

ICLG

The International Comparative Legal Guide to:

Pharmaceutical Advertising 2014

11th Edition

A practical cross-border insight into pharmaceutical advertising

Published by Global Legal Group, with contributions from:

A. Lopes Muniz Advogados Associados

Adams & Adams

Advokatfirmaet Grette DA

Arnold & Porter LLP

Arthur Cox

Biolato Longo Ridola & Mori

Boga & Associates

Clayton Utz

Clifford Chance

CMS Cameron McKenna

CMS, Russia

Debarliev, Dameski & Kelesoska Attorneys at Law

Edwards Wildman Palmer LLP

Faus & Moliner

Herbst Kinsky Rechtsanwälte GmbH

Hwang Mok Park P.C.

Jones Day

Jusmedico Advokatanpartsselskab

Life Sciences Legal Advocaten

Mannheimer Swartling Advokatbyrå

Mehmet Gün & Partners

Nishimura & Asahi

OLIVARES

PDG Avocats

Roschier, Attorneys Ltd.

Schellenberg Wittmer Ltd

Sołtysiński Kawecki & Szlęzak

Subramaniam & Associates (SNA)

Tilleke & Gibbins

Van Innis & Delarue

Vieira de Almeida & Associados

GLG

Global Legal Group

Contributing Editor

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

Account Managers

Assel Ashirbayeva,
Edmond Atta, Beth Bassett,
Antony Dine, Dror Levy,
Maria Lopez, Florjan
Osmani, Paul Regan,
Gordon Sambrooks,
Oliver Smith, Rory Smith

Sales Support Manager

Toni Wyatt

Sub Editors

Nicholas Catlin
Amy Hirst

Editors

Beatriz Arroyo
Gemma Bridge

Senior Editor

Suzie Kidd

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

Information Press Ltd
June 2014

Copyright © 2014

Global Legal Group Ltd.

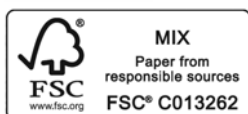
All rights reserved

No photocopying

ISBN 978-1-910083-03-1

ISSN 1743-3363

Strategic Partners



Preface:

■ Preface by Tom Spencer, Senior Counsel, GlaxoSmithKline Plc.

General Chapter:

1 **Social Media and the Pharmaceutical Industry: Managing the Risks** – Jackie Mulryne & Abraham Gitterman,
Arnold & Porter (UK) LLP and Arnold & Porter LLP 1

Country Question and Answer Chapters:

2	Albania	Boga & Associates: Ened Topi & Elona Xhepa	7
3	Australia	Clayton Utz: Colin Loveday & Greg Williams	13
4	Austria	Herbst Kinsky Rechtsanwälte GmbH: Dr. Sonja Hebenstreit & Dr. Isabel Funk-Leisch	25
5	Belgium	Van Innis & Delarue: Dieter Delarue & Heidi Waem	37
6	Brazil	A. Lopes Muniz Advogados Associados: Marcos Lobo de Freitas Levy & Mariana Carneiro Lopes Muniz	48
7	Bulgaria	CMS Cameron McKenna: David Butts & Angelika Dimitrova	56
8	China	Jones Day: Chiang Ling Li & Haifeng Huang	67
9	Czech Republic	CMS Cameron McKenna: Tomáš Matějovský & Radka Lörcincová	77
10	Denmark	Jusmedico Advokatanpartsselskab: Jan Bjerrum Bach & Lone Hertz	86
11	England & Wales	Arnold & Porter (UK) LLP: Silvia Valverde & Ewan Townsend	100
12	Finland	Roschier, Attorneys Ltd.: Mikael Segercrantz & Johanna Lilja	113
13	France	PDG Avocats: Paule Drouault-Gardrat & Juliette Peterka	123
14	Germany	Clifford Chance: Dr. Peter Dieners & Marc Oeben	130
15	Hungary	CMS Cameron McKenna: Dóra Petrányi & Miriam Fuchs	143
16	India	Subramaniam & Associates (SNA): Hari Subramaniam & Aditi Subramaniam	153
17	Ireland	Arthur Cox: Colin Kavanagh & Maebh O’Gorman	163
18	Italy	Biolato Longo Ridola & Mori: Linda Longo & Andrea Moretti	173
19	Japan	Nishimura & Asahi: Somuku Iimura & Yoko Kasai	185
20	Korea	Hwang Mok Park P.C.: Colin Nam & Jong Bae Shin	194
21	Kosovo	Boga & Associates: Sabina Lalaj & Besarta Kllokoqi	202
22	Macedonia	Debarliev, Dameski & Kelesoska Attorneys at Law: Elena Miceva & Emilija Kelesoska Sholjakovska	209
23	Mexico	OLIVARES: Alejandro Luna Fandiño & Erwin Cruz	216
24	Netherlands	Life Sciences Legal Advocaten: <i>mr. ir.</i> Anke E. Heezius	226
25	Norway	Advokatfirmaet Grette DA: Felix Reimers & Erik Helstad	234
26	Poland	Sołtysiński Kawecki & Szlęzak: Dr. Ewa Skrzydło-Tefelska & Katarzyna Bieliszczuk	245
27	Portugal	Vieira de Almeida & Associados: Paulo Pinheiro & Francisca Paulouro	253
28	Romania	CMS Cameron McKenna: Valentina Parvu & Ioana Barbu	263
29	Russia	CMS, Russia: Vsevolod Tyupa	275
30	South Africa	Adams & Adams: Alexis Apostolidis & Pieter Visagie	283
31	Spain	Faus & Moliner: Jordi Faus & Carmela Losada	293
32	Sweden	Mannheimer Swartling Advokatbyrå: Helén Waxberg & Sofia Tot	304
33	Switzerland	Schellenberg Wittmer Ltd: Andrea Mondini & Christine Beusch-Liggenstorfer	314
34	Turkey	Mehmet Gün & Partners: Özge Atılğan Karakulak & Ceren Aral	327
35	USA	Edwards Wildman Palmer LLP: Sharon Blinkoff & Kayla Tabela	337
36	Vietnam	Tilleke & Gibbins: Tu Ngoc Trinh & Tu Thanh Pham	345

Further copies of this book and others in the series can be ordered from the publisher. Please call +44 20 7367 0720

Disclaimer

This publication is for general information purposes only. It does not purport to provide comprehensive full legal or other advice. Global Legal Group Ltd. and the contributors accept no responsibility for losses that may arise from reliance upon information contained in this publication. This publication is intended to give an indication of legal issues upon which you may need advice. Full legal advice should be taken from a qualified professional when dealing with specific situations.

