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The International Comparative Legal Guide to:

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A practical cross-border insight into pharmaceutical advertising

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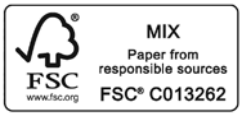

General Chapter:

Country Question and Answer Chapters:

Italy

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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; the last update is dated December 2014. 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 pharmacy.

The scientific department must be independent from the marketing department and its duty is to ensure that the advertising of 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 of 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 the 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 SOPs 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 companies that are members 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 by 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 Expert's 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 Expert's Commission's opinion.
- Advertising to health 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 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 that 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 the 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 the 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 dispose the suspension from reimbursement for a period from 10 days to two years, depending on the seriousness of the irregularity (Section 148.19 of the Decree).

Normally, in the case of alleged infringement, the pharmaceutical company is requested to discontinue the unlawful conduct by the regulatory authority.

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 advertising to HCPs is published by AIFA. Such report outlines the activity carried out by the Agency and the main irregularities of the advertising materials submitted to 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 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 Farmindustria, 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 Farmindustria 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 Farmindustria Code of Professional Conduct.

The prohibition of the 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 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 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 the 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 still at the centre of great debate in Italy after the 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 case *Avastin/Lucentis* 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 the ophthalmic use.

The new rules (Law Decree 36/2014 converted into Law n.79/2014) try to balance private and public interests in a delicate matter such as the off-label use of drugs and the right of the holder of the MA to decide whether or not to register new therapeutic indications. The European bio-pharmaceutical industry made a complaint to the European Commission against the new Italian law on the ground that it is promoting off-label use of medicines for economic reasons.

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

Information regarding clinical trials carried out in respect of an unlicensed medicinal product or off-label indications can be published in the scientific press or when the information is of interest to 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 unauthorised medicines and/or off-label information? 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 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 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 information, nothing prevents a 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 was introduced in the 2011 version of the Farmindustria 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 in 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 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 marketing research company or the 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 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 mentioned in the SmPC?

The Code of Professional Conduct of Farmindustria provides that the information contents 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 omni

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 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 health professionals or scientists is specifically prohibited for the 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 may be made?

The Farmindustria Code of Professional Conduct (question 2.2) prohibits comparisons which cannot be demonstrated and those without a clear objective basis. There is no published guidance in Italy on head-to-head studies 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 the 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 Farmindustria 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 admitted when comparative clinical trials are carried out in order to prove the efficacy of the products. Furthermore, comparative advertisement is admitted also 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 is 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 or in the Code of Professional Conduct of Farmindustria. 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 medicinal products? If so, what restrictions apply?

Provision of samples of medicinal 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 Pharmaceutical companies 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 medicinal product; and
- 10 samples per year (maximum four per visit) for medicinal products on the market for more than 18 months.

The provision of samples is also regulated by Section 2.17 introduced in the 2011 version of the Farmindustria 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 it to eight samples in total for the first 18 months.

Samples of medicinal 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" has 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 content which has a higher value to the operative departments of public hospitals/public health structures and healthcare professionals belonging to such structures.

The Farmindustria 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 a €25 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 (section 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.

Donations of equipment or contracts providing the free use of equipment are also 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 are 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 free of charge, necessary to conduct observational studies, must be limited to the period required to conduct the clinical trial; supply of hardware such as tablets or 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 a medicinal product can be offered free of charge only to the public health structures. A Decree of the Ministry of Health also permitted the supply free of charge of certain educational material to healthcare professionals directly. In principle, there is no prohibition to accept a good that could lead to changes in 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 offers, 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 AIFA during negotiations for 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 the CME events are organised by an "accredited provider" who has the sole responsibility of 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 or recruit participants (i.e. direct invitation) besides the following provided limit. In fact, the direct invitation of a healthcare professional by a sponsor to attend a CME event 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 AIFA, who 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.

Contributions 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 stricter 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 and subject to strict timing limitations.

Strict rules on hospitality to healthcare professionals in connection with their attendance at CME events have recently been 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 attendance at congresses and meetings is possible, except for registration fees, and travelling and lodging expenses as described below.

The payment of hospitality for a 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 the 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 the case of international meetings involving flights of a duration exceeding six hours, it is possible to offer business class flights to speakers and moderators of the official programme of the congress, but this excludes 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, to events more than twice a year. In order to verify the respect of such limit, a company must collect (and keep for a three-year period): (i) the name, date of birth and specialisation of the sponsored healthcare professional together with his consent to communicate such 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 at 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 event (see question 5.2 above), as well as control of the content of the event.

