ICLG

The International Comparative Legal Guide to:

Pharmaceutical Advertising 2016

13th Edition

A practical cross-border insight into pharmaceutical advertising

Published by Global Legal Group, with contributions from:

A. Lopes Muniz Advogados Associados
Adams & Adams
Ambruz & Dark Deloitte Legal
Arnold & Porter LLP
Arthur Cox
Baker & McKenzie
Biolato Longo Ridola & Mori
Bird & Bird LLP
Boga & Associates
Clayton Utz
Clifford Chance
Cooley
Cuatrecasas, Gonçalves Pereira
Dentons Europe CS LLP
Fogler, Rubinoff LLP
Gün + Partners
Haavind
Herbst Kinsky Rechtsanwälte GmbH
Jones Day
Jusmedico Advokatanpartsselskab
KG Law Firm
LCH Law Compliance Health
Life Sciences Legal
Mannheimer Swartling Advokatbyrå
Marić, Mališić & Dostanić OAD
Nishimura & Asahi
OLIVARES
Pestalozzi Attorneys at Law
Roschier, Attorneys Ltd.
Soltysinski Kawecki & Szlezak
Stibbe
Stratulat Albulescu
Subramaniam & Associates

glg
global legal group

global legal group

Contributing Editor
Ian Dodds-Smith, Arnold & Porter (UK) LLP

Sales Director
Florjan Osmani

Account Directors
Oliver Smith, Rory Smith

Sales Support Manager
Toni Hayward

Editor
Caroline Collingwood

Senior Editor
Rachel Williams

Chief Operating Officer
Dror Levy

Group Consulting Editor
Alan Falach

Group Publisher
Richard Firth

Published by
Global Legal Group Ltd.
59 Tanner Street
London SE1 3PL, UK
Tel: +44 20 7367 0720
Fax: +44 20 7407 5255
Email: info@glgroup.co.uk
URL: www.glgroup.co.uk

GLG Cover Design
F&F Studio Design

GLG Cover Image Source
iStockphoto

Printed by
Stephens & George
Print Group
June 2016

ISBN 978-1-911367-01-7
ISSN 1743-3363

Strategic Partners

PEFC Certified
This product is from sustainably managed forests and controlled sources
PEFC/16-33-254
www.pefc.org

General Chapters:

Country Question and Answer Chapters:

France

Laure Le Calvé

Johanna Benichou

LCH Law Compliance Health

1 General – Medicinal Products

1.1 What laws and codes of practice govern the advertising of medicinal products in your jurisdiction?

The advertising of medicinal product is regulated by:

- Articles L.5122-1 *et seq*. and Articles R.5122-1 *et seq*. of the French Public Health Code ("CSP");
- Articles L.121-1 *et seq*. of the French Consumer Code; and
- Law No. 94-665 dated August 4, 1994 which requires that all advertising must be drafted in French.

Companies are expected to comply with various codes, such as:

- the recommendations issued by the National Agency for Medicinal drugs Safety ("ANSM");
- the charter for the Communication and Promotion of Health Products on the Internet and E-media of ANSM (the "Charter");
- the code of practice published by the French pharmaceutical companies' union, "LEEM";
- the EFPIA Code on the promotion of prescription and interactions with healthcare professionals;
- the information charter by the doorstep selling and canvassing for the promotion of the medicinal products signed by the LEEM and the Economic Committee for Medicinal Products ("CEPS"); and
- the code "Information on the medicinal product and editorial advertising" by the LEEM, SPEPS and UDA (media trade unions).

1.2 How is "advertising" defined?

As any form of information including doorstep selling, of canvassing or of incentive, aimed at promoting the prescription, the delivery, the sale or the consumption of medicinal products, except information delivered in the context of their duties, by pharmacists managing hospital pharmacy (Article L.5122-1 of PHC). The following is not included within the scope of this definition:

- correspondence together with, as the case may be, any non-advertising documentation, necessary to answer a precise question related to a specific medicinal product;
- information relating to packaging changes, warnings concerning the adverse effects identified as part of pharmacovigilance as well as sales catalogue and price lists if they do not include information regarding the medicinal products; and
- information relating to human health or human diseases provided that there is no reference, even indirectly, to a medicinal product.

1.3 What arrangements are companies required to have in place to ensure compliance with the various laws and codes of practice on advertising, such as "sign off" of promotional copy requirements?