Italy

Linda Longo



Andrea Moretti



Biolato Longo Ridola & Mori

1 General - Medicinal Products

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

Advertising of medicinal products is governed by Sections 113-128 of Legislative Decree 24th April 2006, No. 219 (“the Decree”) which has implemented in Italy Directive 2001/83/EC (and subsequent modifications) on the Community Code of medicinal products for human use and Directive 2003/94/EC. Other relevant provisions on advertising of medicinal products are set out in Legislative Decree 229/99 regarding continued medical education (“CME”) principles, and Legislative Decree 206/2005 (“Unified consumers’ Code”), as amended by the Legislative Decree 145/2007 on unfair and comparative advertising, implementing Directive 2006/114/EC (“Unified Code on misleading and comparative advertising”).

The Code of Professional Conduct issued by “Farmindustria”, the Italian association of pharmaceutical industries, contains several provisions dealing with the advertising and promotion of medicinal products. The Code is frequently updated, with the last update dated 26th February 2014 implementing in Italy the Transparency and Disclosure obligation contained in the 2013 version of the EFPIA Code (see section 7 below). The rules of the Code have no legal force and are binding only for the members of the association.

1.2 How is “advertising” defined?

Advertising of medicinal products is defined by Section 113 of the Decree, which mirrors article 86 of the Community Code as “*any activity of information, canvassing customers or inducement carried out to promote the prescription, supply, sale or consumption of medicinal products*”.

The Decree, as the Community Code, distinguishes between advertising to the general public and advertising to healthcare professionals (under the Italian rules, this term includes only the professionals who are authorised to prescribe or administer the products).

Any scientific information provided directly or indirectly by pharmaceutical companies (*inter alia* supply of samples, sponsorship of meetings and events, as well as activity of sales representatives) is considered as advertising to healthcare professionals and should be carried out in accordance with the provisions set forth in the Decree.

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?

According to Section 126 of the Decree, each company owner of a marketing authorisation (“MA”) for a medicinal product should establish a “scientific service” within its organisation to be directed by a person who graduated in medicine or in pharmacy.

The scientific department must be independent from the marketing department and its duty is to ensure that the advertising on medicinal products is carried out in compliance with the provisions of the Decree. When the MA is owned by a foreign company, the scientific service must be established within the company representing the MA owner in Italy or within the importer or the distributor or its medicines.

The Italian law does not require a “sign off” procedure for the approval of promotional material, but the Code of Professional Conduct of the Italian pharmaceutical industry association (“Farmindustria”) requires that each member company shall produce by 28th February a certification by an accredited certification entity attesting the compliance with the procedures governing marketing and scientific information activities in the preceding year. Such procedures may include a “sign off” of promotional material to attest its compliance and scientific accuracy.

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?

There are no legal requirements for pharmaceutical companies to have SOP governing advertising activities, but compliance with specific advertising SOPs are required by the Farmindustria Code because in order to get the certification by the accredited entity (see the answer to question 1.3 above), the member companies of Farmindustria should be audited and should give evidence during the audit to comply with the SOPs and guidelines issued by Farmindustria. A simplified procedure of certification can be applied for pharma companies belonging to the Small Industry Committee.

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?

According to the Italian system, both advertising messages to the general public and information provided to healthcare professionals are subject to the prior approval of the Italian regulatory authority.

- Advertising to the general public is subject to several restrictions and is admitted only in respect to over-the-counter medicinal products (“OTC”). Any advertising message addressed to the general public (other than the mere reproduction of the product and the full text of the indications, counter-indications, special notices for its use, interactions, etc.) must be approved by the Italian Ministry of Health after having heard a special Experts’ Commission, the duties and composition of which are regulated by Presidential Decree 86/2007 and Decree of the Ministry of Health of the 12 November 2011. Advertising messages are considered approved if an express denial is not issued by the Italian Ministry of Health within 45 days from the date of the application (“tacit approval”). The opinion of the special Experts’ Commission is not necessary when the advertising is to be published in the press or broadcast by radio and has been approved by an authorised industry body duly recognised by the Ministry of Health. Television advertising of medicines is always subject to the Experts’ Commission’s opinion.
- Advertising to healthcare professionals is subject to a 10-day negative clearance system. Any advertising messages, documents or scientific material, including promotional gadgets (*i.a.* pens, block-notes, calendars, key-USB, etc.), which the companies wish to provide to healthcare professionals, other than the mere reproduction of the Summary of Products Characteristics (“SPC”), must be previously submitted to the Italian Medicines Agency (“AIFA”) and cannot be utilised before the elapse of 10 days after the date of submission.

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?

In the event that the Italian regulatory authorities consider that an advertisement is issued in breach of the rules governing advertisement of medicinal products, the regulatory authority has the power to order such advertising to stop immediately and to impose the publication of a rectification message, in compliance with the conditions provided by the same authority or upon request of the relevant professional orders or in consultation with the National Health Council.

The right to appeal the order of the Italian authority is subject to the general rules of appealing orders issued by public administration, which may vary from a simple recourse to the same authority who issued the appealed order to a jurisdictional recourse to the Regional Administrative Court (“*Tribunale Amministrativo Regionale*” – “*TAR*”).

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?

The penalties imposed in Italy for infringement of the provisions regarding prior approval of advertising have been converted from criminal sanctions into administrative fines:

- In case of infringement of the rules provided in respect of advertising to the general public, a pecuniary administrative sanction of an amount ranging from €2,600.00 to €15,600.00 in accordance with Section 148.15 of the Decree, is inflicted on the offenders.
- In case of infringement of the rules regarding advertising to healthcare professionals, the same administrative sanction provided for breach of the provisions on advertising to the general public shall apply (see Section 148.18 of the Decree). The Italian Medicines Agency, if the case may be, can take the measures described under question 1.6 above to rectify the unlawful message.

Furthermore, when the product in respect to which the unlawful advertising has been committed is included in the list of reimbursable products, the Medicines Agency may also set the suspension from reimbursement for a period from 10 days to two years, depending on the seriousness of the irregularity (see Section 148.19 of the Decree).

Normally, in the case of alleged infringement, the regulatory authority can request that the pharmaceutical company discontinue the unlawful conduct.

The decisions taken by the Italian Medicines Agency and the MOH regarding infringements of the advertising rules set forth in the Decree are not published; however since 2010 a yearly report on the Advertising to HcPs is published by the AIFA. Such report outlines the activity carried out by the Agency and the main irregularities of the advertising materials submitted to the AIFA: it contains interesting guidance on the correct contents of advertising material to HcPs. Normally the Italian Antitrust Authority (“*Autorità Garante della Concorrenza e del Mercato*”) does not take actions in respect to the unfair or illegal advertising of medicinal products because there is a specific competence of the Italian Regulatory Authority.

Infringements of advertising rules may also cause sanctions to the members of Farmindustria, which may vary from a formal warning to discontinue the conduct to the exclusion from the association with application of a pecuniary sanction of no more than €200,000.00.

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?

The only relationship between self-regulatory bodies and the competent authority regarding advertising of medicinal products is set forth in Section 118.6 lett. b) of the Code, pursuant to which if the advertising message of OTC products is approved by a recognised self-regulatory body of the most important association

of advertisers, it is possible to avoid the approval of the special Experts' Commission of the Ministry of Health; in such case, the approval of the self-regulatory body replaces that of the Experts' Commission.

