Promoting Medical Products Globally

Handbook of Pharma and MedTech Compliance

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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 now included in Article 94 of the Community Medicines Code,[1] results from Directive n° 92/28/EEC concerning advertising for medicinal products.

Directive 92/28/EEC was implemented in France by the law of 18 January 1994,[2] the provisions of which were codified in the French Code of Public Health (namely, the *Code de la Santé Publique*, the "FCPH") in Book V on pharmacy.

However, the French legal framework already contained a legal provision regulating the relationships between health professionals and the pharmaceutical industry in the provisions of the law of 27 January 1993[3] which were codified in the FCPH in Book IV, dedicated to the medical professions and medical auxiliaries.

Thus, prior to the implementation of Directive 92/28/EEC, there was already in France a general principle of prohibition of pecuniary advantages or benefits in kind to health professionals.

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[1] Directive 2001/83/EC of the European Parliament and Council, dated 6 November 2001, 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).

[2] Law n° 94-43 dated 18 January 1994 relating to public health and social protection, JORF dated 19 January 1994.

[3] Law n° 93-121 dated 27 January 1993 JORF dated 30 January 1993.

The so-called Anti-Gift (*anti-cadeaux*) Law of 27 January 1993 was codified in FCPH Article L.4113-6. Moreover, this article complements the provisions of FCPH Article L.4113-8 which state, in essence, that health professionals

are prohibited from receiving, in any form whatsoever, directly or indirectly, interests or rebates proportional to the number of units prescribed or sold, whether it be a question of medicinal products or of devices of any nature.

A circular dated 9 July 1993[4] spelled out the content of Article L.4113-6, providing that the provisions of the Anti-Gift Law have to be interpreted in the light of Directive 92/28/EEC.

The approach of directive 92/28/CEE and that of the law of 27 January 1993 were, however, distinct. In effect, where the European text forbade pharmaceutical companies from giving benefits to health professionals, the pre-existing French law forbade health professionals from receiving these benefits from pharmaceutical companies.

The Patients' Rights Law of 4 March 2002[5] modified the provisions of the Anti-Gift Law. Henceforth, the provisions of Article L.4113-6 also forbid health product companies from procuring advantages for health professionals.

The 4 March 2002 law also introduced a new principle for transparency which, together with Article L.4113-13, provides for the following obligation for healthcare professionals:

The members of the medical profession who have connections with business and establishments which produce or develop health products or counseling organizations 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 declared by the relevant professional body for the health professional concerned. According to the implementing decree of the law of 4 March 2002, the public shall be informed via the presentation of the professional concerned, either in writing at the beginning of articles published by the

[4] Circular dated 9 July 1993 relating to the enforcement of Article L.365-1 of the French Code of Public Health, JORF dated 6 August 1993.
[5] Law n° 2002-303 dated 4 March 2002 relating to patients' rights and quality of the health system, JORF dated 5 March 2002.

written press or on the internet, or orally at the beginning of public events or speeches by the audiovisual press.[6]

The question of promoting health products by way of relationships between health 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. This analysis should be supplemented, if appropriate, by a reference to regulations concerning advertising for medicinal products.

Hence, these relationships are governed by a general principle of prohibition which puts an end to improper practices that tend to be an incentive to prescription. However, this principle is subject to exceptions enabling the health products industry to continue its role in the dissemination of scientific knowledge concerning medicinal products and in fundamental research, and it is mitigated by certain rules concerning advertising. Beyond such exceptions, Article L.4113-6 *in fine* specifies that its particular rules do not apply to the notion of "normal working relations," which is subject to discussion in practice and which must thus be clarified. Finally, non-compliance with the rules governing the advantages granted to medical 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 Bertrand Law of 29 December 2011 (the "Bertrand Law").[7] This law adds Article L.1453-1 — which requires that the health product companies disclose to the public all the contracts entered into with healthcare professionals, as well as any benefit granted to such healthcare professionals — to the FCPH. As of the drafting date of this chapter, the implementing decree which is to detail the provisions of this new disclosure obligation has not yet been published.

The Bertrand Law has also reorganized the French Authority for the Safety of Health Products ("AFSSAPS"), reinforcing its power and changing its name. The AFSSAPS is now called the National Agency for the Safety of Medicinal Products and Other Health Products ("ANSM").

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[6] Decree n° 2007-454 dated 25 March 2007, relating to the agreements and relations between the members of certain medical professions and certain companies and modifying the French Code of Public Health (inclusion of a new Article R.4113-110 of the FCPH).

[7] Law n° 2011-2012 of 29 December 2011 for the reinforcement of the safety of medicinal products and health products, JORF 30 December 2011.

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

The principle is formulated in FCPH Article L.4113-6, paragraph 1, which provides:

> The members of the medical professions mentioned in the present book, as well as students preparing a diploma to practice the same medical professions, and their associations, are prohibited from receiving pecuniary advantages or benefits in kind, in any form whatsoever, directly or indirectly, provided by companies which provide services, produce or market products reimbursed by the mandatory social security regimes. These businesses are also prohibited from offering or procuring such advantages.

Article 24 of the Medical Code of Ethics[8] incorporates this prohibition principle, and also specifies that physicians are prohibited from requesting such advantages.

The advantages in question are subject to a prohibition that thus principally targets medical professionals, in so far as they are granted by precisely defined companies.

Definition of Advantage

Definition

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

The prohibited advantage must be understood as being that which is 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. This

[8] Decree n° 95-1000 dated 6 September 1995 relating to the Medical Code of Ethics, as codified in Articles R.4127-1 to R.4127-112 of the FCPH.

approach entails the consequence, in particular, 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 which 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 EUR220 per patient on average, whereas this kind of study is in practice generally paid EUR75 per patient (the surgeons were therefore sentenced to a EUR2,875 fine)[9].

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.

A physician was sentenced to a fine of EUR1,220 for having taken advantage of a fixed-price tourism package in addition to the costs related to his business trip in Cuba.[10]

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.