Companies must have a department in charge of advertising which must be under the supervision of the responsible pharmacist who must ensure compliance with the legislation, including the scientific validity of this information.

1.4 Are there any legal or code requirements for companies to have specific standard operating procedures (SOPs) governing advertising activities? If so, what aspects should those SOPs cover?

No, although this is obviously recommended. However, in order to practice pharmaceutical sales visits, companies must be certified and must comply with the certification referential established by the Public Health Authority ("HAS").

1.5 Must advertising be approved in advance by a regulatory or industry authority before use? If so, what is the procedure for approval? Even if there is no requirement for prior approval in all cases, can the authorities require this in some circumstances?

Any advertising whether to healthcare professionals ("HCP") or the public must be first authorised ("visa") by ANSM.

The visa is considered as delivered by ANSM if no answer is given within two months further to the receipt of the request's file. ANSM may request additional information which suspends the two-month timeframe. The visa request must be made only during a specific time of the year, as per a calendar established by ANSM. The visa is issued for a two-year period.

1.6 If the authorities consider that an advertisement which has been issued is in breach of the law and/or code of practice, do they have powers to stop the further publication of that advertisement? Can they insist on the issue of a corrective statement? Are there any rights of appeal?

Yes, advertising can be prohibited by ANSM. The visa can also be

suspended in case of emergency or withdrawn by ANSM in certain cases.

The ANSM decision is published on its website. Companies are able to appeal against such decision before the Administrative Court.

1.7 What are the penalties for failing to comply with the rules governing the advertising of medicines? Who has responsibility for enforcement and how strictly are the rules enforced? Are there any important examples where action has been taken against pharmaceutical companies? To what extent may competitors take direct action through the courts?

Penalties may be pronounced against the company and the responsible pharmacist by ANSM and the Court. The criminal penalties (pronounced by a Court) depend on the infringement and may amount to a fine of EUR 150,000 for individuals and imprisonment of up to one year, and EUR 750,000 for companies.

Financial penalties may also be pronounced by ANSM up to EUR 150,000 (for individuals), and up to 30% of the company's turnover made on the product concerned, within the limit of EUR 1,000,000 (for companies).

Following a prohibition of advertising pronounced by ANSM, the CEPS may decide to sentence the infringing company to a fine, in an amount as high as 10% of the turnover without VAT made by the company with the considered product over the last 12 months preceding the discovery of the breach.

1.8 What is the relationship between any self-regulatory process and the supervisory and enforcement function of the competent authorities? Can and, in practice, do, the competent authorities investigate matters drawn to their attention that may constitute a breach of both the law and any relevant code and are already being assessed by any self-regulatory body? Do the authorities take up matters based on an adverse finding of any self-regulatory body?

There is a relationship between the CODEEM, a self-regulatory committee, and ANSM. Indeed, the CODEEM can be seized notably by ANSM for a potential reflection, expertise or work relating to an ethical question.

The suspension or a radiation decision must be published by the CODEEM. Therefore, ANSM can be aware of such sanctions.

However, the individual opinion issued from the CODEEM to a member is not published.

1.9 In addition to any action based specifically upon the rules relating to advertising, what actions, if any, can be taken on the basis of unfair competition? Who may bring such an action?

A competitor may sue the non-compliant company on the basis of unfair competition. The author of the unfair competition may be sentenced to indemnify the competitor for the loss of profit incurred due to the unfair competition practices, such as non-compliant advertising.

Companies claiming that unfair competition is made, may also request from the Court a ban on the advertising under emergency proceedings.

2 Providing Information Prior to Authorisation of Medicinal Product

2.1 To what extent is it possible to make information available to healthcare professionals about a medicine before that product is authorised? For example, may information on such medicines be discussed, or made available, at scientific meetings? Does it make a difference if the meeting is sponsored by the company responsible for the product? Is the position the same with regard to the provision of off-label information (i.e. information relating to indications and/or other product variants not authorised)?

Information about an unauthorised medicine may be available to HCPs provided that it is not promotional (for instance the information cannot be delivered by the salesforce) under the following circumstances:

- If the information is institutional (see question 6.5).
- In medical congresses with independent scientific committees or in meetings organised by scientific societies related to the advancement of a research, or in scientific congresses or meetings sponsored by a pharmaceutical company.

This position is the same with regard to the provision of off-label information.