In respect of the self-regulatory body of Farindustria, there is no relationship or interference between the investigation or findings of the self-regulatory body and the activity of the Ministry of Health/Italian Medicines Agency, even if the rules applicable to advertising set forth in the Farindustria Code of Professional Conduct are often similar to the rules set forth in the Code.

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?

Violation of the rules set forth in the Decree may also constitute an act of unfair competition, although, according to court precedents, there is no coincidence between an act which is prohibited pursuant to the Decree and an act of unfair competition. Control on the regularity of advertising carried out by pharmaceutical companies is often exercised by competitors who may take action both by informing the AIFA and/or the industry association (when its members are involved) of the diffusion by a competitor of an irregular advertising message, or by taking legal action before the civil court when the contents of the advertising or the behaviour of the competitor is such as to constitute unfair competition.

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)?

Section 114.1 of the Decree provides that advertising of medicinal products may relate only to products for which the marketing authorisation has been issued, either in accordance with the national procedure or under the centralised EMA procedure. The prohibition, which reflects the provision of the Community Code, is also contained in the Farindustria Code of Professional Conduct.

The prohibition of advertising of an unlicensed product cannot be interpreted in such a restrictive manner as to conflict with the principles set forth in the Italian Constitution regarding the development of culture and of scientific and technical research, as well as the freedom to express, verbally or in writing, his own opinion, and the liberty of the press. Therefore, at scientific meetings, it is possible for independent speakers belonging to the scientific community to provide information regarding new active ingredients or new off-label indications, and to discuss recent developments of clinical trials regarding unlicensed products, or indications. In such a case, however, the reference to the product is generally made to the active ingredient only. Furthermore, upon specific request of healthcare professionals, it is possible to provide information or copies of reports of scientific studies of a product not yet authorised in Italy, but authorised abroad (see question 2.4 below).

For the sake of completion it should be added that off-label use of pharmaceutical products is currently at the centre of great debate in Italy, and new rules have been issued after a recent decision by the Italian Antitrust Authority ("Agcm") in the case *Roche-Novartis/Farmaci Avastin e Lucentis*.

Agcm fined Roche and Novartis for over €180 million on the grounds that they had created a cartel for the sale of two drugs, Avastin and Lucentis. According to the decision of the authority, the two pharma companies put in place a "complex collusive strategy" in order to exclude from the market the cheaper drug, Avastin (used off-label in the ophthalmic field), so to "channel demand towards the much more expensive drug Lucentis". It is quite interesting to note that in the *Avastin/Lucentis* case the promotional action of the holder of the product used off-label was addressed to prevent the sale for off-label use in order to favour (according to Agcm) the more expensive drug specifically approved for ophthalmic use.

The new rules (Law Decree 36/2014 is still to be converted into Law) try to balance the private and public interest in a delicate matter such as the off-label use of drugs and the right of the holder of the MA to decide on the registration of its therapeutic indications. In Italy off-label use is admitted and reimbursed by the NHS only when there are no approved therapeutic alternative drugs.

2.2 May information on unauthorised medicines be published? If so, in what circumstances?

Information regarding clinical trials carried out in respect of an unlicensed medicinal product can be published in the scientific press or when the information has an interest for the general public (for instance, when it concerns a significant development in an area/disease of general interest). The information can also be published in the lay press, provided that the commercial name or trademark of the product is not mentioned. The Decree provides that at "International" congresses, the distribution, in the original language, of information material complying with the marketing authorisation issued in the foreign country is permitted, provided that healthcare professionals of such foreign country are attending the meeting. See also the answer to question 3.6 below.

2.3 Is it possible for companies to issue press releases about medicinal products which are not yet authorised? If so, what limitations apply?

According to the Decree, it is prohibited to mention in the lay press, television and radio broadcasting the name of a medicinal product when such reference may favour the use of the product. No regulatory provisions or guidelines in the Code address the issue of "press releases"; it is common practice, however, to consider press releases permitted when they are related to a potential important development for the company's business, do not contain the commercial name of the new product and when they specify that the product is not yet licensed in Italy. It is important that the message provides financial and scientific information to the market and does not have a mere promotional nature.

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

As indicated above, all information distributed to healthcare professionals must be previously submitted to the Italian regulatory authority and may be utilised only after the elapse of 10 days after

the filing with the AIFA. Information regarding an unlicensed medicinal product will not be approved by the AIFA; therefore, distribution by the initiative of the pharmaceutical company is not possible.

For unlicensed indications, it is permitted to provide healthcare professionals with information such as reprints of scientific articles concerning clinical trials. This information will also be subject to the prior control of the Italian Medicines Authority, which may or may not approve the contents.

When healthcare professionals specifically request the information, nothing prevents the company from supplying the same, provided that the information is not rendered under an advertising form and is limited to what is required to reply to the enquiry. The provision of this information, consistent with article 86.2 of the Community Code, cannot be construed as advertising.

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 Italy?

The *Ludwigs* case had no impact on the Italian legislation or practical guidance. In Italy non-approved medicinal products can be imported upon submission by the prescribing physician of a request of authorisation to the regulatory authorities. The pharmacies are not involved in this process and in the Decree there are no rules comparable to those of the “*Arzneimittelgesetz*” (“AMG”) in respect to which the ECJ issued the decision.

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?

There are no specific rules or guidelines dealing with this issue; according to the general principles, this kind of information can be provided only upon request of the institutions. Since the pricing of reimbursable products in Italy is fixed by the regulatory authority in accordance with a “price and reimbursement negotiation procedure” which takes place after the issue of the marketing authorisation, it is unlikely that, in Italy, such information would be provided/requested at such an early stage.

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

A general rule on collaboration between healthcare professionals and pharmaceutical companies has been introduced in the 2011 version of the Farindustria Code of Professional Conduct (section 4.1) and it is therefore applicable to the relationship with a healthcare professional. According to such rule, pharmaceutical companies may collaborate with healthcare professionals for consultancy services (such as speakers at congresses, participation at observational studies, training and educational services) provided, however, that the following criteria are fully complied with: i) the agreement with the healthcare professional is in written form; ii) the healthcare professional must undertake to disclose his

relationship with the pharmaceutical company whenever he speaks or writes in public on a subject which is part of the consultancy agreement; iii) any compensation paid to the healthcare professional for such consultancy must be reasonable and appropriate, taking into account the “market value” of the services rendered; and iv) the company must keep the documentation on the consultancy agreement for a period of at least three years and the decision on such initiatives are to be taken at the higher executive management level of the company.

Moreover, when the healthcare professional is a full-time employee of a public body (such as a public university or hospital), the prior consent of the employer is also required.

