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General Chapter:

Country Question and Answer Chapters:

EDITORIAL

Welcome to the fourteenth edition of *The International Comparative Legal Guide to: Pharmaceutical Advertising*.

This guide provides the international practitioner and in-house counsel with a comprehensive worldwide legal analysis of the laws and regulations of pharmaceutical advertising.

It is divided into two main sections:

One general chapter. This chapter provides an overview of off-label use in the EU and U.S.

Country question and answer chapters. These provide a broad overview of common issues in pharmaceutical advertising laws and regulations in 29 jurisdictions.

All chapters are written by leading pharmaceutical lawyers and industry specialists and we are extremely grateful for their excellent contributions.

Special thanks are reserved for the contributing editor Ian Dodds-Smith of Arnold & Porter Kaye Scholer LLP, for his invaluable assistance.

Global Legal Group hopes that you find this guide practical and interesting.

The *International Comparative Legal Guide* series is also available online at www.iclg.com.

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PREFACE

It is a pleasure to have again been asked to provide the preface to *The International Comparative Legal Guide to: Pharmaceutical Advertising*, which is now in its fourteenth edition.

This year the guide contains one general chapter written by Arnold & Porter Kaye Scholer LLP and 29 individual chapters, the new ones of which are Russia, Singapore, Taiwan and Ukraine. The general chapter comprehensively covers the area of medicine off-label use in the EU and the U.S. Despite plenty of activity in the area, including a European Commission Report, the chapter suggests that little has been decided in either jurisdiction in this vexed area to provide certainty for manufacturers, and thereby patients, going forward.

As with other current editions in the ICLG series that I use as a reference point, this edition will be my first port of call when faced with thorny questions concerning pharmaceutical advertising.

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1 General – Medicinal Products

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

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

The Code of Professional Conduct issued by "*Farmindustria*", the Italian association of pharmaceutical industries, contains several provisions dealing with the advertising and promotion of medicinal products. The Code is frequently updated; the last update is dated October 2016. The rules of the Code have no legal force and are binding only for the members of the association.

1.2 How is "advertising" defined?

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

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

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

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

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

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

The Italian law does not require a "sign off" procedure for the approval of promotional material, but the Code of Professional Conduct of the Italian pharmaceutical industry association (*Farmindustria*) requires that each member company shall produce by 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 or to employ personnel with a specific role? If so, what aspects should those SOPs cover and what are the requirements regarding specific personnel?

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

activity are set forth in the Decree and concern the director of the Scientific Service who is responsible for the information on products placed on the market. The director of Scientific Service must have a degree in medicine or pharmacy or similar scientific degree as specified in the relevant provision. (Section 126 of the Decree). The Decree also requires that all the personnel (reps/in charge of promotion *vis-à-vis* HCPs) have a degree in specified medical or life scientific disciplines (Section 122).

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

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

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

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

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

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

1.7 What are the penalties for failing to comply with the rules governing the advertising of medicines? Who has responsibility for enforcement and how strictly are the rules enforced? Are there any important examples where action has been taken against pharmaceutical companies? If there have not been such cases please confirm. To what extent may competitors take direct action through the courts in relation to advertising infringements?

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

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

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

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

The decisions taken by the Italian Medicines Agency and the MOH regarding infringements of the advertising rules set forth in the Decree are not published; however, since 2010, a yearly report on advertising to HCPs is published by AIFA. Such report outlines the activity carried out by the Agency and the main irregularities of the advertising materials submitted to AIFA: it contains interesting guidance on the correct contents of advertising material to HCPs. Normally the Italian Antitrust Authority (*Autorità Garante della Concorrenza e del Mercato* ("*AGCM*")) 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. AIFA and AGCM on 19th January 2017, signed a memorandum of understanding in order to increase enforcement in the pharmaceutical sector by strengthening their investigation powers and facilitating the exchange of data. The two authorities agreed that they will inform each other on cases concerning alleged violations of rules enforced by one of them.

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

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

The only relationship between Self-Regulatory Bodies and the competent authority regarding advertising of medicinal products is set forth in Section 118.6 lett. b) of the Code, pursuant to which if the advertising message of OTC products is approved by a recognised Self-Regulatory Body of the most important association of advertisers, it is possible to avoid the approval of the special Experts' Commission of the Ministry of Health: in such case, the approval of the Self-Regulatory Body replaces that of the Experts' Commission.

