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The International Comparative Legal Guide to:
Pharmaceutical Advertising 2011

A practical cross-border insight into pharmaceutical advertising

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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, in 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 23rd September 2009. The rules of the Code have no legal force and are binding only for the members of the association.

In respect to advertising to the general public, the code of IAP – *Istituto di Autodisciplina Pubblicitaria*, the Italian Institution for Advertising Self-Regulation also deals with advertising of medicinal products.

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 professionals qualified to prescribe or supply medicinal 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 health 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.

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 SOP governing advertising activities, but compliance with specific advertising SOP are required by the Farmindustria Code because in order to get the certification by the accredited entity (see the reply under question 1.3 above), the companies' member of Farmindustria should be audited and should give evidence during the audit to comply with the SOP and guidelines issued by Farmindustria.

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 health 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 the 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. Advertising messages are considered approved if an express denial it 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 opinion.

- Advertising to health professionals is now subject to a 10-day negative clearance system. Any advertising messages or documents which the companies wish to provide to medical practitioners, 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. At any time the Italian regulatory authority can prohibit or suspend their diffusion.

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 to the offenders.
- In case of infringement of the rules regarding advertising to health 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 AIFA and the MOH regarding infringements of the advertising rules set forth in the Decree are not published. 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. Only one in September 2004 - the Italian Antitrust Authority - ruled that the advertising message contained in promotional material addressed to health professionals and distributed by sales representatives of a pharmaceutical company relating to a prescription drug was misleading because the information contained on the properties of the drug were incomplete and incorrect. The Authority prohibited the further diffusion of the promotional material containing the advertising. The decision is important because the Authority stated that it was competent to decide on the issue of advertising of medicinal products because the advertising subject of the proceedings had not been specifically approved by the Ministry of Health: indeed the promotional material distributed by the sale representatives was allegedly intended to be "for internal use only" and had not been submitted for the prior tacit approval to the Ministry of Health (now the Italian Medicines Agency, or AIFA).

Infringements of advertising rules may also cause sanctions to the members of Farmindustria. The Code of Professional conducts provides for the following sanctions depending on the seriousness of the violation:

- Temporary suspension from the association.
- Application of a sanction of a maximum amount of €200,000.
- Expulsion from the association.

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/AIFA, 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 health 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's 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 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 principles or new off-label indications, 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 health 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).

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 be published also 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 physicians of such foreign country are attending the meeting. Thus, it would not be permitted to organise a meeting abroad for Italian doctors only and to provide information and distribute materials (not previously submitted to the Medicines Agency) regarding unlicensed products.

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 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 health professionals by the company? If so, must the health professional request the information?

As indicated above, all information distributed to health professionals must be previously submitted to the Italian regulatory authority and may be utilised only after the elapse of the 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 health professionals with information such as reprints of scientific articles concerning clinical trials. Also this information will be subject to the prior control of the Italian Medicines Authority who may or may not approve the contents.

When the health 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 May information 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 after the issue of the marketing authorisation, it is unlikely that, in Italy, such information would be provided/requested at such an early stage.

2.6 Is it possible for companies to involve health 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 the health professional and pharmaceutical companies has been introduced in the new section 4.1 of the 2009 version of the Farmindustria Code of Professional Conduct and it is therefore applicable to the relationship with a health professional. According to such rule, pharmaceutical companies may collaborate with health professionals for consultancy services (such as speakers at congresses, participation to observational studies, training and educational services) providing, however, that the following criteria are fully complied with: i) the agreement with the health professional is in written form; ii) the health 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 health 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 professional is a full-time employee of a Public Body (such as Public University or Hospital), the prior consent of the employer is also required.

In respect of involvement of the professionals in market research, if no compensation is provided and the number of health 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 the sales representatives).

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

3 Advertisements to Health Professionals

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

The Decree provides that any advertising of medicinal products to health professionals (under the Italian rules this term includes only the professionals who are authorised to prescribe or administer the 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 principle/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 physicians, the Decree substantially mirrors the provisions of the Community Code, requiring that all information contained in the documentation to be supplied to physicians 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 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 omnicomprehensive 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 are contained in medical reviews and scientific articles, it is possible to include such information in the advertising material, provided that they are 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?

Health professionals cannot endorse personally the products it would be in conflict with in their Code of Ethics. Endorsement of health 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 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 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 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 article 25 of the Code of Self Regulations, issued by IAP and updated on the 16th January 2009 ("*Advertising of over-the-counter medicinal products and curative treatments must avoid (.....) claiming that the efficacy of the medicine or the treatment is equal to or better than others*"). There are no precedents of such advertising to the general public.

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

Distribution of scientific papers and/or proceedings of congresses to doctors is permitted subject to prior submission to the Italian Medicines Agency ("AIFA"), pursuant to the 10-day negative clearance system described in question 1.3 above.

The AIFA issued in 2010 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: 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 a 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 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 health professionals with samples of products? If so, what restrictions apply?

Provision of samples of products to health professionals is regulated by section 125 of the Decree.