In respect of involvement of the healthcare professionals in market research, if no compensation is provided and the number of healthcare professionals involved is very large, it is possible that the “market research” be regarded as a promotional campaign on an unauthorised drug; in this case it is important to check the contents of the market research and who will collect the information (an independent market research company or sales representatives).

There are no guidelines or instructions issued by the Italian regulatory authority on this specific topic.

3 Advertisements to Healthcare Professionals

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

The Decree provides that any advertising of medicinal products to professionals qualified to prescribe or supply medicinal products must always include the information contained in the “SPC” and specify the classification for the purpose of the supply. An exception to the above rule is set forth in article 119.4 of the Decree, according to which it is possible to publish an advertisement (normally in the specialised medical press) containing only the name of the product with the scientific name of its active ingredient/s and, as the case may be, the name of the marketing authorisation holder and of the distributor.

In respect to the contents of advertising messages addressed to healthcare professionals, the Decree substantially mirrors the provisions of the Community Code, requiring that all information contained in the documentation to be supplied to healthcare professionals must be up-to-date, verifiable and sufficiently complete to enable the receiver to form his own opinion. Quotations isolated from the text from which they are excerpted are not allowed when they appear partial.

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

The Code of Professional Conduct of Farindustria provides that the information content of any advertising message of medicinal products must always be documented and documentable. Exaggerated statements, universal and exaggerated claims and indemonstrable comparisons without any objective basis are inadmissible. Apart from ministerial authorisations, no comprehensive statements are admissible, such as “the preferred drug”, “absolutely innocuous”, “fully tolerated” or similar, and no categorical assertions must be made stating that a product has no collateral effects or toxicity risk. Both the Decree and the Code of Professional Conduct provide that scientific citations must accurately

portray the meaning intended by the author(s). The texts, tables and other illustrations taken from medical reviews or scientific works must be reproduced faithfully and in full, and with an exact indication of the source. No citations are admissible that appear partial and/or contradictory with respect to the author's intentions when separated from the context in which they originally appeared.

If the information regarding the studies is contained in medical reviews and scientific articles, it is possible to include such information in the advertising material, provided that it is faithfully and fully reproduced and that the text is filed with the AIFA at least 10 days before the dissemination.

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

Healthcare professionals cannot personally endorse the products, because such behaviour would be in conflict with their Code of Ethics. Endorsement of healthcare professionals or scientists is specifically prohibited for advertising of medicines to the general public.

If a favourable opinion is contained in a scientific article, it is possible to entirely reproduce such article and utilise it as advertising material in compliance with the requirements set forth in the Decree (see question 3.2 above).

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 are made?

The Farindustria Code of Professional Conduct (see question 2.2 above) prohibits comparisons which cannot be demonstrated and those without a clear, objective basis. There is no published guidance in Italy on the number of head-to-head studies or patients required in a trial for such an objective comparison to be made.

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 which had not yet been authorised in Italy?

Comparative advertisement is governed by Legislative Decree 206/2005, as amended by Legislative Decree 145/2007 on unfair and comparative advertising, implementing Directive 2006/114/EC. No specific rules relating to comparative advertising of medicinal products are contained in the Decree or in the Farindustria Code of Professional Conduct, therefore the general principles contained in the unfair advertising Law, as well as in the Decree, shall apply.

In practice, in respect to ethical products, the use of another company's brand name is permitted when comparative clinical trials are carried out in order to prove the efficacy of the products. Furthermore, comparative advertisement is also permitted to outline the different price as compared to a competing product.

The use of comparative advertising with respect to advertising of medicines to the general public is prohibited by the Decree (article 117).

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

Distribution of scientific papers and/or proceedings of congresses to

healthcare professionals are permitted subject to prior submission to the Italian Medicines Agency ("AIFA"), pursuant to the 10-day negative clearance system described in question 1.5 above.

In 2010, the AIFA issued two Circular letters on this subject, clarifying that in respect to international conferences only, pharmaceutical companies can disseminate information material in accordance with the marketing authorisation in force in other countries. Information material is defined as follows: a summary of product characteristics authorised in other EU countries; congressional records; and scientific papers, provided they are complete and have been submitted to the AIFA. When the medicinal product is not authorised in Italy, the material should visibly contain wording that the product (or the new therapeutic indication) is not authorised in Italy.

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

No rules in respect to "teaser" advertising are contained in the Decree and in the Farindustria Code of Professional Conduct. This kind of advertising, however, does not comply with the general principle of transparency of advertising messages and, therefore, it is not used in Italy to promote medicinal products.

4 Gifts and Financial Incentives

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

Provision of samples of products to healthcare professionals is regulated by Section 125 of the Decree.

Free samples can be provided only to healthcare professionals authorised to prescribe the product and samples can be supplied by the sales representatives of the company only in response to a written request signed and dated from the recipient. The unsolicited provision of samples is not allowed in Italy. The pharmaceutical company must keep evidence of such requests for an 18-month period.

Free samples can be provided to healthcare professionals in the following limited numbers:

- eight samples per year (maximum two per visit) during the first 18 months after the launch of the product; and
- 10 samples per year (maximum four per visit) for products on the market for more than 18 months.

Provision of samples is also regulated by Section 2.17, introduced in the 2011 version of the Farindustria Code of Professional Conduct, which mainly reflects the above-mentioned provision except for the number of products that can be provided; the Decree provides the maximum of eight samples per year during the first 18 months from the placing in the market of the product, whilst the Code, to comply with the new EFPIA Code, restricts the eight samples in total for the first 18 months.

Samples of products containing psychotropic or narcotic substances cannot be supplied to healthcare professionals.

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

According to article 123 of the Decree, the offer or promise of gifts of pecuniary or other kinds of advantages to healthcare

professionals or pharmacists in connection with the promotion of medicinal products is prohibited, unless they are of “negligible value” and they are relevant to the practice of the healthcare professional. In addition, practitioners must not solicit or accept any such prohibited gifts.

Such prohibition is also confirmed in article 2.13 of the Code of Professional Conduct, which refers to gifts “perceived” as having negligible value.

The Decree does not contain a criteria/amount to consider a gift of “negligible value” established. The Guidelines of “regional regulation on scientific information relating to medicinal products approved on the 20th April 2006 by the Conference of the Presidents of the Italian Region” and several regional regulations of the activity of scientific information provide for a limit of €20 per year per professional. The Decree of the Ministry of Health on the 14th April 2008 expressly permitted the gifts of scientific publications and books, registration to medical and scientific online newsletters, CDs, DVDs or a password for access to a website of scientific contents which has a higher value to the operative departments of public hospitals/public health structures and healthcare professionals belonging to such structures.

The Farindustria Code of Professional Conduct, in order to increase control on gift distribution, provides that all gifts must be purchased and distributed by the main office of the pharmaceutical company. The Code also introduced the amount of €25 as the limit for a gift to be considered of “negligible value”. Scientific material exceeding such value must be donated to the institution to which the healthcare professional belongs (article 2.14 – see question 4.4 below). This provision is stricter than the regulation of the above-referred Decree.