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

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

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

2 Providing Information Prior to Authorisation of Medicinal Product

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

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

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

For the sake of completion, it should be added that off-label use of pharmaceutical products has been at the centre of great debate in Italy after the decision in March 2014 by the AGCM in the case *Roche-Novartis/Farmaci Avastin e Lucentis*.

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

The decision of the AGCM was appealed by Roche and Novartis before the Administrative Court (TAR Lazio), who confirmed the fine, but the TAR ruling has been further appealed by the two pharma companies before the Council of State.

On 11 March 2016, the Council of State, with order n. 966/2016, decided to submit a number of questions to the ECJ for a preliminary ruling on the correct interpretation of Section 101 TFEU in connection with the determination of the relevant market for a medicinal product utilised off-label.

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

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

Information regarding clinical trials carried out in respect of an unlicensed medicinal product or off-label indications can be published in the scientific press or when the information is of interest to the general public (for instance, when it concerns a significant development in an area/disease of general interest); the information can also be published in the lay press, provided that the commercial name or trademark of the product is not mentioned. The Decree (Section 124.7) provides that at "International" congresses, the distribution, in the original language, of information material complying with the marketing authorisation issued in the foreign country is permitted, provided that healthcare professionals of such foreign country are attending the meeting. See also the answer to question 3.6 below.

2.3 Is it possible for companies to issue press releases about unauthorised medicines and/or off-label information? If so, what limitations apply? If differences apply depending on the target audience (e.g. specialised medical or scientific media vs. main stream public media) please specify.

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

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

As indicated above, all information distributed to healthcare professionals must be previously submitted to the Italian regulatory authority and may be utilised only after the elapse of 10 days after the filing with the AIFA. Information regarding an unlicensed medicinal may not be sent to health care professionals by the initiative of the pharmaceutical company.

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

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

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

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

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

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

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

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

A general rule on collaboration between healthcare professionals and pharmaceutical companies is set forth in section 4.1 of the Farmindustria Code of Conduct and it is therefore applicable to any relationship with a healthcare professional. According to such rule, pharmaceutical companies may collaborate with healthcare professionals for consultancy services (such as speakers at congresses, participation in observational studies, training and educational services, advisory boards) provided, however, that the following criteria are fully complied with: i) the agreement with the healthcare professional is in written form; ii) the healthcare professional must undertake to disclose his relationship with the pharmaceutical company whenever he speaks or writes in public on a subject which is part of the consultancy agreement; iii) any compensation paid to the healthcare professional for such consultancy must be reasonable and appropriate, taking into account the "market value" of the services rendered; and iv) the company must keep the documentation on the consultancy agreement for a period of at least three years and the decision on such initiatives are to be taken at the higher executive management level of the company.

Moreover, when the healthcare professional is a full-time employee of a Public Body (such as a public health structure or public hospital), the prior consent of the employer is required when a compensation is paid to the healthcare professional.

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

3 Advertisements to Healthcare Professionals

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

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

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

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

The Code of Professional Conduct of Farmindustria provides that the information contents of any advertising message of medicinal products must always be documented and documentable. Exaggerated statements, universal and exaggerated claims and indemonstrable comparisons without any objective basis are inadmissible. Apart from ministerial authorisations, no omni comprehensive statements are admissible, such as "the preferred drug", "absolutely innocuous", "fully tolerated" or similar, and no categorical assertions must be made stating that a product has no collateral effects or toxicity risk. Both the Decree and the Code of Professional Conduct provide that scientific citations must accurately portray the meaning intended by the author(s). The texts, tables and other illustrations taken from medical reviews or scientific works must be reproduced faithfully and in full, and with an exact indication of the source. No citations are admissible that appear partial and/or contradictory with respect to the author's intentions when separated from the context in which they originally appeared.

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

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

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

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

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

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

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

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. References to competitor's product or indication which had not yet been authorised in Italy or in EU (centralised authorisation) may be possible if supported by comparative clinical trials.