2.2 May information on unauthorised medicines and/or off-label information be published? If so, in what circumstances?

In special editions medical press publishers may publish all or part of the research presented in medical congresses with independent scientific committees or in meetings organised by scientific societies.

If the special editions publish data of research which has not been validated by French authorities, they must include a warning about it on their first page.

Such publications cannot include advertising of unauthorised medicines that are referred to in the research.

The diffusion of such editions and the selection of the HCPs concerned by the subject are exclusively performed by the medical press publishers and should not be repeated.

2.3 Is it possible for companies to issue press releases about unauthorised medicines and/or off-label information? If so, what limitations apply?

Press releases may qualify as promotion so that such press releases on unauthorised products or off-label information must not be issued.

However, they can organise press conferences on important topics outside any promotional purposes. The conditions of the use of the press dossier related to such press conferences are specified in the Charter of information on medicine and editorial advertising issued by LEEM, SPEPS and UDA.

The companies may send chief editors of medical journals a press release on topics which do not justify a press conference.

2.4 May such information be sent to healthcare professionals by the company? If so, must the healthcare professional request the information?

Yes, if such information is included in correspondence, accompanied, as the case may be, by any non-promotional document, necessary to answer a specific question of a healthcare professional on a particular medicine.

2.5 How has the ECJ judgment in the *Ludwigs* case, Case C-143/06, permitting manufacturers of non-approved medicinal products (i.e. products without a marketing authorisation) to make available to pharmacists price lists for such products (for named-patient/ compassionate use purposes pursuant to Article 5 of the Directive), without this being treated as illegal advertising, been reflected in the legislation or practical guidance in your jurisdiction?

French law already provides that price catalogues and price lists are not considered as advertising provided that they do not include any promotional information on the medicine.

2.6 May information on unauthorised medicines or indications be sent to institutions to enable them to plan ahead in their budgets for products to be authorised in the future?

No, since this information would qualify as advertising.

2.7 Is it possible for companies to involve healthcare professionals in market research exercises concerning possible launch materials for medicinal products or indications as yet unauthorised? If so, what limitations apply? Has any guideline been issued on market research of medicinal products?

Yes, under the limitation that such market research exercises be non-promotional. There are no official guidelines issued on that subject.

3 Advertisements to Healthcare Professionals

3.1 What information must appear in advertisements directed to healthcare professionals?

All the information that must appear is referred to under Article R.5122-8 of PHC, notably the name of the product, the product's pharmaceutical form, the marketing authorisation number, the posology.

3.2 Are there any restrictions on the information that may appear in an advertisement? May an advertisement refer to studies not mentioned in the SmPC?

The information must be accurate, updated, verifiable and sufficiently exhaustive to enable HCPs to make their own judgments on the therapeutic value of the product.

Each chart, quotation or illustration taken from medical journals or scientific literature must be quoted faithfully. Their source must be precise. Any written mention thereof must be clearly legible.

The studies referred to must have been published in a peer-reviewed journal, and/or must have been realised in the conditions of use as defined under the marketing authorisation and other official references.

Non-published clinical studies may be referred to provided that they have been also utilised for the marketing authorisation request or for the opinion of the Transparency Commission (reimbursement of the product).

3.3 Are there any restrictions to the inclusion of endorsements by healthcare professionals in promotional materials?

The promotional message for a medicinal product, mainly based on results of an opinion survey, is prohibited. However, it may be allowed if such results are in line with the marketing authorisation, the opinion issued by the Transparency Commission and proper use of the product.

3.4 Is it a requirement that there be data from any, or a particular number of, "head to head" clinical trials before comparative claims may be made?

No; however, please see question 3.2, and since comparative advertisements are strictly regulated, please also see question 3.5.

3.5 What rules govern comparative advertisements? Is it possible to use another company's brand name as part of that comparison? Would it be possible to refer to a competitor's product or indication which had not yet been authorised in your jurisdiction?

Any comparative advertising may identify, implicitly or explicitly, a competitor. The advertisement must:

- not be misleading or likely to be misleading;
- relate to products fulfilling the same needs or having the same purpose;
- objectively compare one or more essential, pertinent, verifiable and representative characteristics of the products, one of which may be price, and must include efficiency and security of use criteria;
- present results faithfully and clearly. Sources must be accurately quoted and results must be able to be checked. The number of patients and the type of analysis must be specified;
- not take undue advantage of the reputation attached to a trademark, manufacturer's brand or service mark, to a trade name, to other distinctive marks of the competitor or to the designation of origin as well as the protected geographical indication of a competing product;
- not bring discredit or denigration of the marks, trade names, other distinctive signs, goods, services, activity or situation of the competitor;
- not create confusion between the advertiser and the competitor or between the advertiser's marks, trade names, other distinctive signs, goods or services and those of the competitor; and
- not present goods or services as an imitation or reproduction of goods or services benefiting from a protected mark or trade name.