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?

It is common practice in Italy for pharmaceutical companies to give gifts or study grants to public hospitals or universities. The procedures for acceptance of donations and grants are regulated by the by-laws/statutes of the public entity (or by guidelines issued by the competent region) and the company must strictly comply with such procedures.

Also, donations of equipment or contracts providing the free use of equipment are possible, but in order to avoid abuse (such as donations made in order to promote the sale of spare parts or of medical devices necessary for the regular functioning of the equipment), strict limitations have been introduced as to the terms and conditions for acceptance by the public entity of such gifts. Direct funding of the costs or donations of money is generally not admitted by the statutes of the public bodies.

The Code of Professional Conduct permits this kind of grant, provided that they are always properly documented in writing and the decision is taken at a central level. A rule of the Code of Professional Conduct provides that supply of equipment necessary to conduct observational studies free of charge must be limited to the period necessary to conduct the clinical trial; supply of hardware such as tablets and portable computers to healthcare professionals for the conduct of observational studies is not permitted.

According to the Code of Professional Conduct, it is not possible to sponsor, either directly or indirectly, organisations which have no national or international scientific standing.

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?

Section 123.2 of the Decree provides that any scientific education or work material not specifically related to the medicinal product can be offered free of charge only to the public health structures. A Decree of the Ministry of Health also permits the supply, free of charge, of certain educational material to a healthcare professional directly. In principle, there is no prohibition to accept a good that could lead to changes to prescribing patterns, provided that the donation of the good is not specifically linked or contingent to the purchase of medicinal products or increases in the volume of purchase.

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?

The purchase of medicinal products by institutions belonging to the National Health System normally takes place through tender procedures, in compliance with the public procurement regulations.

When the invitation to tender provides the possibility to offer discounts linked to the volume of products, it is possible for the company to offer these discounts; such offer, however, can be made only during the tender procedure and discounts applied thereafter are not admitted. When the negotiated procedure is followed, there is more flexibility for negotiation of discounts and it is possible to enter into supply agreements which provide for volume-related discounts. In such case, it is necessary to comply with the competition rules (retrospective discounts to be calculated for a maximum of three months and paid at the end of the period).

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?

As described in questions 4.3 and 4.4 above, this kind of arrangement is not permitted in order to avoid any abuse.

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?

The following are the schemes introduced by the AIFA during the negotiations for the price and reimbursement of expensive prescription-only medicines:

- Cost Sharing: special discount applied to the initial cycles of therapy for all eligible patients.
- Risk Sharing: special discount applied to the initial cycles for non-responder patients after the first re-evaluation.
- Payment by Results: total refund applied to the initial cycles for non-responder patients after the first re-evaluation.

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

Pharmaceutical companies may partially or totally sponsor CME events provided, however, that CME events are organised by an “accredited provider” who has the sole responsibility for the scientific content of the programme and the selection of the speakers. The sponsor, therefore, cannot address the agenda and/or the topics of the events, select speakers and moderators and recruit participants (i.e. direct invitation) besides the following provided limit. In fact, the direct invitation of healthcare professionals by a sponsor to attend to CME events is allowed up to the limit of 33% of the required CME credits per each professional (on a three-years basis). The economic relationship between the CME provider and the sponsor must be evidenced in writing by means of a sponsorship agreement in which all the grants and the payments must be disclosed.

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? Is there a threshold applicable to the costs of hospitality or meals provided to a healthcare professional?

Hospitality to healthcare professionals is regulated by Section 124 of the Decree, which deals with hospitality to healthcare professionals in connection with attendance at congresses and meetings.

The offer of hospitality to healthcare professionals in connection with attendance at meetings is considered a sponsorship of the meeting and, as such, is subject to a prior authorisation of the AIFA. In order to obtain the authorisation, an application containing, *inter alia*, the details of the expenses is to be submitted 60 days before the day of the meeting by the pharmaceutical company to the AIFA, which shall issue its approval after 45 days from receipt of the application. The authorisation procedure is carried out through the AIFA website and to this purpose pharmaceutical companies are to be registered in the relevant database established within the Medicines Agency. The local governments of the place where the event will be held (regions and autonomous provinces) are also involved in the authorisation process.

Contribution to an event and offers of hospitality are subject to several restrictions and limitations (see question 5.2 below) which are also applicable to events being held abroad.

The provisions of the Farmindustria Code of Professional Conduct dealing with congresses and hospitality offered to healthcare professionals substantially reflect those of the Decree, provided, however, that there are more strict limitations regarding the offer of hospitality. According to the Code, hospitality can also be offered in connection with visits to manufacturing/research premises of pharmaceutical companies for technical reasons but are subject to strict timing limitations.

Strict rules on hospitality to healthcare professionals in connection with their attendance at CME events have been recently introduced (see question 4.8 above).

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?

No compensation to healthcare professionals for the attendance at

congresses and meetings is possible, except for registration fees, and travelling and lodging expenses as described below.

The payment of hospitality for the professional participating in the meeting is strictly limited to a period starting 12 hours before the beginning of the event and ending 12 hours after the end. The Decree generally provides that the character of the hospitality should not prevail on the technical and scientific purpose of the event. In no event can the hospitality be extended to spouses or third parties. Section 3.16 of the Farmindustria Code, as amended in the 2014 version, provides that the offer of hospitality during congresses in Italy may also include meals and beverages within the fixed amount of €60.00 per each person per meal. In case of meetings held abroad, reference should be made to the local Code of Conduct, providing, however, that the general principle of “sobriety” is guaranteed.

According to Section 3.3 of the Farmindustria Code, pharmaceutical companies may offer only economy class air travel and can offer hospitality only in hotels not exceeding the four stars category. In case of international meetings involving flights of a duration exceeding 6 hours, it is possible to offer business class flights to speakers and moderators of the official programme of the congress, but excluding those who are presenting a poster. Moreover, the Code provides that pharmaceutical companies may not invite healthcare professionals to congresses, scientific meetings and, in general, events more than twice per year. In order to verify the respect of such limit, the company must collect (and keep for a 3-year period): (i) the name, the date of birth and the specialisation of the sponsored healthcare professional together with his consent to communicate this data to the Farmindustria Control Committee; and (ii) a statement attesting his compliance with the national and/or local rules on communication to the employees of his (sponsored) participation to the event. Such restriction is not applicable to speakers and discussion leaders and to participants of CME events not invited directly by the company. The Code provides that at least 10% of the invited doctors must be below 40 years of age.

It is possible to pay compensation only to the speaker/s of the meeting, provided that the conditions set forth under article 4.1 of the Farmindustria Code are met (see question 2.7 above).

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 participation of pharmaceutical companies as sponsors of scientific meetings is subject to strict limits concerning hospitality arrangements for healthcare professionals attending the events (see question 5.2 above), as well as the control on the content of the events.