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

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

Distribution of scientific papers and/or proceedings of congresses to healthcare professionals is permitted subject to prior submission to the Italian Medicines Agency ("AIFA"), pursuant to the 10-day negative clearance system described in question 1.5 above.

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

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

4 Gifts and Financial Incentives

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

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

Free samples can be provided only to healthcare professionals authorised to prescribe the product and samples can be supplied by the sales representatives of the company only in response to a written request Pharmaceutical companies must keep evidence of such requests for an 18-month period.

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

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

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

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

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

According to article 123 of the Decree, the offer or promise of gifts of pecuniary or other kinds of advantages to healthcare professionals or pharmacists in connection with the promotion of medicinal products is prohibited, unless they are of "negligible value" and they are relevant to the practice of the healthcare professional. In addition, practitioners must not solicit or accept any such prohibited gifts.

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

The Decree does not contain a criteria/amount to consider a gift of "negligible value" established. The Decree of the Ministry of Health on 14th April 2008 expressly permitted the gifts of scientific publications and books, registration to medical and scientific online newsletters, CDs, DVDs or a password for access to a website of scientific content which has a higher value to the operative departments of public hospitals/public health structures and healthcare professionals belonging to such structures.

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

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

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

Donations of equipment or contracts providing the free use of equipment are also possible, but in order to avoid abuse (such as donations made in order to promote the sale of spare parts or of medical devices necessary for the regular functioning of the equipment) strict limitations have been introduced as to the terms and conditions for acceptance by the public entity of such gifts. Direct funding of the costs or donations of money are generally not admitted by the statutes of the public bodies. No monetary limits are provided. Donations of significant amount (the limit is generally those in excess of 20,000.00/30,000.00 Euro) shall require the notarial form.

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

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

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

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

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

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

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

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

As described in questions 4.3 and 4.4 above, this kind of arrangement is generally 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?

Refund schemes are a consolidated practice introduced by AIFA during negotiations for price and reimbursement of expensive prescription-only medicines, the following are the schemes typically applied:

- 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.

Such schemes are in continuous evolution and creative solutions are often submitted by AIFA during price and reimbursement negotiations in particular in respect to innovative expensive new products.

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

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

4.9 What general anti-bribery rules apply to the interactions between pharmaceutical companies and healthcare professionals or healthcare organisations? Please summarise. What is the relationship between the competent authorities for pharmaceutical advertising and the anti-bribery/anti-corruption supervisory and enforcement functions? Can and, in practice, do the anti-bribery competent authorities investigate matters that may constitute both a breach of the advertising rules and the anti-bribery legislation, in circumstances where these are already being assessed by the pharmaceutical competent authorities or the self-regulatory bodies?

Rules aimed to prevent corruption of the health care professionals and health care organisations of the National Health System are contained in the Decree which i) prohibits gifts to HCPs except those of negligible value and linked to the professional use, and ii) regulates congress and conferences sponsored by the industry by requiring the prior authorisation of AIFA, controlling the relevance and scientific contents of the event, restricting hospitality offered to HCPs. There is no relationship at the moment between the regulatory authority in charge to control such promotional activity (AIFA) with the anti-bribery and anti-corruption enforcement authorities (Criminal Investigations) or self-regulatory bodies (Farmindustria). Criminal investigations which have involved alleged corruption and bribery by pharma companies often originated by investigations carried out at the Public Hospitals by investigational police and involved also grants for clinical studies. Farmindustria controls through yearly audits carried out by certified auditing companies the promotional activities of its members. Implementation of the transfer of value disclosure encourages transparency as anti-corruption measure. Several pharmaceutical companies operating in Italy (both those belonging to multinational groups and the small local pharma-companies) have adopted the measures set forth in the Decree 231/2001 in order to prevent the occurrence of the criminal offences and reduce the risk of being affected by the "administrative liability" in case specific criminal offences are committed by a manager, officer or consultant.

5 Hospitality and Related Payments

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

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

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

Contributions to an event and offers of hospitality are subject to several restrictions and limitations (see question 5.2 below) which are also applicable to events being held abroad. Hospitality to Italian healthcare professional offered in another country shall be subject to the prior authorisation of AIFA and it is the responsibility of the local affiliate to comply with the Italian rules.