Direct or Indirect Advantages

Finally, said 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

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[9] Court of Appeal of Montpellier, 3rd correctional chamber, 3 December 1998 case n° 1538.
[10] TGI of Brest, 16 February 1999, case n° 464/99.

a health professional individually in the end. In such a case, the third parties are intermediaries, as, for instance, when the 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 which receives such funds.

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 corporation that owned a clinic was sentenced to a fine of EUR3,050. The physician held 23 percent of the shares of the corporation, which in turn was the 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. Thus, the Court of Appeal ruled that said article was applicable to that case since:

> the advantage granted to a company through which physicians exercise 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.[11]

The precedent set by the Court of Appeal of Angers, which was confirmed by the Criminal Chamber of the Supreme Court (*Cour de Cassation*) in a decision dated 29 September 1999,[12] must not, however, be taken as voiding the provisions of the FCPH related to advertising for pharmaceutical companies, which authorize, under specific conditions, gifts made by the pharmaceutical companies to legal entities.

[11] Court of Appeal of Angers, correctional chamber, 25 March 1999 case n° 245.
[12] Cass. Crim., 29 September 1999 case n° 99.83300.

Healthcare Professionals Targeted by the Prohibition

FCPH Article L.4113-6 refers to the members of the medical professions identified in the "Present Book." The book in question is Book 1 of the fourth part of the FCPH relating to the health professions. The book covers the category of the medical professions, which includes physicians, midwives and dental surgeons.

Nurses,[13] masseur-physiotherapists,[14] speech therapists and orthoptists[15] are also subject to the prohibition principle even if they are part of the category of medical auxiliaries and not of the medical professions. The same holds true for pharmacists.[16]

Articles L.4343-1 and L.4311-28 of the FCPH explicitly provide that Article L.4113-6 applies to members of these professions. Moreover, the courts have already applied FCPH Article L.4113-6 by sentencing a nurse to pay a fine of EUR3,050 for having received EUR1,070 from a pharmaceutical company for the purpose of purchasing medical equipment for herself.[17]

The same applies to pharmacists (chemists). The law of 23 December 1998 concerning social security financing for the year 1999 in fact added Article L.4221-17 to the FCPH, referring to the provisions of FCPH Article L.4113-6. In practice, that text affects dispensing pharmacists and hospital pharmacists.

The law of 4 March 2002 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.

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[13] Article L.4311-28 of the FCPH.
[14] Article L.4321-19 of the FCPH.
[15] Article L.4321-1 of the FCPH.
[16] Article L.4221-17 of the FCPH.
[17] Tribunal de Grande Instance of Albi, judgment dated 27 May 1999 quoted by T. Pléan, "*La loi anti-cadeaux, premiers éléments de jurisprudence* [first cases relating to the Anti-Gift Law]", Contracts, Competition, Consumptions, n° 116, July-August 2000.

Finally, the Bertrand Law has included students preparing to practice any of the medical professions mentioned above, as well as associations of healthcare professionals and associations of students.

Companies Targeted by the Prohibition to Receive Advantages

FCPH Article L.4113-6 deals with the advantages granted by companies "providing services or producing or marketing products reimbursed by the mandatory social security regimes."

Companies Subject to and Companies Exempt from the Principle of Prohibition

Companies which market reimbursed products are obviously affected here, as are companies which market medical devices paid for by social security entities. Companies which do not market any reimbursed products are not affected.

However, Article L.4113-6 is echoed in the rules relating to advertising for medicinal products. FCPH Article L.5122-10 *in fine*[18] 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…

The prohibition, expressed here in terms of 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. The prohibition applies to all pharmaceutical companies, and thereby meets the objective laid down in the Community Regulation of ensuring healthcare professionals' independence by developing a set of rules guaranteeing that the persons authorized to prescribe or deliver medicinal products are in a position to carry out that task with complete objectivity, without being influenced by direct or indirect incentives.

[18] Article L.5122-10 of the FCPH implements Article 9 of directive 92/28/EEC (Article 94 of the Community code on medical products)

Intermediaries

The notion of indirect advantage, as construed by the Court of Appeal of Angers on the assumption that the intermediary (a corporation in which the physicians hold shares) is the beneficiary of the advantage in question, must also cover the situation where a company would offer the advantage indirectly through a company or a “screen” association. The circular of 9 July 1993 specifies in effect, that the scope of Article L.4113-6 includes communication companies or any other structure acting on behalf of companies that, themselves, are affected by its application.

The reasoning is the same with respect to advantages emanating from foreign companies. The principle of prohibition should apply, if moreover it were established that the said foreign companies are part of a group which includes other companies meeting the criteria laid down in Article L.4113-6.

Hence, the notions of advantage of members of the medical profession and of companies have a very broad scope. However, the principle prohibiting advantages is subject to exceptions.

The Exceptions to the Prohibition Principle

The principle of prohibition of advantages granted to healthcare professionals by companies manufacturing or commercializing health products admitted to reimbursement does not apply on two sets of cases.

Article L.4113-6 itself provides, first of all, for two exceptions relating to research contracts and to hospitality offered during events of a scientific or promotional nature. Moreover, the regulations on advertising of medicinal products explicitly authorize, subject to certain conditions, the pharmaceutical industry to deliver medicinal product samples free of charge to certain health professionals, provide them with advantages when the said advantages are of negligible value, and make financial grants.

The Exceptions Provided for by FCPH Article L.4113-6

Article L.4113-6 is aimed at ensuring greater transparency in the relationship between health professionals and the health products industry. However, such an objective must not prevent research activities or actions which promote medical training.

Two exceptions are explicitly provided for in Article L.4113-6: one for contracts concerning research or scientific evaluations concluded between

manufacturers and healthcare professionals; and the other for hospitality offered to such persons during events of a scientific or promotional nature. These two exceptions are admissible only if the procedure for requesting a prior opinion from the competent professional associations is observed.