According to Section 124.3, companies can sponsor only those meetings related to scientific topics and connected with research and development in the pharmaceutical field.

In order to verify the compliance with the above-indicated rules, a company sponsoring a scientific event must submit the application described in question 5.1 above to the Italian Medicines Agency containing, *inter alia*, the details of the expenses and the scientific programme of the event.

More specific and strict rules on the content of events are provided in connection with sponsorship of CME events (see question 4.8 above).

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

Italian law does not contain specific provisions on payments made by pharmaceutical companies to healthcare professionals to provide expert services. Particular attention must be given to payments to healthcare professionals who are entitled to prescribe products reimbursed by the National Health System. If not justified and properly documented, such payments can generate suspicions of hiding an improper practice in violation of article 123 of the Decree and Sections 170-172 of the Royal Decree 1265/1934 (the so-called “*comparaggio*”) on corruption.

The Italian Supreme Court (*Corte di Cassazione*, 26.09.2011-16.01.2012, n. 1207) stated that when payments are made to healthcare professionals belonging to the public sector (National Health System) for the purpose of prescribing medicinal products, the crime of corruption applies rather than the less serious crime set forth in Section 123 of the Decree.

Furthermore, except in a few cases, any compensation for services rendered by healthcare professionals who are employed full-time by public entities (hospitals/universities) must receive the prior clearance of the relevant employer (see also question 5.5 below). New anti-corruption rules have been recently introduced that require private entities to communicate to public employers the payment made to public servants no later than 15 days after such payment.

In general, it is possible to pay a healthcare professional a fee for attendance as a speaker at meetings or focus groups (see question 5.2 above). The *Farmindustria* Code of Professional Practice outlines certain requirements which must be followed when entering into scientific cooperation agreements with doctors.

Direct payments of investigators in charge of clinical trials sponsored by the company are not permitted; all payments should be made to the institutions to which the investigators belong and direct negotiations with the investigator/team of investigators is not permitted.

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

Clinical trials of marketed medicinal products may only be approved pursuant to specific regulations. The performance by pharmaceutical companies of observational clinical studies is subject to compliance with the provisions laid down in the Circular of the Ministry of Health of the 2nd September 2002, No. 6, in the AIFA Resolution of the 20th March 2008, which established the guidelines for the classification and conduct of observational studies, and with section 4.3, introduced in the 2008 edition of the *Farmindustria* Code of Professional Conduct. Payments for such studies are made to the institutions conducting the studies (local health office, hospital, university, etc.) and not directly to the doctors. Pharmaceutical companies may provide the investigators involved in such trials with instrumental and software support (excluding hardware). Supply of the above-mentioned tools must be conducted via the institutions involved in the study, i.e. local health offices, universities, hospital boards, etc., and their use must be exclusively for the purpose of completing the studies. At the end of the study, the equipment or tools must be returned and evidence of the re-delivery must be kept by the pharmaceutical companies concerned.

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

There are no guidelines in the *Farmindustria* Code of Professional Conduct or in the Decree relating specifically to payments to healthcare professionals for participating in market research. Any consulting or services arrangements providing a payment to doctors who are employed full-time by public entities, hospitals or universities must be previously notified to, and receive the clearance of, the relevant employer. Exceptions to the obligation to obtain prior clearance are for payments made for the following activities: collaborations with newspapers, magazines, encyclopaedias and similar publications; royalty or lump sum payments for use of intellectual property; and participation in congresses and seminars, compensation consisting in the mere refund of documented expenses. Payment to take part in market research does not fall within such exceptions.

All payments to doctors must be justified and properly documented. Any promotional material must obtain the prior clearance of the AIFA.

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?

Advertising of non-prescription medicinal products to the general public is possible within the limits and restrictions provided by Sections 115 to 118 of the Decree, which reflect the provisions of the Community Code.

Advertising shall contain certain minimum information and shall not contain misleading or untrue data or statements.

In particular, advertising of non-prescription medicines to the general public shall:

- be made in such a way that the promotional nature of the message is clear and the product must be clearly identified as a medicinal product;
- include the name of the medicinal product and of the active ingredient, in the event the product is composed of only one active ingredient, and shall contain an express invitation to read carefully the instructions on the leaflet or on the outer packaging; and
- not contain those data or statements, listed by Section 90 of the Community Code, which may mislead consumers on the nature or effects of the product.

Any advertising message must be authorised by the Ministry of Health (see question 2.1 above).

Penalties for infringement of the rules on advertising are described in question 1.7 above.

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

The Decree expressly prohibits advertising to the general public of prescription-only medicines or of products containing psychotropic or narcotic substances.

In derogation of such prohibition, the Medicines Agency may authorise only vaccination campaigns promoted by pharmaceutical companies.

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?

Section 113.2 paragraph d) of the Decree provides that the information relating to human health or human diseases are not subject to the rules concerning medicinal product advertising, provided that they do not include any reference to a medicinal product, even indirectly. The name of the company can be mentioned as the promoter of the campaign.

Disease awareness campaigns are therefore permitted, but are subject to the restrictions provided by Section 115.5 of the Decree, according to which printed materials, radio and television transmission and in any message which does not have an advertising character, but is addressed to the general public, shall not mention the name of the product when the context of the message may favour the use of the product.

It is possible to distribute to the general public only educational material on the disease and/or medical problem without mentioning the commercial name of the product or any reference to the product either directly or indirectly.

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

As explained above, it is not possible to advertise prescription products and, therefore, it is not possible to issue a press release on prescription medicines to non-scientific journals when such press-release has an advertising/promotional content.

Normally pharmaceutical companies provide information to the general public on a new product through the press at the time of its launch. In this case, it is tolerated that the new drug is announced also in the lay press, provided that only the name of the active ingredient is mentioned and the information appears as an editorial. See also question 2.3 above.

From time-to-time information regarding prescription drugs is published in the press, even the non-scientific press (in special "Health/Medicine inserts") by specialised journalists (who must comply with their Code of Professional Conduct) to whom pharmaceutical companies provide the necessary information. These "Health/Medicine inserts" often contain special issues on diseases or medical problems, but they are always edited by journalists.

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

No regulatory provisions address this issue. New text of article 1.1 of the Farindustria Code excludes from the scope of the Code the communication of non-promotional information on the company's activity, such as those addressed to investors and the press, including financial data and description of research and development programmes.

The publication of such information is permitted and is in compliance with the Italian corporate rules when they are related to a potential important development for the company's business and they do not contain the commercial name of the new product,

and when they specify that the product is not yet licensed in Italy. It is important that the message provides financial and scientific information to the shareholders and financial community and does not have a mere promotional nature. The Farindustria Code provides that at such communication events no hospitality should be offered to healthcare professionals attending the event except in special circumstances with the prior authorisation of the Audit Committee.