If the advertisement refers to studies, see question 3.2.

3.6 What rules govern the distribution of scientific papers and/or proceedings of congresses to healthcare professionals?

If the information is made within a promotional scope, companies must obtain a visa and insert mandatory legal mentions on the promotional material.

3.7 Are "teaser" advertisements (i.e. advertisements that alert a reader to the fact that information on something new will follow, without specifying the nature of what will follow) permitted?

The teaser must be analysed on a case-by-case basis in order to determine whether it is considered as an advertisement in view of the information mentioned in it. The reference to the medicinal product could for instance qualify the teaser as promotional.

4 Gifts and Financial Incentives

4.1 Is it possible to provide healthcare professionals with samples of medicinal products? If so, what restrictions apply?

Samples of medicines may be supplied to HCPs who are qualified to prescribe or provide such medicines only in internal pharmacies of healthcare institutions on their written, dated and signed request.

The samples must be identical to the medicines and marked "free sample".

Such supply is permitted only during the first two years following the first marketing of the medicine in France, whether the product is new, or whether it has a new dosage or pharmaceutical form if there is an extension of the indication.

A maximum of four samples per recipient per year can be supplied; each sample being identical to the smallest packaging sold and supplied with a copy of the summary of product characteristics.

The company must organise a control and monitor such supply.

The supply is forbidden when made:

- by the sales force of the company; and
- in pharmacies other than the internal pharmacies of healthcare institutions.

Samples of narcotics or psychotropes may not be supplied.

4.2 Is it possible to give gifts or donations of money to healthcare professionals? If so, what restrictions apply?

No, this is forbidden. However, HCPs may receive gifts provided that they are of negligible value (less than EUR 30 excluding VAT in total per year and per beneficiary) and related to the professional practice of the beneficiary.

4.3 Is it possible to give gifts or donations of money to healthcare organisations such as hospitals? Is it possible to donate equipment, or to fund the cost of medical or technical services (such as the cost of a nurse, or the cost of laboratory analyses)? If so, what restrictions would apply?

This is always forbidden for private health institutions. Donations of money or in-kind advantages may be made to public healthcare institutions notably under the following restrictions:

- For donations only: be disinterested and justified by the company policy.
- In any case:
  - comply with the rules of public tenders;
  - ensure that they do not lead to favouritism and corruption;
  - comply with the rules of the MedTech Europe Code of Ethical Business Practice, dated December 2, 2015;
  - do not benefit directly or indirectly to HCPs exercising within the institution;
  - must be provided for in a contract; and
  - be made public on the transparency website by the companies.

4.4 Is it possible to provide medical or educational goods and services to healthcare professionals that could lead to changes in prescribing patterns? For example, would there be any objection to the provision of such goods or services if they could lead either to the expansion of the market for, or an increased market share for, the products of the provider of the goods or services?

Informational or educational goods may be provided to HCPs provided that they are directly related to the professional exercise of the beneficiary and intended for the direct care of the patients.

Items of medical utility may be provided to HCPs provided that they are directly intended for the education of the HCPs and the care of the patients and that they do not reduce the costs normally borne by the HCPs in their everyday practice.

Such goods and items must not be promotional.

4.5 Do the rules on advertising and inducements permit the offer of a volume-related discount to institutions purchasing medicinal products? If so, what types of arrangements are permitted?

Volumes-related discounts to public health institutions purchasing medicines are allowed provided that they comply with competition law, prohibiting notably illegal cartels and abuse of dominant position, and public tender rules.

Volumes-related discounts to private health institutions purchasing medicines are allowed provided that they comply with commercial law. In this connection, they must notably:

- be set out in the general terms and conditions for sales of any manufacturing company and communicated to the institution on his request. Such document must include the amount and conditions under which any buyer may benefit from the discount;
- appear on the invoice;
- not be applied retroactively;
- comply with competition law prohibiting notably illegal cartels and abuse of dominant position; and
- not constitute an act of unfair competition.