Agreements Concluded Between Healthcare Professionals and Companies which have Research or Scientific Evaluation Activities as their Purpose

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

> However, the foregoing paragraph [principle of prohibition of advantages] does not apply to the advantages provided for in agreements concluded between the members of the said medical professions and companies if 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 assured. It does not apply to the advantages provided for in agreements concluded between companies and students preparing a diploma to practice a health care profession if the purpose of such agreements relates to research activities in the framework of the preparation of their diploma.

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

Clinical Trials

With respect, first of all, to the clinical trial agreements, all stages in research are covered.

Clinical trials are ranked in the first category of research on the human being, pursuant to the new classification provided for by the Law of 5 March

2012.[19] This category encompasses interventional trials defined as research which "include[s] for the persons interventions which are not justified by their usual medical treatment."[20] Such researches may pertain to medicinal products or medical devices. All clinical trials from phase 1 to phase 4 are concerned.

Pursuant to the law regarding research on the human being, clinical trials, prior to their launch, must be submitted to the Committee for Protection of Persons (*Comité de Protection des Personnes*, the "CPP") for a prior opinion, and then authorized by the ANSM. Once the ANSM delivers its authorization based on a favorable opinion of the CPP, the condition that the contract must have research or scientific evaluation activity as its real purpose is assumed to be met, and companies must then ensure that the compensation paid to the health professional according to the contract is commensurate with the requested services.

The fact is that the ANSM authorization does not, at the same time, exclude the possibility that the clinical trial agreements concerned may also have consequences for investigators in terms of promotion or of incentives to prescribe.

Thus the health professional's remuneration must be in proportion to the assignment and work load requested from him/her. That work load is measured by the number of observations to be 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. In general, abuses could potentially occur in connection with phase 4 of clinical trials, when the medicinal product is already being marketed and when it may be difficult to determine the borderline between clinical trial *per se* and studies aimed at demonstrating the interest of the medicinal product and thus masking, *ipso facto*, a promotional approach or an incentive to prescribe. When investigators conducting research are remunerated each time a patient is included in such research, the National Board of Physicians' Association requires in practice 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 absence of such a limit, the National Board considers that investigators are incentivized to

[19] Law n° 2012-300 of 5 March 2012 regarding researches on the human being, JORF of 6 March 2012.
[20] Article L.1121-1 of the FCPH.

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."[21]

Other Research or Scientific Evaluations

This refers in particular to "non-interventional" trials[22] or non-clinical tests (e.g., in pharmacology or in toxicology). Since the Law of 5 March 2012, non-interventional trials fall under the scope of the regulations governing research on the human being. As from 1 July 2014,[23] these trials will have to be submitted to the CPP for prior opinion, as provided for by FCPH Article L.1123-6 amended by the Law of 5 March 2012.

This means that for clinical trial agreements, it will be possible in the future to consider for non-interventional trial agreements that the favorable opinion of the CPP justifies the real nature of the research or of the scientific evaluation, and that the competent professional association merely has to control the proportionality of the compensation to the work requested from the healthcare professional.

The examination of the conformity of the research contracts to the requirements of Article L.4113-6 is carried out by the competent association of the profession of which the researching professional is a member, within the framework of the prior notification procedure with the competent professional association.

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

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

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[21] Article L.1121-1 of the FCPH.

[22] Non-interventional trials are defined by FCPH Article L.1121-1 as research in which "all medical care are practiced and products used as usual, without any additional diagnostic, treatment or monitoring procedures" (new definition provided for by the Law of 5 March 2012).

[23] Article 1 § I-9°-b) of the Law of 5 March 2012.

> It [the principle of prohibition] also does not apply to the hospitality offered, directly or indirectly for promotional events or for events of a strictly professional and scientific nature when it is provided for under an agreement concluded between the company and the health professional and is submitted for its opinion to the departmental board of the competent professional association before its application, and as long as said hospitality is on 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 medical profession, for hospitality offered, directly or indirectly, to scientific events if such hospitality is reasonable in level and limited to the scientific purpose of the event.

The principle of prohibition should not prevent the health products industry from contributing to the financing of symposia, seminars or study days aimed at updating knowledge, research or practices in given scientific domains. Nor should it prevent companies from launching continuing medical training actions.

Thus, invitations to informational or promotional meetings organized by the industry or the material assistance granted by the industry to healthcare professionals or students to take part in conferences or scientific meetings organized, in particular, by "scientific societies," constitute one of the most important aspects of the relationship between healthcare professionals and the health products industry.

Hence, companies retain the option of organizing promotional events on the occasion of the launch of a new product for example, and of contributing financially to health professionals' participation in meetings, seminars or conferences, whether such events are held in France or abroad.

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 health professionals must not be ostentatious and must simply enable such persons to attend meetings of interest to them, under normal conditions.

On this point, companies may not cover the expenses of the accompanying spouse or family of the professional benefiting from the invitation. If the professional would like to be accompanied by someone close to him, he must pay for the additional cost. Thus 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, "it may not be extended to persons other than the professionals directly concerned"[24] (reference can also be made to the Tribunal of Grasse

[24] 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* [first cases relating to the anti-gift law]", Agreements, Competition, Consumptions, n° 116, July-August 2000.

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 children[25] ; and the Tribunal of Clermond Ferrand judgment dated 15 March 2010 in which a pharmaceutical company was sentenced to a fine of EUR20,000[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 professional.

Topics addressed at such meetings must correspond to the practical interest of the professional invited to take part therein. 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.

Meals accompanying the events must remain incidental and necessary. A dinner organized in a restaurant to allow health 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 National Board of Physicians' Association 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 health 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 health professional has been 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]

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[25] TGI of Grasse, 26 February 1999, case n° 99/895.
[26] TGI of Clermond Ferrand, Criminal Section, 15 March 2010.
[27] Court of Appeal of Rennes, 3rd correctional chamber, 21 July 1998 case n° 1249/98.