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

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

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

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

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

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

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

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

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

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

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

In general, it is possible to pay a healthcare professional a fee for attendance as a speaker at meetings or focus groups (see question 5.2 above). The Code of Farmindustria outlines certain requirements which must be followed in order to enter into scientific cooperation agreements with doctors (see also question 5.7 below).

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

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

Clinical trials of marketed medicinal products may only be approved pursuant to specific regulations. The performance by pharmaceutical companies of observational clinical studies is subject to compliance with the provisions laid down in the AIFA Resolution of the 20th March 2008, which established the guidelines for the classification and conduct of observational studies and with Section 4.3 introduced in the 2008 edition of Farmindustria Code of Professional Conduct. Payments for such studies are made to the institution where the study is conducted (local health office, hospital, university, etc.) and not directly to the doctors. Pharmaceutical companies may provide the investigators involved in such trials with instrumental and software support (excluding hardware). Supply of the above-mentioned tools must be conducted via the institutions involved in the study, i.e. local health offices, universities, hospital boards, etc., and their use must be exclusively for the purpose of completing the studies. At the end of the study, the equipment or tools must be returned and evidence of the re-delivery must be kept by the pharmaceutical companies concerned.

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

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

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

6 Advertising to the General Public

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

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

Any advertising message must be authorised by the Ministry of Health (see question 1.5 above).

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

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

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

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

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

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

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

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

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

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

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

6.4 Is it possible to issue press releases concerning prescription-only medicines to non-scientific journals? If so, what conditions apply? Is it possible for the press release to refer to developments in relation to as yet unauthorised medicines or unauthorised indications?

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.

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

No regulatory provisions address this issue. Article 1.1 of the Farmindustria Code excludes from the scope of the Code the communication of non-promotional information on the company's activities, such as those addressed to investors and the press including financial data and descriptions of research and development programmes.

The publication of such information is permitted and is in compliance with the Italian corporate rules when it is related to a potential important development for the company's business and it does not contain the commercial name of the new product, and when it specifies that the product is not yet licensed in Italy. It is important that the message provides financial and scientific information to the shareholders and financial community and does not have a mere

promotional nature. The Farmindustria Code (Section 1.1) provides that at such communication events no hospitality should be offered to healthcare professionals attending the event except in special circumstances with the prior authorisation of the Audit Committee.

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

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

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

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

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

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

Pharmaceutical companies must include within their own internet sites a list of the patient associations that they sustain.

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

No regulatory provisions or Farmindustria code address this issue. Direct delivery to the patients is excluded because it would be in conflict with data protection rules and advertising rules. Items for the benefit of patients may be provided through the health structure or the health care professional provided they have no advertising content.

7 Transparency and Disclosure

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

Posting of clinical trial summary results in European Clinical Trials Database (EudraCT) has become mandatory for sponsors as of 21st July 2014.

A general obligation for companies to disclose the expenses incurred for clinical trials was introduced in 2014 in the Farmindustria Code issued in February 2014. The newly established article 5.8 (R&D Expenses), and became effective from the year 2016 with reference to the data of the previous year, provides that expenses for research and development (i.e. trials as defined by the Good Laboratory Practice, clinical trials as defined by Directive 2001/20/CE and prospective observational studies which imply collection of data by single or a group of doctors) must be disclosed on an aggregate basis on the website of the company.

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

7.2 Is there a requirement in the legislation for companies to make publicly available information about transfers of value provided by them to healthcare professionals, healthcare organisations or patient organisations? If so, what companies are affected (i.e. do these requirements apply to companies that have not yet been granted a marketing authorisation and/or to foreign companies), what information should be disclosed, from what date and how?

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

7.3 Is there a requirement in your self-regulatory code for companies to make publicly available information about transfers of value provided by them to healthcare professionals, healthcare organisations or patient organisations? If so, what companies are affected (i.e. do these requirements apply to companies that have not yet been granted a marketing authorisation and/or to foreign companies), what information should be disclosed, from what date and how? Are companies obliged to disclose via a central platform?

The disclosure rules introduced in the Farmindustria Code have become effective in 2016 in respect to transfer of values effected in the year 2015 and shall be carried out on an annual basis. If the Company is a member of Farmindustria the disclosure requirements apply also to companies that have not yet been granted a marketing authorisation.