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

The Decree does not regulate the issue of the support by the industry to patient associations. The Farindustria Code has specifically addressed the issue of the "Relations between Pharmaceutical Companies and Patient Associations" and established that any form of economic support, whether direct or indirect, by the pharmaceutical company towards a patient association must comply with the following criteria: a specific and preliminary agreement aimed at regulating the amount of financing and the reasons for its disbursement must be reached. For this reason, each pharmaceutical company must develop a standard internal procedure ("SOP") for the approval of this category of agreements.

The public utilisation by a pharmaceutical company of the logo or material owned by a patient association must be authorised in advance by the association. In order to acquire such authorisation, the objectives for, and the manner of, using the logo must be clearly defined.

Any form of sponsorship by pharmaceutical companies *vis-à-vis* patient associations must be transparent and without promotional objectives.

No company can request to be the sole financier of a patient association.

In all cases in which journeys or other forms of hospitality are provided, the provisions set out in the Code on conferences and congresses shall apply.

The pharmaceutical companies must include within their own Internet sites a list of the patient associations that they sustain.

7 Transparency and Disclosure

7.1 Is there an obligation for companies to disclose details of ongoing and/or completed clinical trials? If so, what information should be disclosed, and when and how?

A general obligation for companies to disclose the expenses incurred for clinical trials has recently been introduced by the latest version of the Farindustria Code issued in February 2014. The newly established article 5.8 (R&D Expenses), which will become effective from the year 2016 with reference to the data of the previous year, provides that expenses for research and development (i.e. not clinical trials as defined by the Good Laboratory Practice, clinical trials as defined by Directive 2001/20/CE and prospective observational studies which imply collection of data by a single or a group of doctors) must be disclosed on an aggregate basis.

Moreover, expenses for investigator meetings, advisory boards and hospitality are also to be disclosed when they are clearly connected to R&D activities.

7.2 Has your national code been amended in order to implement the 2013 EFPIA Code on Disclosure of Transfers of Value from Pharmaceutical Companies to Healthcare Professionals and Healthcare Organisations and, if so, does the change go beyond the requirements of the EFPIA Disclosure Code or simply implement them without variation?

The 2014 version of the Farmindustria Code has accepted without significant changes the 2013 EFPIA Code on Disclosure of Transfers of Value from Pharmaceutical Companies to Healthcare Professionals and Healthcare Organisations. The new disclosure rules shall become effective from 2016 in respect to transfer of values effected in the year 2015. The implementation is still in progress.

The following are the main points of the disclosure obligation: (i) each company member of Farmindustria must document and disclose any transfer of value effected in favour of a HcP/HcO as defined in the Code using the structure set forth in Schedule 1 of the Farmindustria Code; (ii) companies must set up a specific SOA for the acquisition of the consent of the HcP allowing the disclosure of data; and (iii) the disclosure obligations must be fulfilled on an annual basis within the first 6 months of the subsequent year of the expenses. The relevant documents, including the form of HcP consent to publication, must be kept by the Company for 5 years, whilst the information shall remain accessible to the general public for 3 years after the first publication.

Transfer of value regarding OTC products, gifts of negligible value, sample, meals and accommodations are excluded from the application field of disclosure obligations.

Transfer of value to HcPs regarding the participation at congresses and events (limited to participation fees, travel and accommodation) and consultancy services rendered according to written agreement must be disclosed on an individual basis. In case a HcP refuses to give his consent, the disclosure can be effected on an aggregate basis. Transfer of value to HcOs regarding donations and grants (either cash or benefits in kind), contribution to costs related to congresses, including sponsorship to HcPs to attend such events, and fees for service and consultancy arising from a written agreement must be disclosed on an individual basis.

When a transfer of value is made to an individual HcP indirectly through a HcO the transfer is required to be disclosed only once (non-duplication principle).

7.3 If the EFPIA Disclosure Code has not been implemented in Italy, is there a requirement in law and/or 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 information should be disclosed, from what date and how?

As mentioned above, the EFPIA Disclosure Code has been introduced in Italy without relevant modification and shall be fully in force from 2016.

8 The Internet

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

The Decree does not contain specific provisions on the advertising

of medicinal products through the Internet or through the websites of pharmaceutical companies. Therefore, the ordinary rules on advertising of medical products are applicable, including the distinction between advertising to the general public and to healthcare professionals.

The information that can be made available to the general public on the websites of pharmaceutical companies is only that relating to OTC/non-prescription products and must reproduce the information described in question 6.1 above.

The matter concerning pharmaceutical companies' websites and the limits of their content is also regulated by a letter of the Ministry of Health, dated the 22nd March 2000 ("Internet sites and advertising of medicinal products for human use") and the subsequent guidelines issued by the same Ministry on the 17th February 2010 on new communication systems for the advertising of medicinal products.

It should also be mentioned that Section 4.5 of the Farmindustria Code of Professional Conduct provides that any Internet website owned or managed by an Italian company or by a company operating within Italy must guarantee the clear identity of the sponsor and the correctness of the information provided therein, as well as to disclose to the users/visitors the purposes and the addressees of the website. In any case, access to information on prescription drugs must be limited to healthcare professionals.

The controls on the websites are mainly focused to prevent the activity of online sales of unauthorised products.

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?

As provided by the Farmindustria Code and by the above-mentioned guidelines issued by the AIFA, the access on websites to additional information on prescription drugs must be reserved to healthcare professionals (including pharmacists).

In order to comply with such requirement, pharmaceutical companies must request the users of their websites to complete a registration form before granting a password which will allow access to the site.

Except for so-called "Institutional advertising", all advertising material relating to medicinal products must be previously submitted by the AIFA to obtain the authorisation pursuant to Section 120 of the Decree (see question 1.8 above).

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?

The matter concerning direct or indirect links to or from other websites and placement of banners and frames on third parties' websites has been specifically regulated by the guidelines issued in February 2010 by the MoH. In general, the MoH clarified that banners and frames are considered as advertising media, and therefore advertising already authorised to be published or issued on or by different media cannot be placed "online" without a new specific authorisation from the Regulatory Agency. The request for such authorisation is to be filed by the company who actually promotes the product without taking into account the website where the banner or frame is placed.

With reference to direct and/or indirect links, the MoH specifies:

- (i) use of a link to address the visitor of a pharmaceutical company website to another website which contains authorised advertising material is allowed, providing, however, that a warning stating: *“the user is leaving the (company’s) website containing promotional materials authorised pursuant to the legislation on pharmaceutical advertising actually in force”*, is given;
- (ii) use of a link to address the visitor of a website containing authorised promotional materials to a different website not containing promotional materials in the Italian language subject to the authorisation (i.e. general information on health education) is allowed providing that the same above-mentioned warning is given; and
- (iii) use of a link to address the visitor of a website containing authorised promotional material to a different website containing material which is subject to the authorisation but has not been authorised is not allowed.

The company cannot be held responsible when the warning is given: it may be responsible for infringement of the advertising rules when the duty to give the warning is not fulfilled or when a disallowed link is used.