The determination of the place where the event takes place is currently governed by the guidelines jointly adopted in 2007 by the French Association of Pharmaceuticals Manufacturers ("Leem"), the French Association of Medical Devices Manufacturers ("SNITEM") and the National Council of the Professional Association of Physicians ("CNOM")[28], which refer to Article 9 of the European Federation of Pharmaceutical Industries and Associations ("EFPIA") Code[29]. The main principle of Article 9 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.

Finally, 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).

Submission Procedure for Prior Opinion of Professional Associations

Pursuant to FCPH Article L.4113-6, for the purpose of benefiting from the exception to the general principle of prohibition on advantages, the proposed research contract or the proposed invitation to a scientific event must be submitted ahead of time to the appropriate professional association. The said notification is incumbent upon the health products company, which must request an opinion.

The professional associations for medical professions (namely, physicians, midwives and dental surgeons), as well as the professional association for pharmacists, are already organized for the examination of the requests for prior opinion submitted by companies.

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[28] Document for the interpretation and implementation of FCPH Article L.4113-6, 21 June 2007, jointly adopted by Leem , SNITEM and CNOM.

[29] EFPIA Code of Practice on the promotion of prescription-only medicines to, and interactions with, healthcare professionals (Amended following Statutory General Assembly approval of 14 June 2011).

As far as medical auxiliaries are concerned, the law of 4 March 2002 had created a professional council grouping, in particular for nurses, masseur-physiotherapists, speech therapists and orthoptists. It had been anticipated to have this professional council give prior opinion on proposals submitted by companies in compliance with the Anti-Gift Law. However, the creation of this professional council has been cancelled. A Law of 2006[30] has created a professional association for nurses[31] and a Law of 2004[32] has created a professional association for masseur-physiotherapists.[33] Today, the professional associations for nurses and for masseur-physiotherapists are elaborating their process to examine requests for prior opinion submitted by companies, but issues are still arising as the implementing decree of FCPH Article L.4113-6 is limited in scope to medical professions, to the exclusion of medical auxiliaries.[34]

Request for Advice by the Company

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

> All the agreements between members of medical professions or students and companies [contracts and invitations to meetings, seminars or conferences] are, before their application, submitted for opinion to the district board of the competent professional association or, if their scope is national or covers more than one district, 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 health professionals, before the implementation of the agreement. If there is no response from the association within the applicable time period, the opinion is

[30] Law n° 2006-1668 of 21 December 2006 creating a professional association for nurses, JORF of 27 December 2006.
[31] FCPH Article L.4312-1.
[32] Law n° 2004-806 of 9 August 2004 regarding public health, JORF of 11 August 2004.
[33] FCPH Article L.4321-14.
[34] FCPH R. 4113-104 only refers indeed to contracts and hospitality with members of the medical professions.

considered positive. The company must inform the competent professional association when the convention is implemented.

The decree mentioned above was adopted in March 2007[35] and provides for a period of one month for opinions concerning hospitality offered during scientific events and a period of two months for research or scientific assessment agreements or, in case of urgency, a unique period of three weeks[36]. If the file submitted to the professional association is not complete, the professional association must notify the company, after which the clock stops until the submission of the complete file.[37] However, as far as hospitality is 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[38].

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

- the draft agreement identifying the company;
- the amount of compensation, terms and conditions of the determination of compensation, and the advantages granted to the professional;
- the names of the professionals concerned, with their title, specialty and professional address;
- the document of collection of data relating to the research or scientific assessment activities; and
- the 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 invitation to the event;
- the nature of the paid services on the occasion of the event in question and the amount of the accommodation, food and registration fees;

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[35] Decree n° 2007-454 of 25 March 2007, regarding conventions and interactions between health product companies and healthcare professionals and modifying the French Code of Public Health, JORF of 28 March 2007.
[36] FCPH Article R.4113-107.
[37] FCPH Article R.4113-106.
[38] Document for the interpretation and implementation of FCPH Article L.4113-6, 21 June 2007, jointly adopted by Leem, SNITEM and CNOM.

- the contemplated detailed program of the event; and
- the list of members of medical professions to whom the invitation was sent, with their specialties and professional addresses.[39]

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 contract, 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. The evaluation of risks is very important since, in case of subsequent investigations of the French Authority for Consumption, Unfair Competition and Fraud Affairs (namely the *Direction Générale de la Concurrence, de la Consommation et de la Répression des Fraudes*, the "DGCCRF"), criminal proceedings could be triggered.

Compliance with Article L.4113-6 is subject, finally, to the review by the courts. In a decision dated 29 June 1999, the Court of Appeal of Paris ruled, regarding the hospitality offered to physicians for a conference, that the opinion issued by the professional association was strictly advisory, and that Article L.4113-6 does not in any way require physicians to make sure that the professional association's opinion has been requested in advance by the company and that the said opinion is positive. In that case, the association's opinion was negative, but since the physicians might have thought that the procedures relating to the said hospitality complied with the requirements laid down in Article L.4113-6 and that the association's opinion was positive, neither the pharmaceutical company nor the physicians were sentenced.[40]

This precedent in French case law is important since it specifies that the opinion given by the professional association is only advisory. However, it is no longer applicable since the law of 4 March 2002, which modified Article L.4113-6 to provide for the obligation for companies to forward negative opinions to health professionals before the execution of the agreements or hospitality.

The opinion of the competent professional association is only advisory; it must be reiterated that if the professional association gives its approval, such

[39] FCPH Article R.4113-105.
[40] Court of Appeal of Paris, 11th correctional chamber, A, 29 June 1999 case n° 98/03995.

approval does not avoid the proof of subsequent violation of Article L.4113-6.[41]

Lastly, it must be highlighted that the Law of 29 December 2011 has amended Article L.4113-6 providing for a new obligation incumbent on companies. Since 30 December 2011, companies are obliged to notify the professional association which has issued a prior opinion of the date when the contract is effective or the date when the hospitality is offered.

Since Article L.4113-6 does not provide any further details, it should be considered that this new obligation applies whether the prior opinion of the professional association is positive or negative. In the absence of any time period, it is advisable for companies to address such notification as soon as possible.