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

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

Transfer of value to HCPs regarding the participation in congresses and events (limited to the participation fees, travel and accommodation) and consultancy services rendered according to written agreement must be disclosed on an individual basis. In the case a HCP refuses to give his consent, the disclosure can be

effected on an aggregate basis. Transfer of value to HCOs regarding donations and grants (either cash or benefits in kind), contribution to costs related to congresses, including sponsorship to HCPs to attend such events, and fees for services and consultancy arising from a written agreement must be disclosed on an individual basis.

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

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

Each pharma company member of Farmindustria shall make best efforts in order to obtain the consent of individual healthcare professionals to the publication, utilising an appropriate informative and consent form in compliance with the Italian Privacy Code. In the case an individual healthcare professional refuses to give his consent, the disclosure can be effected on an aggregate basis. In such case for each category of transfer of values it shall be specified:

- the number of beneficiaries covered by such disclosure, both on an absolute basis and as a percentage of the total beneficiaries;
- the aggregate data attributable to the non-consenting HcPs; and
- the percentage of transfers of value as an aggregate of the total transfers.

8 The Internet

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

The Decree does not contain specific provisions on the advertising of medicinal products through the internet or through websites of pharmaceutical companies. Therefore, the ordinary rules on the advertising of medical products are applicable, including the distinction between advertising to the general public and to healthcare professionals.

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

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

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

Furthermore, starting from the end of June 2016 the pharma companies members of Farmindustria must disclose via their web site any transfer of value effected in favour of a HcP/HcO (as defined in the EFPIA Code) during the preceding year.

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

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

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

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

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

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

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

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

(i) use of a link to address the visitor of a pharma company website to another website which contains authorised advertising material is allowed providing, however, that a warning stating: "*the user is leaving the (company's) website containing promotional materials authorised pursuant to the legislation on pharmaceutical advertising actually in force*", is given;

(ii) use of a link to address the visitor of a website containing authorised promotional materials to a different website not containing promotional materials in the Italian language subject to the authorisation (i.e. general information on health education) is allowed providing that the same above-mentioned warning is given; and

(iii) use of a link to address the visitor of a website containing authorised promotional material to a different website containing material which is subject to the authorisation, but has not been authorised is not allowed.

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

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

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

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

The Farmindustria Code contains the obligation for pharmaceutical companies to publish on their websites, for at least three months during the first quarter of each year, any amount granted to patient associations and the scope of the grant and the obligation to publish the information regarding the transfer of values to healthcare professionals and health care organisations as described in questions 7.3, 7.4 and 8.1 above.

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

The use of social media by pharmaceutical companies is regulated for OTC medicinal products by recent Guidelines issued by the MoH on 6th February 2017.

Pursuant to these Guidelines, it is permitted to provide advertising messages (imagine, script, video, audio) using Facebook only on the right column of the "wall" of the social network. This kind of insertion shall contain only an imagine (single/multiple), a short text, and the link to the website.

The content of the advertising message through social media must be previously authorised by the MoH as describe in question 1.5 above. Under the Guidelines, when submitting the advertising message to the MoH for the relevant approval, the company must also specify to which website the message shall redirect the user.

For what concern YouTube, the channel can be utilised for advertising messages which have been already authorised and with the interaction buttons (like, share, comment) turned off.

Finally, under the Guidelines, advertising through other social media such as Instagram and Twitter is not allowed.

9 Developments in Pharmaceutical Advertising

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

The increase in the use of web platforms of the Regulatory authority to manage clinical trials, regulatory procedures, advertising authorisation and price and reimbursement procedures continues.

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

It is expected that the transparency rules introduced in 2016 may increase interest of press and general public to interrelations of industry with health care professional with possible impact on advertising initiatives such as conferences and meetings and on grants and donations to healthcare organisations.

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

There has been a general trend of the Public Health structures to restrict authorisations for remunerated consultancy agreements between HcP and pharma companies. Introduction of an Anti-corruption officer/watchdog in all the public health structures responsible increased the set of practices and regulations aimed to preventing corruption and conflicts of interest and increasing transparency.

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