This does not apply to discounts for medicines and generic products to pharmacies which are strictly constrained by the law.

4.6 Is it possible to offer to provide, or to pay for, additional medical or technical services or equipment where this is contingent on the purchase of medicinal products? If so, what conditions would need to be observed?

Yes, it is possible under certain conditions.

For public health institutions, public tenders may authorise the proposal of associated services which are contingent to the purchase of medicinal products.

For private health institutions, additional services or equipment which are contingent to the purchase of medical products may be provided or paid for if they are part of commercial negotiations complying with commercial law.

4.7 Is it possible to offer a refund scheme if the product does not work? If so, what conditions would need to be observed? Does it make a difference whether the product is a prescription-only medicine, or an over-the-counter medicine?

No the offer of a refund scheme in such case would be considered as a promotional offer since it may qualify as an advantage to the patients, which is forbidden.

There is no difference between whether the product is a prescription-only medicine or an over-the counter medicine.

4.8 May pharmaceutical companies sponsor continuing medical education? If so, what rules apply?

Yes, companies may sponsor certain associations or learned societies or any other legal entity which offer continuing medical education provided notably that such sponsorship must not constitute a particular advantage to an HCP.

The sponsorship cannot be made to an association which represents members of HCPs or students intending to become an HCP.

In case of a sponsorship made to an association, the companies should notably check that its statutes allow such sponsorship.

5 Hospitality and Related Payments

5.1 What rules govern the offering of hospitality to healthcare professionals? Does it make a difference if the hospitality offered to those healthcare professionals will take place in another country and, in those circumstances, should the arrangements be approved by the company affiliate in the country where the healthcare professionals reside or the affiliate where the hospitality takes place? Is there a threshold applicable to the costs of hospitality or meals provided to a healthcare professional?

Hospitality may be offered to an HCP bound by the anti-gift legislation in the context of his/her attendance to a professional or scientific congress or other event, provided that (Article L.4113-6 of PHC):

- the event has an exclusively professional or scientific character;
- the hospitality is limited to the professional or scientific part of the event;
- the hospitality is reasonable, accessory, not extended to the HCPs' relatives;
- a submission file is sent to the relevant professional board, for prior opinion, one month before the event; and
- the company notifies to the professional board, the effective attendance of the HCP to the event, no later than one month after the event.

There is no difference between whether the event takes place in France or abroad, although the medical boards tend to consider that only events taking place in France should be offered.

The medical board has set the following threshold:

- for accommodation: EUR 300 (incl. VAT) including two meals;
- for meals: EUR 60 (incl. VAT); and
- for transport: 1st class train, flight in economy class.

5.2 Is it possible to pay for a healthcare professional in connection with attending a scientific meeting? If so, what may be paid for? Is it possible to pay for his expenses (travel, accommodation, enrolment fees)? Is it possible to pay him for his time?

Yes, it is possible provided, however, that the HCP provides services, such as being a speaker (please see question 5.4). In this connection, it would not be possible to pay him only for his attendance time.

For the payment of the expenses, see question 5.1.

5.3 To what extent will a pharmaceutical company be held responsible by the regulatory authorities for the contents of, and the hospitality arrangements for, scientific meetings, either meetings directly sponsored or organised by the company or independent meetings in respect of which a pharmaceutical company may provide sponsorship to individual healthcare professionals to attend?

The medical board does not have any power to sanction companies. However, the violation of such legislation may be criminally sanctioned:

- For individuals: a fine of up to EUR 75,000 and imprisonment of up to two years and a complementary penalty (temporary interdiction of exercising the profession).
- For companies: a fine of up to EUR 375,000 and complementary penalty (such as the ban to participate in public tenders).

5.4 Is it possible to pay healthcare professionals to provide expert services (e.g. participating in advisory boards)? If so, what restrictions apply?

Yes, if the following conditions are fulfilled:

- An agreement must be concluded between the HCP and the company.
- The services must be real.
- The payment is made at fair market value and is justified by the level of services.
- The agreement is submitted to the medical board for prior opinion.
- The payments must not be calculated on the basis of the number of products prescribed or sold by the HCP.
- The company notifies to the board if the agreement has eventually been implemented.

5.5 Is it possible to pay healthcare professionals to take part in post-marketing surveillance studies? What rules govern such studies?

Yes (see question 5.4).