Communication of the Contracts by the Professionals

Pursuant to Article L.4113-9 of the FCPH, physicians and dental surgeons must communicate to the departmental board of their professional association the contracts relating to the practice of their professions, as well as the contracts 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.

This communication must take place, at the latest, one month after the signing of the contract 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 contracts constitutes a disciplinary fault that may be sanctioned by the relevant professional association.

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

[41] In particular, upon an inspection by DGCCRF: Court of Appeal of Montpellier, 3rd Criminal Section, 3 December 1998 case n° 1538; Court of Appeal of Montpellier, 3rd Criminal Section, 9 February 2009, case n° 224; TGI of Clermond Ferrand, Criminal Section, 15 March 2010.

Notification of the Contracts Relating to Research or Scientific Evaluations to the Manager of the Health Establishment in which the Activities are Conducted

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

It must be ascertained that the person responsible for the establishment has agreed to the organization of research activities or scientific evaluations in the establishment.

Article L.4113-6 does not specify who is responsible for such notification. As such obligation of notification follows the obligation for the companies to refer the contracts to the competent professional association in order to obtain its opinion, it seems that it is the duty of the companies to notify the manager of the establishment of such contracts.

For clinical trials, this obligation is clearly incumbent on the company since the regulations on clinical trials provide that the "sponsor" of the clinical trial must inform the manager of the health establishment when the trial is performed within the facilities of such establishment.[42]

For non-interventional trials, as the law does not make any provision on this point, the research agreement or the contract relating to a scientific evaluation may stipulate that the health professional is responsible for informing the person in charge of the health establishment.

Practices Authorized by Regulations on Advertising

Like Article L.4113-6, which applies, above all, to health professionals, the regulations on advertising for medical products explicitly authorize pharmaceutical companies to provide such health 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 FCPH which relate to advertising for pharmaceutical establishments, and those provisions also allow pharmaceutical companies to make gifts to encourage research or training of health professionals.

[42] FCPH Article L.1123-13.

Delivery of Free Samples

Article L.5122-10 of the FCPH authorizes the supply of free samples to "persons authorized to prescribe or to deliver drugs within the framework of pharmacies for internal use."

This means that pharmaceutical companies may give free samples only to physicians and to hospital pharmacists, 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 make such deliveries spontaneously since the initiative is not theirs.

Furthermore, Article L.5122-10 of the FCPH 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 is prohibited for samples of medicinal products containing substances classified as psychotropic drugs or narcotics, or to which all or part of the regulations concerning narcotics apply.

When delivery thereof is authorized, these samples must be identical to the medicinal products concerned and bear the indication "free sample."

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

- Each supply of free samples must be in response to a written request, dated and signed, from the addressee.
- For each medicinal product, only a limited number of samples may be provided, with a limit of 10 per year and per addressee, 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 provides that samples must be delivered in reply to written requests from physicians only. As a result, the charter relating to the medical representation as signed between Leem and the Economic Committee of Health Products (*Comité Economique des Produits de Santé*) specifies that medical representatives may not deliver samples.[43]

It must also be highlighted that Article R.5122-17 has been amended in 2012[44] and now provides that free samples are only authorized during the first two years following the first 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.

Beyond delivery of free samples, pharmaceutical companies are also authorized to give health professionals advantages of negligible value.

Advantages of Negligible Value

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

As far as pharmaceutical companies are concerned, the provisions of Article L.5122-10 *in fine* of the FCPH concerning advertising for medicinal products and R.5124-65 of the FCPH concerning advertising for pharmaceutical establishments state that it is forbidden to grant, offer or promise to healthcare professionals a bonus, a pecuniary advantage or a benefit in kind unless they are of negligible value and, as required by Article 94-1 of the

[43] Charter on sales medical representatives as signed between Leem and the Economic Committee of Health Products (*Comité Economique des Produits de Santé*) dated 21 July 2005, Article 2-d.
[44] Decree n° 2012-741 of 9 May 2012 regarding regulations on advertising for medicinal products for human use, JORF of 10 May 2012.

Community Code on Medicinal Products,[45] relate to the practice of the medical or the pharmaceutical profession.

Although the abovementioned provisions are limited in scope to pharmaceutical companies, it is admitted in practice that medical device manufacturers can also grant advantages of negligible value.

The guidelines jointly adopted by Leem, SNITEM and CNOM on 21 June 2007 provide for an annual threshold of EUR30 (tax excluded) per healthcare professional and per company.[46]

In practice, this possibility is now very limited since the charter on sales medical representatives as signed between Leem and the Economic Committee of Health Products prevents medical representatives from delivering small gifts to professionals.[47]

Grants by Pharmaceutical Companies

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

- The recipient of the grant must necessarily 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.
- The grant must only aim at encouraging research or continuing medical education and Article R.5124-66 provides that the grant must not have the actual purpose of providing a healthcare professional with an individual advantage.
- The grant must be declared in advance to the Regional Health Agency ("ARS") of the region where the beneficiary entity's registered office

[45] 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.
[46] Document for the interpretation and implementation of FCPH Article L.4113-6, 21 June 2007, jointly adopted by Leem, SNITEM and CNOM.
[47] Charter on sales medical representatives as signed between Leem and the Economic Committee of Health Products (*Comité Economique des Produits de Santé*) dated 21 July 2005, Article 2-d.

is located. In practice, that 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 a physicians' association. The notion of indirect advantage, as construed in the precedents, requires pharmaceutical companies to make sure that their grants do not, in the end, benefit a practitioner in an individual way and thus become subject to the prohibition of advantages set forth in Article L.4113-6.

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, as well as for an affidavit issued by the person in charge of said entity containing an undertaking to use the amounts given in accordance with the corporate purpose described in the articles, and not to use them for the personal expenditures of a member of the entity. These two documents are attached to the file transmitted in advance to the ARS.

Indeed, the circular of 9 December 1996 on advertising for pharmaceutical companies[48] specifies that it is up to the ARS to verify that the articles of association of the beneficiary entity do allow it to receive grants.