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

In the above-mentioned Circular letter and guidelines of the Ministry of Health, it is specified that promotional material which has an institutional nature, such as information on the pharmaceutical company in general, or initiatives of a cultural or not-for-profit nature, can be contained in the website without the necessity of being authorised and can also be addressed to the general public.

With respect to advertising medicinal products to the general public on a pharmaceutical company’s website, the Circular specifies that the Internet is to be considered, in all respects, as advertising media, and therefore the rules applicable to the advertising of OTC medicinal products shall be applicable. It is also forbidden to publish promotional material which has not been authorised on their website.

The 2011 version of Farindustria Code introduced the obligation starting from the year 2013 for pharmaceutical companies to publish on their website, for at least three months during the first quarter of each year, any amount granted to patient associations and the scope of the grant.

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

There are no rules, laws or guidance containing specific rules on the use of social media by pharmaceutical companies, and therefore the general principles on Internet and website use should be taken into account.

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?

No significant development of the Italian rules relating to

pharmaceutical advertising have taken place in the last year except the implementation of the new rules of the EFPIA codes.

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

A further increase in the advertising of over-the-counter medicinal products through the Internet channel is expected. The matter has been regulated by guidelines issued by the Ministry of Health in February 2010, and, due to the liberalisation of the selling channels of OTC and SOP medicinal products, it is expected that the sector and the related advertising shall increase.

The recently issued Decree 17/2014 (implementing Directive 2011/62/EU) regulated distance sale of medicinal products. According to the Decree, distance sale of prescribed medicines is prohibited whilst the sale of OTC products is allowed only through a duly authorised pharmacy website. The provisions of the Decree on distance sale will become effective one year after the publication of the Delegated acts of the EU Commission.

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

Increase of the use of web platforms to manage the regulatory procedures and advertising authorisation. Increase of transparency through the implementation of the EFPIA Code on Disclosure of Transfers of Value from Pharmaceutical Companies to Healthcare Professionals and Healthcare Organisations and publication on the website of the National Medicine Agency of the details of procedures, question and answers, annual reports on the activity of the public administration, “Open AIFA” events and other initiatives for the development of transparency in the relationship with the industry and the general public.

9.4 Has your national code been amended in order to implement the 2013 version of the EFPIA Code on the promotion of prescription-only medicines to, and interactions with, healthcare professionals (the EFPIA HcP Code) and, if so, does the change go beyond the new requirements of the EFPIA HcP Code or simply implement it without variation?

The Farindustria Code has recently been amended to implement certain provisions of the 2013 version of the EFPIA HcP Code.

As requested by section 10.05 of the EFPIA HcP Code, the Italian Pharma Companies Association fixed a threshold for meals offered to HcPs during attendance at congresses and events in the amount of €60.00 (see question 5.2 above). The provision will become effective from the 1st of July 2014.

The Italian Code has not been amended to implement the new rules on promotional material of negligible value introduced in the 2013 version EFPIA HcP Code as section 2.13 of the Farindustria Code is considered to be already in compliance with the relevant section of the EFPIA Code.

**Linda Longo**

Biolato Longo Ridola & Mori
Via Ludovisi, 35
00187 Rome
Italy

Tel: +39 06 323 3001
Fax: +39 06 323 4238
Email: linda.longo@blrm.it
URL: www.blrm.it

Education: Rome University La Sapienza (LL.D., 1979 *magna cum laude*); Bar membership: admitted, 1984, Rome.

Linda Longo has been a named partner at Biolato Longo Ridola & Mori, Rome since 1992. She was an associate at Studio Avv. Ercole Graziadei from 1979-1984, and a partner at Manca Amenta Biolato Corrao & Co from 1985-1992.

She is involved in general counselling to companies, with a special orientation to pharmaceutical, biotech, medical devices and the food industry. She is familiar with regulatory and compliance matters relating to pharmaceutical products and medical devices.

She is also involved with merger and acquisitions, shipbuilding contracts, ship financing and maritime law issues.

She is the co-author of the Italian Chapter of "EC Legal Systems". An introductory Guide" Sheridan & Cameron, Butterworth 1992, and contributed to the Italian chapter of "International Food Law" published by Prospect Media Pty Ltd in 2000, edited by J.Kellam and E. T. Guarino. She is co-author of the Italian chapter of the comparative study "A practical guide to National Competition Across Europe" published by Kluwer Law International, 2007.

Languages: Italian, English and French.

**Andrea Moretti**

Biolato Longo Ridola & Mori
Via Ludovisi, 35
00187 Rome
Italy

Tel: +39 06 323 3001
Fax: +39 06 323 4238
Email: andrea.moretti@blrm.it
URL: www.blrm.it

Education: Rome University La Sapienza, (LL.D. 1997); Bar membership: admitted, 2000, Rome.

Andrea Moretti joined Biolato Longo Ridola & Mori, Rome in 1998 and has been a partner since 2005. He is involved with general civil and commercial practice, trademarks, intellectual property, pharmaceutical, medical devices and food law. He also specialises in litigation and competition law issues. He contributed to a comparative study between 22 jurisdictions as co-author of the chapter dedicated to Italy, of "International Food Law", Prospect Media, 2000. He is co-author of the Italian chapter of the book "A practical guide to National Competition Across Europe" published by Kluwer Law International, 2007.

Languages: Italian and English.

BLR&M
BIOLATO LONGO RIDOLA & MORI

studio legale associato

The firm was established on the 1st of January 1985 as a result of a de-merger of former Studio Avv. Ercole Graziadei. The founders of the firm have all been partners or associates of Studio Avv. Ercole Graziadei.

Since the date of its establishment, the firm has been active in all areas of civil and commercial law, with a strong international orientation particularly in mergers and acquisitions, corporate law, shipping, pharmaceutical and food law, labour, real estate, and intellectual property.

The firm advises pharmaceutical companies in connection with healthcare and pharmaceutical laws and regulations, and has developed significant expertise in regulatory matters concerning marketing authorisation, pricing and advertising of medicinal products, as well as clinical trial issues. The firm also advises clients in the industry in respect to issues relating to sales representatives, co-marketing and co-promotion agreements, licence agreements, mergers and acquisitions of pharmaceutical companies, and compliance. The firm has also been dealing in respect to legal issues relating to food stuffs, dietetic products and medical devices.

For further information please refer to the firm's website: www.blrm.it.

Other 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
- Environment & Climate Change Law
- Franchise
- Insurance & Reinsurance
- International Arbitration
- Lending & Secured Finance
- Litigation & Dispute Resolution
- Merger Control
- Mergers & Acquisitions
- Mining Law
- Oil & Gas Regulation
- Patents
- Private Client
- Product Liability
- Project Finance
- Public Procurement
- Real Estate
- Securitisation
- Shipping Law
- Telecoms, Media & Internet
- Trade Marks



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