5.6 Is it possible to pay healthcare professionals to take part in market research involving promotional materials?

Yes (see question 5.4).

6 Advertising to the General Public

6.1 Is it possible to advertise non-prescription medicines to the general public? If so, what restrictions apply?

Yes, if the medicine is not reimbursable by mandatory French social security system and if the marketing authorisation does not contain any prohibition or restrictions on advertising due to a possible risk to public health.

Advertising of a medicine under a temporary authorisation of use is forbidden.

The promotional character of the advertising must be obvious, the product must be clearly identified as a medicine, the advertising must contain, at least, the mandatory legal mentions (Article R. 5122-3 of PHC) and cannot include certain allegations (Article R. 5122-4 of PHC). Such advertising must be subject to ANSM's visa.

6.2 Is it possible to advertise prescription-only medicines to the general public? If so, what restrictions apply?

No. However, advertising campaigns for products presented as suppressing the desire to smoke or reducing tobacco addiction and for vaccines are possible.

The conditions for non-institutional campaigns for vaccines are specified under Articles L.5122-6 and L. 5122-8 of PHC.

6.3 If it is not possible to advertise prescription-only medicines to the general public, are disease awareness campaigns permitted encouraging those with a particular medical condition to consult their doctor, but mentioning no medicines? What restrictions apply?

Disease awareness campaigns are possible if they do not include any direct or indirect reference to a medicine.

This non-promotional information can refer, in a non-exclusive manner, to the available therapeutics, whether medicinal, surgical or not.

The therapeutic classes resulting from the ATC classification can be indicated if they do not include a single medicine.

The disease awareness campaigns must not be misleading, notably by encouraging an over diagnosis or an over treatment.

6.4 Is it possible to issue press releases concerning prescription-only medicines to non-scientific journals? If so, what conditions apply?

Yes, if such press release does not include any allegation, any cheerful description, any lyrical style or any promotion of a specific characteristic of the product (decision of Court of Appeal of Versailles of June 25, 2014 No. 14/03658).

6.5 What restrictions apply to describing products and research initiatives as background information in corporate brochures/Annual Reports?

Such information must have a scientific, technical or financial character and must not promote a medicine or a company's research development opportunities and fields.

The name of the medicine, the International Non-proprietary Names and the therapeutic class may be mentioned.

Any other information related to a medicine is promotional.

Any terms involving a hierarchy, such as "leader", etc., and qualifying a medicine can be used if it is specified to be linked to turnover, market share, quantity sold, etc. They must not be used if they are referring to a comparative assessment of therapeutic benefits.

The use of distinctive signs recalling the medicine may be requalified as advertising.

6.6 What, if any, rules apply to meetings with, and the funding of, patient organisations?

There are no specific rules on advertising that apply to patient organisations during meetings.

Such associations can receive funding from companies.

A written agreement must be concluded between the company and the patient association in case of funds procured to the latter by the company. This agreement must specify the amount of the funding, its purpose, and, if applicable, a description of any indirect significant funding.

The company must disclose on the transparency website the funds procured to any patient association.

6.7 May companies provide items to or for the benefit of patients? If so, are there any restrictions in relation to the type of items or the circumstances in which they may be supplied?

The direct supply of free medicine samples to patients for promotional purposes and their supply to publicly available premises at pharmaceutical or medical congresses is forbidden (Article L. 5122-10 of PHC).

Also, medicine advertising to the general public cannot include any objects or products or material advantages, which can be direct or indirect (Article R. 5122-4 of PHC).

7 Transparency and Disclosure

7.1 Is there an obligation for companies to disclose details of ongoing and/or completed clinical trials? If so, is this obligation set out in the legislation or in a self-regulatory code of practice? What information should be disclosed, and when and how?

Companies have to transmit information concerning clinical trials to ANSM which discloses such information on a national database unless the companies, as a sponsor, refuse the disclosure for legitimate reasons. Such database is made available on ANSM's website. The information to be disclosed on the database are notably the title of the clinical trial, its EudraCT number and a description of the clinical trial.

The sponsor must transmit the results of the study in the form of a report to ANSM, within one year following the end of the study, which will be disclosed on ANSM's website.

7.2 Is there a requirement in the legislation for companies to make publicly available information about transfers of value provided by them to healthcare professionals, healthcare organisations or patient organisations? If so, what companies are affected, what information should be disclosed, from what date and how?