It must be noted that, in practice, this legal framework is voluntarily applied by medical device manufacturers.

Finally, it must be emphasized that the Bertrand Law of has inadvertently modified FCPH Article L.4113-6 in a way that leads to consider that grants to associations of healthcare professionals are now prohibited. The industry, the professional associations, and even the administration, agree to state that this prohibition results from a wrong drafting of Article L.4113-6 and the Parliament did not intend to forbid grants to associations of healthcare professionals.

[48] Circular DGS n° 96-741 dated 9 December 1996 relating to advertising in favor of pharmaceutical entities, BOMTAS 96/51.

As from the 30 December 2011 (the publication date of the Bertrand Law), and as long as this drafting is not corrected by a new law, parties to financial grant agreements are in a grey zone and must assess the risks to enter into such agreements. The issue can be summarized in the three situations, as follows:

- The company willing to make a financial grant and the association which would benefit from such grant agree to consider that the amendment of FPCH Article L.4113-6 results from a wrong drafting of the Parliament and that, therefore, violation of this new prohibition would likely not be sanctioned. The concerned parties thus enter into the financial grant agreement.
- In contrast, the company willing to make a financial grant and/or the association which would benefit from such grant consider that, even if this prohibition results from a wrong drafting, the prohibition is clearly stated in the provisions of FCPH Article L.4113-6 and can trigger criminal sanctions. The concerned parties thus do not enter into the financial grant agreement.
- Lastly, the companies can update their compliance policies referring to FCPH Article L.4113-6 *in fine*, which provides that the funding of continuing medical education remains out of the scope of the prohibition provided by said article. Companies can therefore consider that financial grants made to associations of healthcare professionals for the purpose of supporting continuing medical education are still authorized (as opposed to financial grants aimed at encouraging research).

It must finally be noted that this new prohibition appears to be limited in scope to grants which are made only to the benefit of associations. Financial support granted to other legal entities such as private clinics or hospitals seem to still be authorized.

Scope of the Prohibition of Advantages, Scope of the Preliminary Submission Procedure and Notion of "Normal Working Relations"

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

> The provisions of such article would not either subject to agreement the normal working relations nor prohibit the financing of continuing medical training.

The notion of “normal working relations” as mentioned above is not defined and leads to various interpretations in practice.

The circular dated 9 July 1993[49] had specified that "normal working relations" would include, for example, "the missions, employment contracts or participation in scientific advices" and that such relations would not fall within the scope of Article L.4113-6 to the extent that the payment made to the health professionals is not disproportionate with regard to the service rendered.

In principle, it could be considered that certain interactions between companies and healthcare professionals do not lead to any advantage in favor of such professionals and therefore do not fall under the general prohibition as provided for in Article L.4113-6, or at least, do not need to be submitted for prior opinion to the competent professional association.

However, in 2001, the DGCCRF published a restrictive interpretation of the notion of "normal working relations" in response to a request for interpretation presented by the CNOM:

> Except for the employment contract between a physician and a company providing for precise duties, various particular situations such as health professionals' participations as speaker in a symposium organised by companies, writing of articles for manufacturers, participation to scientific committees of pharmaceutical companies, training sessions by health professionals upon request of companies on the occasion of implementation of new techniques or new materials, can be analysed as particular cases which relate to the very broad notion of "clinical research and/or scientific evaluation," and as the case may be, relate to the principle of hospitality, in connection with "promotional events or events of a strictly professional and scientific nature…

According to the DGCCRF, "these situations, subject to the appreciation of the Courts, should fall in the scope of Article L.4113-6 except for agreements without financial counterpart or if the financial counterpart is of 'negligible value' (including working meals with a representative of the Industry, delivery of samples of products or demonstration equipment of a negligible value)."

[49] Circular dated 9 July 1993 relating to the enforcement of Article L. 365-1 of the French code of public health, JORF dated 6 August 1993.

The DGCCRF appeared to consider that the activities relating to research or scientific evaluation, and the activities pertaining to the hospitality offered during promotional or scientific events as mentioned in paragraphs 2° and 3° of Article L.4113-6 had to be interpreted as broadly as possible in order to comply with the notification procedure before the professional associations the most attractive scope as possible. The scope of activities, which can be considered as part of "normal working relations" and, as such, excluded from such procedure, became therefore very limited in practice.

Then, with the guidelines jointly adopted by Leem, SNITEM and CNOM in June 2007,[50] the issues raised by the scope of the notification of contracts to professional associations were clarified.

According to these guidelines (which contain no reference to the notion of "normal work relations"), certain contracts relate to activities other than for which the related contracts must be submitted for prior opinion. Such contracts remain subject in the scope of FCPH Article L.4113-9.[51]

Therefore, the guidelines provide that the contracts which remain out of the scope of the notification by companies to professional associations for prior opinion are the contracts relating to the following activities:

- Training sessions organized by physicians for other physicians (e.g., learning surgery protocols)
- Drafting of publications which do not pertain to research activities performed for companies
- Attendance for companies to advisory boards which are not linked with research
- General presentations in congresses (excluding the presentation of research results)
- Bibliography researches
- Training for companies' staff (in particular, sales medical representatives)

Before their publication, these guidelines were reviewed by the DGCCRF, and it did not raise any issues regarding the above position.

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[50] Document for the interpretation and implementation of FCPH Article L.4113-6, 21 June 2007, jointly adopted by Leem, SNITEM and CNOM.

[51] Notification of contracts by physicians themselves to their professional association at the latest one month after their effective date.

Therefore, since 2007, the abovementioned contracts were no longer submitted to professional associations for prior opinion.

However, the position of the guidelines has become invalid since the Bertrand Law came into force. Indeed, FCPH Article L.4113-6 as amended by this law provides now that all contracts between health product companies and healthcare professionals must be submitted to the competent professional associations for prior opinion. The guidelines jointly adopted in 2007 should thus be updated accordingly in the future to remove this position as it leads now to discrepancies with the law.

