality offered for scientific or promotional events.

Article L. 4163-2 of the FPHC also provides for the same sanctions for the targeted health sector companies for having offered or procured advantages for members of the medical profession in violation of Article L. 4113-6 of the FPHC. These sanctions may be imposed against both individuals (e.g., legal representative of the company if individually prosecuted) and the company itself.

In this respect, the Article L. 4163-2 of the FPHC provides that legal entities can be held criminally liable under the conditions provided in Article 121-2 of the French Criminal Code.⁵⁸ In this case, the sanctions applicable to legal entities are fines equal to up to five times the fines levied against individuals for the same infraction in application of Article 131-38 of the French Criminal Code. Therefore, a company, as a legal entity, can be sanctioned with a fine of up to EUR375,000 (i.e., five times EUR75,000) for violating Article L. 4113-6 of the FPHC.

⁵⁷ Tribunal of Clermont-Ferrand, Criminal Section, 15 March 2010.

⁵⁸ Under French law legal persons may be held liable for criminal offenses committed on their behalf by one of their representatives or bodies. The criminal liability of companies does not exclude that of individuals or accomplices for the same facts.

Moreover, individuals who violate Article L. 4113-6 of the FPHC can be prohibited from carrying out a professional activity (for up to 10 years) and the following additional penalties may be imposed against legal entities⁵⁹:

- Prohibition (of up to five years) from engaging in, directly or indirectly, one or several professional or social activities within which the offense was committed
- Being placed under judicial supervision (for up to five years)
- Closing down the legal entity's facilities used to commit the offense (for up to five years)
- Debarment from public procurement (of up to five years)
- Publication of the decision

In addition, sanctions imposed against legal entities must be reported to the CEPS. CEPS is the public entity responsible for the pricing of medicinal products or medical devices covered by the French Health Insurance Programme, by way of agreements with the companies that market them. It must be noted that the pricing agreements signed between CEPS and companies may include obligations for such companies to limit their budgets allocated to the promotion of certain reimbursable medicinal products.

Violations of the Rules Concerning Promotion

The statutory definitions of promotion for health products (both medicinal products and medical devices) are extremely broad. In particular, they extend to “any form of information” with certain statute-defined limited exceptions.⁶⁰ The ANSM controls the advertising of health products and is empowered to take

⁵⁹ Article L. 4163-2 of the FPHC referring to sub-paragraphs 2 to 5 and 9 of Article 131-39 of the French Criminal Code as regards legal entities.

⁶⁰ Article L. 5122-1 of the FPHC for promotion of medicinal products, Article L. 5223-1 of the FPHC for promotion of medical devices.



administrative sanctions against companies in the event of a violation of the advertising rules. Moreover, the provisions of the FPHC on advertising also contain criminal sanctions.

Noncompliance with the Disclosure Obligation Provided for by the French Sunshine Act

Article L. 1454-3 of the FPHC provides for a criminal fine of up to EUR45,000 against individuals for intentional noncompliance with the disclosure obligations under Article L. 1453-1 of the FPHC, and a fine of up to EUR225,000 against legal entities pursuant to Article L. 1454-5 of the FPHC.

Moreover, the following additional penalties may be imposed against individuals⁶¹:

- Diffusion of the decision and of a statement informing the public of this decision
- Display of the decision
- Ban on the exercise of civic rights
- Prohibition of carrying out public functions, commercial or industrial activities
- Prohibition of manufacturing, packaging, importing and marketing products mentioned in Article L. 5311-1 of the FPHC for a maximum duration of five years.

⁶¹ Article L. 1454-4 of the FPHC.

The following additional penalties can be imposed against a legal entity⁶²:

- Prohibition (of up to five years) from engaging in, directly or indirectly, one or several professional or social activities within which the offense was committed
- Being placed under judicial supervision (for up to five years)
- Closing down the legal entity's facilities used to commit the offense (for up to five years)
- Debarment from public procurement (of up to five years)
- Prohibition (of up to five years) from proceeding with a public tender offer or from making an initial public offering
- Prohibition (of up to five years) from issuing a check or using a payment card
- Confiscation of the object that has been used in or intended for use in committing the offense, or the proceeds of the offense
- Publication of the decision

⁶² Article L. 1454-5 of the FPHC referring to sub-paragraphs 2 to 9 of Article 131-39 of the French Criminal Code.



This third edition of "Promoting Medical Products Globally. Handbook of Pharma and MedTech Compliance" is intended to provide an overview of the applicable compliance laws governing the cooperation between the medical industry and physicians in Europe, North America, Latin America and the Asia Pacific region. It highlights the legal framework within which medical device and pharmaceutical companies cooperate with health care professionals. It deals with common sponsoring practices such as invitations, conferences and financial grants for research, personnel and equipment as well as other promotional activities such as the giving of gifts, samples and other items and services which are of interest to health professionals. We trust that the third edition is a useful resource for lawyers, compliance officers, managing directors and managers in marketing and medical departments of the medical industry to assess the legal impact on their promotion and marketing activities involving healthcare professionals or medical institutions.

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