Companies which manufacture or commercialise notably medicinal products, or provide services linked to such products must make information public, on the transparency website (for example, the name of the parties, the signature date, the purpose of the agreement) concerning all the agreements concluded with and the advantages (transport, accommodation, meal) procured notably to (Article L.1453-1 of PHC):

- HCPs;
- associations of HCPs;
- associations of patients; and
- healthcare institutions.

The information must be transmitted by the companies on the website within the following timeframes:

- for agreements: within 15 days after the execution of the agreement (this should be modified in the near future); and
- for advantages: no later than August 1 for advantages granted during the first half of the same year and no later than February 1 for advantages granted during the second half of the previous year.

The transparency legislation will evolve soon, and the companies will also have to publish the compensations paid to the above listed health operators.

7.3 Is there a requirement in your self-regulatory code for companies to make publicly available information about transfers of value provided by them to healthcare professionals, healthcare organisations or patient organisations? If so, what companies are affected, what information should be disclosed, from what date and how? Are companies obliged to disclose via a central platform?

The EFPIA disclosure code which requires the publication of the transfers of value provided to HCPs and healthcare organisations, applies to the LEEM as a member of EFPIA. Therefore, pharmaceutical companies, members of the LEEM, have to comply with the provisions of the EFPIA code.

The first disclosure will be made by June 30, 2016, for payments made in 2015.

7.4 What should a company do if an individual healthcare professional who has received transfers of value from that company, refuses to agree to the disclosure of one or more of such transfers?

The individual may not refuse it since this disclosure is a legal obligation.

8 The Internet

8.1 How is Internet advertising regulated? What rules apply? How successfully has this been controlled?

Internet advertising is regulated by the same advertising rules set out in PHC and by the Charter for the communication and the promotion of health products on the internet and the e-media issued by ANSM.

The website must notably indicate the identification of the operator, the intended recipients and the type of information provided.

It must be structured, present the website plan from the homepage and clearly separate the promotional pages from the non-promotional ones. Promotional webpages must clearly indicate that they are advertising, if their content is not obviously promotional.

Each promotional webpage must comply with the advertising rules set out in PHC, notably regarding the compulsory legal mentions and must have received a visa from ANSM.

The information must be regularly updated, the date of the last update must be specified and the information directed to foreign recipient must be identified as such.

ANSM controls advertising of medicinal products over the internet.

8.2 What, if any, level of website security is required to ensure that members of the general public do not have access to sites intended for healthcare professionals?

Real access restrictions to sites intended for HCPs must be implemented by companies, such as, the granting of a personal access code after a verification of the quality of such professional.

8.3 What rules apply to the content of independent websites that may be accessed by a link from a company-sponsored site? What rules apply to the reverse linking of independent websites to a company's website? Will the company be held responsible for the content of the independent site in either case?

Hypertext links are possible provided they do not aim at infringing the rules on advertising.

Such links which give access to the homepage of a website must be prioritised compared to those which give access to any other page. However, it is possible to have:

- for public official websites: a link to all pages;
- for peer-review websites: a link to the tables of content; and
- for congress websites: a link to the programme pages.

The change of websites must be clearly indicated by a message to the visitor or a new tab with a new page opened.

When appropriate, each website must have its own security system implemented to restrict the access to HCPs unless the company's website and the independent website have common content authentication services.

The company is responsible for the link on the first level it creates with the independent website.

8.4 What information may a pharmaceutical company place on its website that may be accessed by members of the public?

See question 6.1.

Information which is institutional, related to human health or human diseases, adverse-reaction warnings within a pharmacovigilance context, and price catalogues and price lists, may be accessed by members of the public as long as such information complies with PHC, the ANSM recommendations and the Charter.

General information on the pharmaceutical company's medicines may be accessed by the members of the public provided that it complies with the Charter.

8.5 Are there specific rules, laws or guidance, controlling the use of social media by companies?

Advertising of medicines to the general public, in the form of a "product" page, is not possible on open social networks unless the functions "comment" and "like" are deactivated.

The function "share" from a promotional page of a website to an open social network is also forbidden.

9 Developments in Pharmaceutical Advertising

9.1 What have been the significant developments in relation to the rules relating to pharmaceutical advertising in the last year?

There were not any significant developments in 2015, except the decree No. 2015-647 of June 10, 2015 relating to veterinary medicinal products.