Today, it appears that the notion of "normal work relations" can be useful only for lunches offered in the day-to-day relationship with healthcare professionals and out of the "hospitality" offered during scientific events. Such lunches remains out of the scope of the notification procedure for prior opinion, but is still subject to the general prohibition of advantages. Payments made by companies to cover such lunches must thus be reasonable in level. The national board of the professional association for pharmacists ("CNOP") refers to a threshold of EUR54 under which a lunch can reasonably be offered to a pharmacist.[52]

Transparency: The "French Sunshine Act"

In addition to the general principle prohibiting any advantage and providing for the ethical control of contracts and hospitality by associations of healthcare professionals, the Bertrand Law[53] provides for a new transparency regime regarding interactions between health product companies and healthcare professionals. This new regime is called the "French Sunshine Act," referencing the US Sunshine Act that France has followed.

France has indeed adopted a new disclosure obligation incumbent on health product companies, which must make available to the public any contracts they entered into with healthcare professionals, any hospitality for scientific events and any advantage they offer to healthcare professionals.

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[52] CNOP: anti-gift procedure, http://www.ordre.pharmacien.fr/Nos-missions/Le-role-de-l-Ordre-dans-les-missions-de-sante-publique/Dispositif-anti-cadeaux.

[53] 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 French Sunshine Act also increases the regime for the declarations of interests for the experts involved in the various decision-making processes regarding health products in France.[54]

As of the date of drafting of this chapter (20 July 2012), the implementing decree which details the disclosure obligation has not yet been published.

Disclosure Obligation Incumbent on Companies

The new transparency regime for interactions with healthcare professionals is codified under new FCPH Article L.1453-1, as follows:

Companies manufacturing or commercializing products that are listed by FCPH Article L.5311-1-II or providing services in connection with such products are obliged to make available to the public the existence of any contracts entered into with:

- healthcare professionals whose practice is governed by Title IV of the FCPH;
- associations (i.e., non-profit organizations) of healthcare professionals;
- associations of students;
- associations of health system users (i.e., patients' associations);
- health establishments (i.e., both public hospitals and private clinics);
- foundations, medical societies and advisory societies or bodies operating in the health products sector;
- press publishing companies, broadcasters of radio or television services and publishers of public online communications services;
- publishers of product prescription and delivery aid software; and
- legal entities providing training sessions for the healthcare professionals mentioned above.

The same disclosure obligation applies, beyond a threshold that must be determined by the implementing decree, to any benefits in cash or in kind offered by companies, even indirectly, to healthcare professionals and other entities mentioned above.

The implementing decree must detail the conditions for the enforcement of this disclosure obligation, the information which must be made available to the public, particularly the purpose of the contracts and their date, as well as

[54] FCPH new Articles L.1451-1 *et seq*.

the process for disclosure and the updating of the information disclosed. This implementing decree must also provide for the conditions under which the associations of healthcare professionals shall be involved in this regard.

Companies Bound by the Disclosure Obligation

FCPH Article L.1453-1 refers to "companies manufacturing or commercializing products that are listed by FCPH Article L.5311-1-II or providing services in connection with such products."

The French Sunshine Act is much broader in scope than the Anti-Gift Law (FCPH Article L.4113-6).

The Anti-Gift Law indeed 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 FCPH Article L.5311-1 which draws upon the list of all the health products for which the ANSM is competent, with no reference to their reimbursement status.

Therefore, various medical device manufacturers, whose devices are not admitted to reimbursement and thus remain out of the scope of the Anti-Gift Law, fall under the scope of the French Sunshine Act (in particular, manufacturer of medical or hospital equipment).

The same applies to the pharmaceutical sector, in particular, for biotechnology companies manufacturing medicinal products which are not yet marketed and thus not yet admitted to reimbursement.

Lastly, players on other health product markets are covered by the French Sunshine Act as the products they market are listed under FCPH Article L.5311-1. This is, in particular, the case for companies of the cosmetics sector.

Healthcare Professionals and Other Entities Targeted by the Disclosure Obligation

The notion of healthcare professionals in the framework of the French Sunshine Act is broader in scope than the same notion under the Anti-Gift Law. FCPH Article L.1453-1 refers to all professionals whose practice is

regulated by Part IV of the FCPH, in particular opticians,[55] and also to those entities which are listed above, in particular associations of healthcare professionals and associations of patients.

Information to Disclose

FCPH Article L.1453-1 provides that companies must make available to the public the existence of contracts, as well as advantages.

The Law of 29 December 2011 specifies that this obligation applies to contracts which are effective as of 1 January 2012 or which become effective after that date, as well as advantages granted after that date.[56]

The implementing decree is to detail the nature of the information to disclose regarding the contracts, the existence of which must be made available to the public, as well as the information regarding the hospitality and advantages offered to the healthcare professionals and the other entities targeted by FCPH Article L.1453-1.

The decree also determines the value threshold under which the advantages of "negligible value" will not fall within the scope of the disclosure obligation.

Process for Disclosure

It will also be up to the government to detail in the implementing decree the support for disclosure to the public (likely the internet) and the time periods for successive disclosures and updating.

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[55] In addition to the HCPs already covered by FCPH Article L.4113-6 (physicians, midwives, dental surgeons, nurses, masseur-physiotherapists, speech therapists, orthoptists, and pharmacists), FCPH Article L.1453-1 also covers the following health practitioners: assistants who assist pharmacists within pharmacies in town or hospitals' pharmacies; podiatrists; occupational therapists; psycho motorists; technicians of medical imaging centers; technicians of biological analysis laboratories; opticians, specialists for hearing aid prosthesis; specialists of prosthesis for disabled persons; dieticians; assistants for patients care; assistants for children care; ambulance drivers; and students preparing to enter the professions covered by the Part n° IV of FCPH.

[56] Article 41-II of the Law of 29 December 2011.