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 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.

Additional 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*") or 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 prior clearance of the relevant employer (see also question 5.5 below). New anti-corruption rules have recently been introduced and have imposed to private entities the duty to communicate to a public employer a payment made to a public servant no later than 15 days after the 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 Code of Farmindustria outlines certain requirements which must be followed in order to enter into scientific cooperation agreements with doctors (see also question 5.7 below).

Direct payments to investigators in charge of clinical trials sponsored by the company are not permitted; all payments should be made to the institution to which the investigator belongs and direct negotiations with the investigator/team of investigators are 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 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 Farmindustria Code of Professional Conduct. Payments for such studies are made to the institution where the study is conducted (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 or in the Decree relating specifically to payments to healthcare professionals for participating in market research. Any consulting or service arrangements providing a payment to doctors who are employed full-time by public entities, hospitals or universities must be previously notified to and must 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 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 only of 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 information relating to human health or human diseases is not subject to the rules concerning medicinal product advertising, provided that it does 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 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 only to distribute to the general public 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 Farmindustria Code excludes from the scope of the Code the communication of non-promotional information on the company's activities, such as those addressed to investors and the press including financial data and descriptions of research and development programmes.

The publication of such information is permitted and is in compliance with the Italian corporate rules when it is related to a potential important development for the company's business and it does not contain the commercial name of the new product, and when it specifies 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 Farmindustria 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 support by the industry to patient associations. The Farmindustria Code has specifically addressed the issue of "Relations between Pharmaceutical Companies and Patient Associations" and established that any form of economic support, whether direct or indirect, by a pharmaceutical company towards a patent 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 an internal standard operating procedure (SOP) for the approval of this category of agreements.

The public utilisation by a pharmaceutical company of the logo of, 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 travel compensation or other forms of hospitality are provided, the provisions set out in the Code on conferences and congresses shall apply.

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, 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?

A general obligation for companies to disclose the expenses incurred for clinical trials was introduced in the latest version of the Farmindustria 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. 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 single or a group of doctors) must be disclosed on an aggregate basis on the website of the company.

Moreover, expenses for Investigator Meetings, Advisory Boards or hospitality are also to be disclosed when they are clearly connected to R&D activities.

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?

Disclosure requirements are not provided by the legislation, but have been introduced in the 2014 version of the Farmindustria Code, which has accepted without significant changes the 2013 EFPIA Code on Disclosure of Transfers of Value from Pharmaceutical Companies to Healthcare Professionals and Healthcare Organisations as described in question 7.3 below.

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 disclosure rules introduced in the Farmindustria Code shall become effective in 2016 in respect to transfer of values effected in the year 2015.

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 six months of the subsequent year of the expenses. The relevant documents, including the form of HCP consents to publication, must be kept by the Company for five years whilst the information shall remain accessible to the general public for three years after the first publication.

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

Transfer of value to HCPs regarding the participation in congresses and events (limited to the participation fees, travel and accommodation) and consultancy services rendered according to written agreement must be disclosed on an individual basis. In the 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 services 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 an HCO, the transfer is required to be disclosed only once (non-duplication principle).

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 websites of pharmaceutical companies. Therefore, the ordinary rules on the 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 pharma companies' websites and the limits of their content is also regulated by a letter of the Ministry of Health, dated 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 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 accuracy of the information provided therein, as well as disclose to 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 websites are mainly focused on preventing 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 AIFA, the access on websites to additional information on prescription drugs must be reserved for healthcare professionals (including pharmacists).

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

Except for the 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 (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 that 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 specified:

(i) use of a link to address the visitor of a pharma 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.

A 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 Farmindustria Code contains the obligation for pharmaceutical companies to publish on their websites, 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?

The most significant development is increasing transparency through the implementation of the EFPIA Code on Disclosure of Transfers of Value from Pharmaceutical Companies to Healthcare Professionals and Healthcare Organisations.

There has also been an increase in the use of web platforms to manage regulatory procedures and advertising authorisation.

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

In Italy we do not expect any significant development in the field of pharmaceutical advertising – in particular, no amendments to the Decree are expected.

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

It is expected that the new Italian Anticorruption Authority shall implement measures for the development of transparency in the relationship of regulatory agencies and public health structures with the industry and the general public, which are considered extremely important to prevent corruption and waste in the Italian health system.

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