9.2 Are any significant developments in the field of pharmaceutical advertising expected in the next year?

Law No. 2016-41 of January 26, 2016 of modernisation of our health care system provides that the Government may take through "order", within nine months after its entry into force (January 27, 2016), measures aiming at extending the prohibition of advertising on medicines which risk/benefit ratio are being revaluated, as provided for under article L.5122-3 PHC.

9.3 Are there any general practice or enforcement trends that have become apparent in your jurisdiction over the last year or so?

Pharmaceutical companies tend to be more and more careful about their competitors' promotional practices.

ANSM tends to do the same about pharmaceutical companies' promotional practices.

Acknowledgment

The authors would like to thank Anne-Sophie Margulis for her assistance in the preparation of this chapter. Anne-Sophie is a lawyer, admitted to the Paris Bar in 2015. She holds a post-graduate degree in Health Product and Health Industries Law (Master 2) at Paris Descartes University. She had several professional experiences in the pharmaceutical industry and notably in a UK law firm before joining LCH. She deals with both contentious and non-contentious matters for Life Sciences companies.

Email: anne-sophie.margulis@lcheurope.com.

Laure Le Calvé
LCH Law Compliance Health
13 boulevard Malesherbes
Paris 75008
France

Tel: +331 71 19 93 75
Email: laure.lecalve@lcheurope.com
URL: www.lcheurope.com

Laure Le Calvé co-founded LCH. She was admitted *magna cum laude* to the Paris Bar and has devoted herself to life sciences law for almost 20 years, advising health industry, food and cosmetics businesses both for their contract negotiation and litigation needs.

Laure Le Calvé participates in a number of working groups, including the Legal Affairs Focus Group (LAFG) of EUCOMED and the medical devices advertising group of AFAR (French regulatory affairs society). She is also a member of ACIDIM (a medical devices society). Laure is regularly invited to speak, both in France and abroad at conferences, in particular those organised by SNITEM and ADVAMED.

Johanna Benichou
LCH Law Compliance Health
13 boulevard Malesherbes
Paris 75008
France

Tel: +331 71 19 93 70
Email: johanna.benichou@lcheurope.com
URL: www.lcheurope.com

Johanna Benichou is a lawyer, admitted to the Paris Bar in 2014. She holds a post-graduate degree in Health Product and Health Industries Law (Master 2) at Paris Descartes University. She had several professional experiences in health industries and in law firms before joining LCH. She deals with both contentious and non-contentious matters for Life Sciences companies.

LCH
AVOCATS - PARIS

LCH law firm is a boutique founded by Laure Le Calvé. Our team of lawyers is entirely dedicated to health law and life sciences.

We advise a large number of health stakeholders: pharmaceutical companies, medical device manufacturers, manufacturers of in vitro diagnostic medical devices, cosmetics companies, agro-food industry, CROs, approved healthcare data hosts, healthcare marketing agencies, professional trade unions, health authorities, healthcare professionals, healthcare institutions and insurance companies.

Our clients include a wide range of businesses: from newly created companies to large listed companies, French as well as international businesses.

We also provide tailored training sessions on demand for your teams regarding key legal concerns of your industry.

We have both the ability and the expertise to assist you in your development in France and in your international projects.

Current titles in the ICLG series include:

- Alternative Investment Funds
- Aviation Law
- Business Crime
- Cartels & Leniency
- Class & Group Actions
- Competition Litigation
- Construction & Engineering Law
- Copyright
- Corporate Governance
- Corporate Immigration
- Corporate Recovery & Insolvency
- Corporate Tax
- Data Protection
- Employment & Labour Law
- Enforcement of Foreign Judgments
- Environment & Climate Change Law
- Franchise
- Gambling
- Insurance & Reinsurance
- International Arbitration
- Lending & Secured Finance
- Litigation & Dispute Resolution
- Merger Control
- Mergers & Acquisitions
- Mining Law
- Oil & Gas Regulation
- Patents
- Pharmaceutical Advertising
- Private Client
- Private Equity
- Product Liability
- Project Finance
- Public Procurement
- Real Estate
- Securitisation
- Shipping Law
- Telecoms, Media & Internet
- Trade Marks

glg global legal group

59 Tanner Street, London SE1 3PL, United Kingdom
Tel: +44 20 7367 0720 / Fax: +44 20 7407 5255
Email: sales@glgroup.co.uk

www.iclg.co.uk