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The International Comparative Legal Guide to:

Pharmaceutical Advertising 2009

A practical insight to cross-border Pharmaceutical Advertising work

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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 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 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, the last update is dated 22nd October 2008. 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 MA for a medicinal product should establish a "scientific service" within its organisation to be directed by a person graduated in medicine or in pharmacy.

The scientific department must be independent from the marketing department and is entitled 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) require 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 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 have been recently 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 (see question 9.1 below). 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.

1.5 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 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").

1.6 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 to 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 1.5 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.

An important decision concerning misleading advertising of a medicinal product was taken for the first time by the Italian Antitrust Authority (*Autorità Garante della Concorrenza e del Mercato*) in September 2004. The 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 Italian Medicines Agency).

1.7 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 to the Self Regulatory Body of the Italian pharmaceutical industry association (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 often the rules applicable to advertising set forth in the Farmindustria Code of Professional Conduct are similar to the rules set forth in the Code.

1.8 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 constitute also 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 Medicines Agency 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?

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 EMEA procedure. The prohibition, which reflects the provision of the Community Code, is contained also 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 Medicines Agency. Information regarding an unlicensed medicinal product will not be approved by the Medicines Agency; 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 2008 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 to 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 (if 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?

Consistent with the Community Code, 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 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 (section 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.

3.3 What rules govern comparator 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 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 in 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.

3.4 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.

3.5 Are "teaser" advertisements permitted, which 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 It is 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 number:

- 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 confirmed also 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. For scientific publications having a higher value, the gift must be granted to the hospital/public health structure were the professional is employed and not personally to the health professional.

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 and introduced the amount of €25 as the limit for a gift to be considered of "negligible value" (article 2.14 - see question 4.4 below).

Violation of section 123 of the Decree by the professionals and by the company is sanctioned as a crime with the arrest up to one year and the fine from €400.00 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 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 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 and not to the health professionals. This rule is intended to give transparency to these kinds of gifts and to make them available to all the professionals of the public hospitals. 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 increase in the volume of purchase.

Such prohibition has been recently introduced also in the Code of Professional Conduct (article 2.14) according to which education or work material not specifically related to the medicinal product can be offered free of charge to the health professionals providing however that the value of the material does not exceed the value of €25.

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 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. For example "risk sharing" schemes providing free supply of the products for the first cycle of treatment can be agreed with the Medicines Agency for expensive cancer treating products: in such way if the product is not successful for the patient the cost is borne by the pharmaceutical company.

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 in collaboration with an "accredited provider" (hospital, scientific association, national research institute or training agency) who has the main responsibility on the scientific contents of the programme and on the selection of the speakers. Sponsorship of ECM events

by pharmaceutical companies are authorised by AIFA with the assistance of a National Commission established within the Ministry of Health. The contribution of the company to the event must be disclosed to the Ministry of Health and to AIFA and it is also disclosed on the event programme. A company may propose a programme and its content, choose the venue and suggest the speakers. Conflict of interests between speakers and sponsor must be disclosed to those in attendance and for this purpose the speaker must file a declaration of interest.

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 Italian Medicines Agency. In order to obtain the authorisation, an application containing, *inter alia*, the details of the expenses is to be submitted 60 days before the day of the meeting by the pharmaceutical company to the Italian Medicines Agency, 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 AIFA.

Contribution to an event and offer of hospitality are subject to several restrictions and limitations (see question 5.2 below) which are applicable also 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 more strict limitation 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.

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. For the years 2009 and 2010 the venue of the congress can be a 5 stars hotel in case of national or international congresses organised by Scientific Societies having a number of participants higher than one thousand and five hundred (1,500). Hospitality at the 5 star hotel premises can be offered only to foreign participants; for the Italian doctors the restriction to 4 stars hotel shall continue to be applicable. 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.

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 pharmaceuticals 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).

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 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?

Consistent with article 8 of the Community Code, 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?

Disease awareness campaigns are 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 not having an advertising character but 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 will therefore be possible only to distribute 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. 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.

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 nor 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 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. In Italy various pharmacies sell on their websites OTC products to be delivered directly to the customer by mail. An important decision of the EU Court of Justice, issued in the case C-322/01, has confirmed the lawfulness of such practice: the Court of Justice specified that such possibility is limited to OTC products and, therefore, advertising and sales through the internet of prescription medicines is not allowed.

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.

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 Farmindustria Code of Professional Conduct and by a letter of the Ministry of Health dated 22nd March 2000 ("Internet sites and advertising of medicinal products for human use") 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 the direct or indirect links to other websites appearing in the websites of pharmaceutical companies it 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 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 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.