Free samples can be provided only to professionals authorised to prescribe the product and samples can be supplied by 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 health professionals in 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.

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

4.2 Is it possible to give gifts or donations of money to medical practitioners? 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 health 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 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.

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 of 14 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 an higher value to public hospitals/public health structures and health professionals.

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 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 health professional belongs (article 2.14 – see question 4.4 below). This provision is more strict than the regulation of the above-referred Decree.

Violation of section 123 of the Decree by health professionals and by the company is sanctioned as a crime, with the arrest up to one year and the fine from €400.00 up to €1,000.00. Furthermore, health professionals are subject to the disciplinary sanction of the suspension of the licence to practice for the duration of the criminal penalty.

4.3 Is it possible to give gifts or donations of money to institutions 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 free of charge, necessary to conduct observational studies, must be limited to the period necessary to conduct the clinical trial; supply of hardware to physicians 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 doctors 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. As described under question 4.3 above, a recent Decree of the Ministry of Health also permitted the supply free of charge of certain educational material to the health 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; 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?

These kinds of schemes have been introduced recently as part of the negotiating procedure for the pricing and reimbursement of the medicinal products. Following are the schemes introduced by AIFA during the negotiations for the price and reimbursement for 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 providing, however, that the CME events are organised by an "accredited provider" who has the sole responsibility on the scientific contents of the programme and on 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, direct invitation of a health professional by sponsor to attend to CME events are allowed up to the limit of 33 per cent of the required CME credits per each professional (on a three-year basis). The economical 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. For further reference please also see question 9.1 below.

5 Hospitality and Related Payments

5.1 What rules govern the offering of hospitality to health professionals? Does it make a difference if the hospitality offered to those health professionals will take place in another country?

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

The offer of hospitality to health 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. Also the local governments of the place where the event will be held (regions and autonomous provinces) are involved in the authorisation process. Sponsorship of events being held abroad and grants exceeding €25,822.85 are to be expressly authorised by the AIFA.

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 doctors substantially reflect those of the Decree, providing 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 the pharmaceutical companies for technical reasons and subject to strict

timing limitation.

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

5.2 Is it possible to pay for a doctor 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 health 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.

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. The above-mentioned provision of the Code has been recently modified in order to clarify that such restriction is applicable only to Italian doctors and therefore hospitality in five star hotels can be offered to doctors from foreign countries.

Moreover, pharmaceutical companies may not invite doctors to congresses, scientific meetings and in general to events more then twice per year. Such restriction is not applicable to speakers and discussion leaders.

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 2.6 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 doctors to attend?

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

According to section 124.3, companies can sponsor only those meetings related to scientific topics and connected with the research and the 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 the 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 contents of the event are provided in connection with sponsorship of CME events (see question 4.8 above).

5.4 Is it possible to pay doctors to provide expert services (e.g. participating in focus groups)? If so, what restrictions apply?

Italian law does not contain specific provisions on payments made by pharmaceutical companies to health professionals to provide expert services. Particular attention must be given to payments to doctors 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 11 of the Decree and sections 170-172 of the Royal Decree 1265/1934 (the so-called "*comparaggio*").

Furthermore, except in a few cases, any compensation for services rendered by doctors who are employed full-time by public entities (hospitals/universities) must be previously notified and must receive the clearance of the relevant employer (see also question 5.5 below).

In general, it is possible to pay the professional a fee for the attendance as a speaker at meetings or focus groups (see question 5.2 above). The 2008 edition of the Code of Professional Practice of Farmindustria introduced certain requirements which must be followed to enter into scientific cooperation agreements with the doctors.

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

5.5 Is it possible to pay doctors 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 the new article 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 equipments 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 doctors 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 health professional 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 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 principle, in the event the product is composed only of one active principle, and shall contain an express invitation to read carefully the instructions on the leaflet or on the outer packaging; and
- shall not contain those data or statements, listed by section 90 of the Community Code, which may mislead the 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 1.6 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 be 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 containing 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 principle 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 or guidelines in the Farmindustria Code address this issue: the publication of such information is permitted and 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.

6.6 What, if any, rules apply to meetings with and funding of patient support groups, including any transparency requirement as regards the recording of donations and other support in corporate reports?

The Decree does not regulate the issue of the support by the industry to the patient associations: The Farmindustria Code of professional conduct 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 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 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 the pharmaceutical companies *vis à vis* the 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 the list of the patient associations that they sustain.

7 The Internet

7.1 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 the pharmaceutical companies. Therefore the ordinary rules on advertising of medical products are applicable, including the distinction between advertising to the general public and to health professionals.

The information that can be made available to the general public in the website of the 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 contents 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 4.4 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, 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 health professionals.

7.2 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 health professionals?

As provided by the above-mentioned Farmindustria Code and by the letter of the MoH (and confirmed by the recently issued Guidelines), the access on websites to additional information on prescription drugs must be reserved to health professionals (physicians and pharmacists).

In order to comply with such requirement, the 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 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.

