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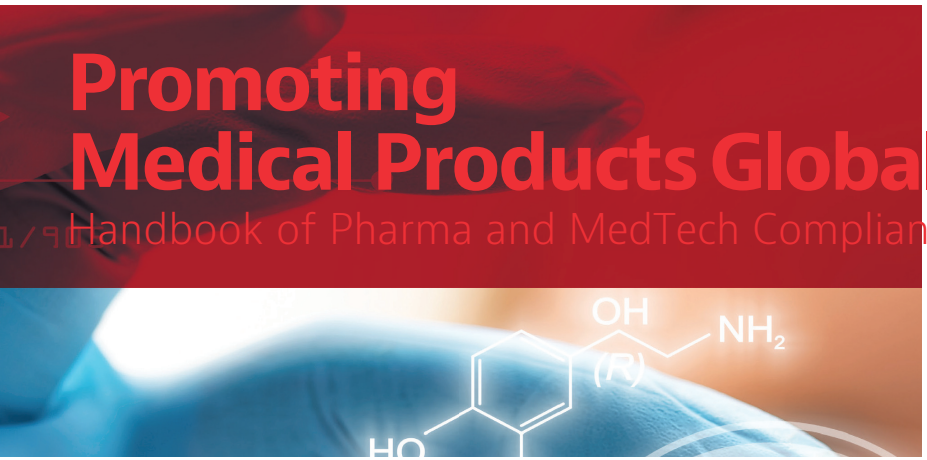
Promoting Medical Products Globally

Handbook of Pharma and MedTech Compliance



ITALY

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Introduction

The promotion of medicine and medical devices in Italy is controlled, in the first instance, by national legislation (implementing, in many instances, Community Directives), but also involves the application of various regulations, guidelines and codes of conduct issued by regulatory authorities and national and international industry associations. When issues arise not specifically provided for in the materials pertaining to medical devices, the trend is to apply principles found in rules and codes developed for medicine and medicinal products.

Broadly speaking, the promotion of medicine and medical devices to healthcare professionals (HCPs) is governed by concerns for accuracy in information, adequacy in education and training, and the avoidance of undue influence over HCP decision-making (including purchasing decisions by public entities). To this end, there are a number of restrictions on how information may be presented to HCPs with respect to seminars, panel discussions, promotional events and the like.

With regard to advertising to the public, it is forbidden to promote medicine and medical devices that require an HCP's prescription or that must be used with the assistance of an HCP. Advertising messages addressed to the public, if allowed by relevant legislation, must in any case be approved in advance by an Advisory Board operating at the Ministry of Health (MoH).

Regulatory Framework

Laws Governing the Promotion of Medicine and Medical Devices

Various pieces of legislation apply to the advertising of medicine and medical devices in Italy, particularly:

- Legislative Decree No. 219 of 24 April 2006 (LD 219), implementing Directive 2001/83/EC, as amended, on the Community Code on medicinal products for human use;
- Section 21 of Legislative Decree No. 46 of 24 February 1997 (LD 46), implementing Directive 93/42/EEC on medical devices;
- Ministerial Decree of 23 February 2006 on medical devices advertising (MD);
- Section 2598 of the Italian Civil Code dealing with unfair competition practices (an aspect which may be relevant in medical devices advertising strategies);
- Legislative Decree No. 206 of 6 September 2005, implementing Directives 84/450/EEC on misleading advertising and 97/55/EC on comparative advertising; and
- On the regional level, the "Guidelines for regional regulations regarding scientific information relevant to medicines" issued on 26 April 2006, providing detailed rules regarding scientific information and advertising of medicine and medical devices to doctors and pharmacists by scientific informers. Based on said Guidelines, the Regions adopted their regulations.

In more detail:

LD 219 sets forth a detailed discipline on advertising to the public and to HCPs. In general terms, it prohibits any advertising of a medicinal product for which a marketing authorization has not been granted. The advertising of a medicinal product must encourage the rational use of

the medicinal product, i.e., by presenting it objectively and without exaggerating its properties, and must not be misleading.

Advertising to health professionals may be made by another pharmaceutical company jointly with the marketing authorization holder by a company that, on the basis of a specific agreement with the holder of the marketing authorization, actually distributes the products in the entire national territory. This means that in Italy, both co-marketing and co-promotion agreements are allowed.

Advertising to the general public of medicinal products that are available on medical prescription only or that contain psychotropic or narcotic substances is prohibited. The prohibition on advertising to the general public also applies to medicine that is reimbursed, even partially, by the National Health Care Service. Notwithstanding these prohibitions, the MoH may authorize vaccination campaigns promoted by the industry. Moreover, the distribution of medicine to the public for promotional purposes is prohibited.