Enforcement

The Law of 29 December 2011 provides that the disclosure obligation shall be enforceable at the date of the publication of the implementing decree or, in the absence of the decree, on 1 August 2012 at the latest. [57]

Since the application of the disclosure obligation appears to be impossible in practice without the implementing decree, it would be appreciated that, in the event that this decree is not yet adopted on 1 August 2012, the French Ministry of Health publishes a moratorium to secure these companies which may decide not to disclose any information, as non-compliance with FCPH Article L.1453-1 can trigger criminal sanctions.

Sanctions

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

First of all, it shall be mentioned that the breach by a company of the provisions of Article L.4113-6 can be considered by a competitor as unfair competition detrimental to its interests. Moreover, violation of such article may also lead to litigation before the commercial courts between competitors.[58]

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

Non-compliance with the principle of prohibition of advantages may be analyzed as an alienation of the independence of the professional who has benefited from the prohibited advantage, and thus allows the professional association to decide disciplinary sanctions. Independent of these professional sanctions, Article L.4113-6 includes criminal sanctions, and disregard thereof may trigger proceedings filed by the *Parquet* (public prosecutor's office).

[57] Article 41-II of the Law of 29 December 2011.
[58] For an enforcement: Court of Appeal of Versailles, 12 ch. 6 May 2003 Pharmacia v/ Alcon, case n° 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, 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.

These disciplinary sanctions do not preclude proceedings that might be filed by the public prosecutor or by individuals in the criminal courts.

Criminal Proceedings

The opinion issued by the professional association in application of Article L.4113-6 is part of a preventive approach. Precedent has confirmed the advisory (i.e., not mandatory) nature of said opinion.

This preliminary procedure does not prevent the triggering of later enquiries. Under the terms of Article L.4113-6 of the FCPH, inspecting pharmacists or inspecting physicians, the inspectors of the ANSM, the 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.

In practice, enquiries are generally carried out by DGCCRF agents. The inspection is conducted during or after execution of the research contract or the scientific or promotional event, and it focuses on the actual conditions of realization of the operations carried out by the companies.

Both the professional associations and the companies may be subject to this type of inspection. For this reason, such companies are advised to keep all documentation establishing the fact that their operation complies with the requirements laid down in Article L.4113-6.

Such inspections may trigger proceedings before the judicial courts. By way of illustration, a pharmaceutical company has been sentenced to a fine of

EUR20,000 following the organization of various dinners with physicians on the occasion of medical congresses. An inspection report of the DGCCRF

had indeed 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.[59]

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

In addition to the main penalty, the courts may prohibit the person from practicing for a period of 10 years.

FCPH Article L.4163-2 of the FCPH also provides for the sanctioning of companies (as legal entities), under the same terms, for having offered or procured advantages for members of the medical profession[60] in violation of Article L.4113-6. In addition, Article L.4163-2 provides that corporate entities can be held criminally liable under the conditions provided in Article 121-2 of the Criminal Code. 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 (Article 131-38 of the Criminal Code). Therefore, a company, as a legal entity, can be sanctioned with a fine of up to EUR375,000 (i.e., EUR75,000 x 5) for violating Article L.4113-6. Furthermore, the sanctions determined for individuals can also be applied to the managers of the companies if they are individually prosecuted.

In addition, sanctions decided against legal entities must be reported to the Economic Committee of Health Products (*Comité Economique des Produits de Santé*, "CEPS").

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[59] Tribunal of Clermond-Ferrand, Criminal Section, 15 March 2010.

[60] Surprisingly, FCPH Article L.4163-2 only refers to "members of medical professions" (i.e., physicians, midwives and dental surgeons), to the exclusion of the other healthcare professionals who are also subject to the prohibition of gifts pursuant to FCPH Article L.4113-6 (i.e., medical auxiliaries and pharmacists). In consequence, should any case of violation of the Anti-Gift Law in connection with an interaction with a medical auxiliary or a pharmacist be brought before a criminal court, the issue regarding the enforceability of the sanctions determined by FCPH Article L.4163-2 could be debatable.

CEPS is the public entity responsible for the pricing of medicinal products or medical devices covered by the French Health Insurance Program, by way of agreements with the companies which commercialize 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. However, it is unlikely that CEPS would require the renegotiation of a pricing agreement in case of a breach of Article L.4113-6 by the signing company. In potential cases where a company may have granted undue advantages to health professionals during a promotional event, it should be demonstrated that the limitations to promotional budgets binding the company pursuant to its pricing agreement have been exceeded. As of today, we have not been aware of practical consequences on pricing agreements which would follow a violation of Article L.4113-6.

Sanctions can also be levied in case of violation of the rules and regulations concerning advertising.

Violations of the Rules Concerning Advertising

The legal definition of advertising for health products is extremely broad. In particular it extends to "any form of information" on such products.[61]

For example, with regard to medicinal products, the scope of this definition includes invitations issued by pharmaceutical companies to health professionals to take part in promotional events, the delivery of free samples and the advantages of negligible value granted to them. Article R.5122-12 of the FCPH also specifies that any type of contribution to financing scientific conferences or meetings constitutes sponsorship that must be characterized as advertising.

The ANSM controls advertising of health products and is empowered to take administrative sanctions against companies in the event of violation of the advertising rules. Moreover the provisions of the FCPH on advertising also contain criminal sanctions.[62]

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[61] FCPH Article L.5122-1 for advertising of medicinal products, FCPH Article L.5223-1 for advertising of medical devices.

[62] See in particular FCPH Article L.5422-9: the granting of, or the promise to offer, to persons prescribing of delivering medicinal products any benefit in cash or in kind, unless the benefit is of negligible value, in the framework of the promotion of medicinal products, can be sanctioned by a criminal fine of up to EUR37,500.

Non-Compliance with the Disclosure Obligation Provided for by the “French Sunshine Act”

FCPH Article L.1454-3 provides for a criminal fine of up to EUR45,000 against any company which does not voluntarily disclose information that must be made available to the public pursuant to FCPH Article L.1453-1.

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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.