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

In the abovementioned Circular Letter of the Ministry of Health it is specified that promotional material having 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.

In 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.

There are no codes of practice on advertising issued by the Italian Medical Device Business Associations.

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.

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.

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 the 6th July 2006 the rules relating to pharmaceutical advertising are those set forth in sections 113-128 of the new Legislative Decree 24th April 2006, No 219 that has implemented the EC Directives on the "Community Code" of Medicinal Products for human use. One of the most significant changes in respect to the rules contained in the previous Decree No 541/1992 is the introduction of the tacit approval for advertising to the general public and the reduction of the period for the tacit approval of promotional information addressed to health professionals from 45 days to 10 days.

The 2008 version of the Farmindustria Code introduced new rules regarding relationships and scientific cooperation between health professionals and pharmaceutical companies.

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

No significant developments are expected.

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

During the last years, as a result of decisions of Farmindustria, there has been a significant reduction in the sponsorship of conferences and in particular in the hospitality offered to health professionals for attendance to such medical conferences. New rules issued by Farmindustria have introduced restrictions in the number of invitations per year per physician, limitations for airplane economy class tickets and hotel category and have imposed that at least 10% of the physicians participating in such events are under 35 years of age.

In the recent years several pharmaceutical companies have been involved in criminal proceedings and have been sanctioned for offences committed by their managers and sales representatives to force the sale of medicinal products reimbursed by the Italian National Health service.

Legislative Decree No. 231 of 8th June 2001 (hereinafter "the Decree") introduced in the Italian legal system the administrative liability of legal entities, companies and associations, in respect to certain criminal offences committed - in the interest or to the benefit of the entity - by individuals who have particular managing or collaborating relationships with the entity itself.

The offences in respect of which the Decree contemplates the administrative liability of the legal entity include those committed against the Public Administration, as provided by articles 24 and 25 of the Decree (for example, undue receipt of public subsidies, fraud against the State, bribery and corruption of public officials and public servants).

The sanctions applicable to the legal entity held responsible for the above offences, affect both the entity's assets and its freedom of action, they are of pecuniary nature and of interdictive nature (for example disqualification from the activity; ban from dealing with the Public Administration, including participating to public tenders; exclusion from State financial subsidies, etc.).

Several pharmaceutical companies operating in Italy (both those belonging to multinational groups and the local pharma-companies)

have adopted the measures set forth in the Decree in order to prevent the occurrence of the criminal offences and reduce the risk of being affected by such "administrative liability" in case a criminal offence is committed by a manager, officer, sale representative or consultant.

Although the adoption of such measures (i.e. the Organization and Management Self-protection Model , the Ethic Code and the institution of a Supervisory Board in charge of verifying the compliance with the Model) does not guarantee to the company the exemption from the administration sanctions in case of occurrence of a criminal offence (because the public prosecutor and the judge have a discretionary power to evaluate the efficacy of actual measures adopted by the company), the generality of the companies operating in the pharma business have considered important to adopt suitable control measures and, indeed, there have been precedents of criminal proceedings involving the "administrative" liability of pharma companies for corruption and fraud to the National Health System (illegal arrangements between physicians, pharmacists and sales representative to supply reimbursable medicinal products on the basis of false prescriptions) in which the companies which have been able to prove to have adopted and implemented suitable control models have reduced or obtained exemption from the "administrative" liability.

During the year 2009 AIFA issued Guidelines addressed to its employees regarding their participation as experts to events such as congresses or written publications. According to such guidelines the members of the Medicines Agency can participate only in events organised by no-profit associations (excluding therefore pharmaceutical companies, but including professional associations and scientific societies) and the participation is to be approved by the General Management of the AIFA after having ascertained that the topic of the event is relevant and of interest for the Agency and that there are no conflict of interests from the participation of the AIFA member to the event.

9.4 Has your national code been amended in order to implement the current version of the EFPIA Code of October 2007?

The latest edition of Farmindustria Code of Professional Conduct (2008) contains references to the EFPIA Code (section 1.1 of the Code) to regulate possible interactions between the two texts and in particular to regulate the applicable provisions in the event of congresses or seminars held abroad.

According to section 1.8 of the Code: *promotional initiatives taking place in Italy, sponsored by companies with head offices in or outside Europe, are subject to the application of the Code of Professional Conduct of the country in which the pharmaceutical companies sponsoring the events are located, and to the application of the EFPIA Code. In case Italian health professionals are involved, the Farmindustria Code of Professional Conduct shall apply.*

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

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