In publications, radio or television broadcasting, or any non-promotional messages to the general public, it is prohibited to mention the name of a medicinal product in a context where this results in the promotion of the consumption of the product.

As for promotion to HCPs, any advertising of a medicinal product to persons qualified to prescribe or supply such products shall always include the essential information contained in the summary of product characteristics of the product authorized at the time the advertising is disseminated, specify the supply classification of the medicinal product and specify the sale price and the conditions for reimbursement by the National Health Care Service.

The documentation on the medicinal product must be filed before the advertisement with the Agenzia Italiana del Farmaco (i.e., the Italian Pharmaceutical Agency) at the MoH and can be supplied to the HCP after the expiration of a term of 10 days from the filing.

Pursuant to Section 118, paragraph 14 of LD 219, certain provisions on advertising medicinal products also apply to medical devices (please see above). Furthermore, the general principles and rules on advertising medicinal products to HCPs are deemed applicable also to medical devices, in line with the trend to regulate the promotion of medicinal products and medical devices to HCPs in the same manner.

Pursuant to Section 21 of LD 46, it is prohibited to advertise to the general public medical devices that must be ordered by, chosen by or ultimately used with the assistance of an HCP.

On the other hand, the advertising of medical devices that do not need an HCP's prescription or assistance must be authorized by the MoH. If the MoH does not send any response to the applicant within 45 days from the application, the advertising of the medical device must be considered implicitly approved.

According to the MD, the categories of medical devices that shall not be advertised to the general public are the following: custom-made medical devices, medical devices that must be ordered by or chosen by an HCP, and medical devices that must be used with the assistance of an HCP.

Section 3 of the MD states that advertising by a company that intends to promote only its own image without referring to a specific product (institutional advertising) must be subject to the general regime for advertising and not to the specific restrictions provided by Italian law on promotion of medical devices.

Section 2598 of the Civil Code states that it is illegal to damage a competing company, in violation of the principles of professional fairness, and to publish information related to competing companies or their products, which may cause damage to the same companies.

Section 2. d of Legislative Decree No. 145 dated 2 August 2007 defines comparative advertising as "any advertising which explicitly

or by implication identifies a competitor, or goods or services offered by a competitor."

According to Section 4 of the same decree, comparative advertising is permitted when the following conditions are met: the proposed comparative advertising is not misleading; it compares goods or services with the same needs or intended for the same purpose; it compares objectively one or more material, relevant, verifiable and representative characteristics of goods and services, which may include price; it does not create confusion among traders; it does not discredit or denigrate trademarks, trade names or other distinguishing marks, goods, services, activities or circumstances of a competitor; for products with designation of origin, it relates in each case to products with the same designation; it does not take unfair advantage of the reputation of a trademark, trade name or other distinguishing marks of a competitor or of the designation of origin of competing products; and it does not present products or services as imitations or replicas of products or services bearing a protected trademark or trade name.

Codes of Conduct and Regulatory Provisions

Further provisions and codes of conduct governing advertising of medicine and medical devices are the Circular of the Ministry of Health dated 28 March 2013 (Circular), for which guidelines were issued on the use of new means of dissemination of advertising of medicine and medical devices, the Code of Ethics of Farmindustria — association of the Italian pharmaceutical industries (Farmindustria Code) and the Code of Ethics issued by Assobiomedica (ABM Code) — Italian Association of Medical Device Companies — which sets forth ethical guidelines regarding the organization of events held by companies for promotional purposes.

The Circular lays down, among others, rules on the use of toll-free numbers in advertisements. The operators of the toll-free numbers are only allowed to provide technical information on medical devices that due to their complexity or to technological innovation require technical assistance for their use. Pre-recorded messages addressed to

the public with a promotional nature are subject to prior authorization by the MoH.

The dissemination of information about medicine and medical devices to healthcare professionals via the internet is permitted without the MoH's authorization, however, the spread of this information must be on websites or on web pages only intended to be viewed by HCPs. To this end, companies must inform the users through a specific disclaimer that the information provided on the sites are only addressed to HCPs. According to the Circular, advertisements authorized by the MoH cannot be automatically published on the internet; further approval is necessary.

Finally, the Circular allows the dissemination of information by email or MMS, with prior permission, only if the company selling medical devices has received a request from the client and the authorization to process the client's personal data. It is not permissible to disseminate advertising via SMS.