7.3 What rules apply to the content of independent websites that may be accessed by 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?

In the Circular letter issued by the Ministry of Health in March 2000, regarding "Internet sites and advertising of medicinal products for human use", it is specified that direct or indirect links to other websites appearing in the websites of pharmaceutical companies is allowed only for the purpose of scientific information and provided that before the access a specific warning is given to the Internet user advising them that the information contained in the linked website may not be in compliance with the Italian rules and that the opinions expressed do not necessarily correspond to the position of the company nor are approved by it. The same warning must appear when the link is to the website of the foreign parent company.

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. The request for such authorisation is to be filed by the company who actually promotes the product without therefore 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 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 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.

7.4 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 institutional qualities 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 be addressed also 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.

8 General - Medical Devices

8.1 What laws and codes of practice govern the advertising of medical devices in Italy?

Advertising of medical devices in Italy is regulated by Legislative Decree 46/1997, which has implemented Directive 93/42/EC (as amended by Directive 2007/47/EC) and by the Decree of the Ministry of Health of 23rd February 2006 "Advertising of medical devices".

Article 21 of Legislative Decree 46/1997 and the above-referred Decree regulate the advertising of medical devices to the general public and provide that no advertising to the general public can be made for custom-made medical devices, medical devices which can be sold only upon medical prescription or can be used only with the assistance of a doctor or of another health professional, whilst the other devices can be advertised to the general public only with the prior authorisation of the Ministry of Health, following the procedure described in question 1.4. If no objections are raised by the Italian Medicines Agency after 45 days from the date of submission of the request of authorisation, the request is considered as approved.

The infringement of the provisions of article 21 of Legislative Decree 46/1997 is no longer punished with a criminal sanction, but with an administrative fine from €2,600.00 to €16,000.00.

Circular of MOH 17.02.2010 in respect of websites of manufacturers of medical devices, specifies that "institutional advertising" is not considered advertising and is not subject to prior authorisation. It can mention the name of the manufacturer and the products individually or as a complex of products. No brand names can be utilised, images or properties of the products.

No specific regulations regarding advertising to health professionals are set forth in the above-referred Decrees: in the lack of specific regulations, the general rules regarding fair advertising shall apply. In particular, all information supplied to doctors or health professionals must be in compliance with the approved label and the information leaflet.

The Code of Ethics of the most important Italian industry association (ASSOBIOMEDICA) contains rules regarding the relationship with health professionals and advertising at conferences and congresses similar to those set forth in the Farmindustria Code.

8.2 Are there any restrictions on payments or hospitality offered to doctors in connection with the promotion of a medical device?

No regulations specifically provide restrictions on payments or hospitality offered to doctors in connection with the promotion of medical devices. However, medical devices are mostly purchased by public entities/enterprises (ASL, Hospitals) belonging to the National Health System. Therefore, to the officers/purchasers of the purchasing public entity, the general rules regarding corruption and bribery as well as fraud and other malpractices in public procurement will apply. These rules will be applicable where the public employee received money or any other benefits in connection with performing or omitting to perform his official duties or when anybody disturbs/manipulates the regular process of the bidding for public procurement supplies.

In recent years, the conflict of interest issue has gained increasing attention also in respect to the relationship between the industry of medical devices and health professionals, including the attendance of public sector physicians to congresses sponsored by medical device manufacturers.

The Code of Ethics of ASSOBIOMEDICA contains restrictions in respect to hospitality offered to health professionals for the attendance to congresses and seminars sponsored by the industry, as well as payments and donations in favour of health professionals and public health structures.

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?

From 1st January 2001, the new CME (continuing medical education) national system, introduced by the agreement between the State and Region of the 5th November 2009, and by the National CME Commission implementing regulation of the 13th January 2010, has become effective. The new rules are aimed to regulate the activities of the entities involved in the CME process, as well as to avoid any possible conflict of interest or other illegal practices between the CEM provider and the sponsor. The main changes introduced by the new system are: (i) the credits granted to those attending to the events are issued by a certified provider and not, as in the past, by the MoH; (ii) the economical aspects of the sponsorship are to be evidenced in writing; and (iii) limits to direct invitation of health professionals by sponsor to participate to the CME event have been provided (see question 4.8 above).

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

There is a general expectation that the use of the Internet as a vehicle to provide information to the general public shall increase. In Italy the rules are still strict but the possibility to efficiently control all the messages disseminated on the web is almost null. The information on the web is disseminated also by way of creation of an "independent" website addressed to patients/general public, with the aim to provide an extensive knowledge on the disease which could lead to an increase in the knowledge of the available therapies and consequently the more appropriate use of the medicinal products.

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

Due to budget restrictions, the general trend from the Government is to reduce the use of the expensive medicinal products (except for life saving products), and reduce the cost of the generic medicinal products. For industry, the trend is to reduce the promotional costs and the cost of the sale force, reducing the number of sales representatives. There are no significant enforcement trends from the AIFA in respect of the promotion of medicinal products.

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