Under the ABM Code and the Farmindustria Code, companies are allowed to promote their products by inviting HCPs to workshops and conferences, for which the companies pay registration fees and any reasonable travel and accommodation costs incurred by the HCPs. In such a case, pursuant to the Farmindustria Code, pharmaceutical companies would be required to disclose the amounts paid for registration fees and/or travel and accommodation costs by publishing the relevant data on their websites. Moreover, if the HCPs attending the company's events (or any event organized to promote the company's products) are employed with the National Health Care Service, the company should send communication to their employee to communicate the initiative.

It is forbidden to pay the lodging costs for an HCP's guests.

Marketing Authorization of Products to be Advertised

Pursuant to LD 219, medicine can be placed on the market only once the marketing authorization has been obtained.

The marketing authorization, according to the national procedure, is granted by the AIFA.

Under LD 46, a medical device bearing the CE mark can be placed on the market or put into use without any further authorization given by the local authorities.

In order to obtain the CE mark, the manufacturer must file an application to determine the quality of the medical device's system with a Notified Body (NB), a technical auditing organization authorized by the MoH, and by the Ministry of Industry, which will examine the file.

If the product complies with the relevant provisions of LD 46, the NB will release a CE declaration of conformity, which is the legal basis for the attachment of the CE mark. Decisions taken by the NB will be valid for a maximum of five years and may be extended for further periods of five years.

Only "class I" medical devices with the lowest safety requirements do not require an application to be filed with an NB. For these devices the relevant manufacturer is allowed to attach the CE mark and place the product on the market after having drawn up a declaration of conformity with the requirements set forth by LD 46 under its sole responsibility.

As a general rule, medicine and medical devices can be placed on the market or put into use only if the relevant marketing authorization and the CE mark have been obtained.

As derogation to the above rule, the following medical devices shall not bear the CE mark: devices intended for clinical investigation, and custom-made devices, provided that the manufacturer is enrolled in the Roster of Manufacturers kept by the MoH, and has communicated to the MoH a list of custom-made devices which have been put into service.

With regard to medicines, the same can be administered to patients — if not authorized — only for compassionate use, provided that they have passed at least phase II of clinical experimentation. In restricted cases, the administration of medicines not authorized in Italy is allowed provided that they are imported from a country in which an authorization has been granted.

Permitted and Prohibited Practices

Pursuant to Italian legislation, an HCP is a physician or other professional enrolled in the professional association recognized by the MoH (e.g., physiotherapist, nurse or podiatrist). We indicate below some of the general rules that pharmaceutical and biomedical companies must follow in relations with HCPs or institutions operating in the healthcare sector, with respect to gifts, sample products, hospitality, entertainment and sponsorship for training, research, employee positions or events.

Gifts

According to Section 123 of LD 219 on advertising of pharmaceutical products (the principles of which also apply to medical devices), no gifts, pecuniary advantages or benefits in kind may be supplied, offered or promised to physicians or pharmacists unless they are of irrelevant value and are in any case instrumental to the practice of medicine or pharmacy.

Furthermore, pursuant to Section 170 of the Consolidated Text of Health Laws (Royal Decree No. 1265 of 27 July 1934 as amended), the physician who inappropriately receives money or other benefits to inflate the number of drug prescriptions or other medical products for pharmaceutical use is punishable by imprisonment of up to one year and with a fine of up to EUR520.

If the pecuniary advantage is offered to HCPs working for public hospitals or entities, the general rules regarding bribery of public officials would apply.

Moreover, according to the Farmindustria Code and the ABM Code, gifts to public officials are authorized if the gifts have a nominal or modest value, and either serve a genuine educational function or are to the benefit of patients. Please note that under Italian law, there is no statutory definition or quantification of "nominal or modest value."

Sample Products

Medicine sample products may be supplied only to physicians authorized to prescribe the same, and must be handed over only by scientific informers. Samples can not be delivered without a written request bearing the date, stamp and signature of the consignee.

Scientific informers can deliver to each HCP, in any visit, two samples of each dosage or pharmaceutical form of a medicine only in the first 18 months following the first marketing of the same and within a maximum amount of eight samples.

As for sample products offered to medical institutions, it is worth noting that the tender regulations published by the awarding authorities usually request to supply a certain number of free samples.

Hospitality

Under the Farmindustria and ABM Codes, hospitality is allowed subject to the following requirements: if the HCP works for a public hospital or entity, a prior written notification should be sent to the employer; the company shall not bear the expenses related to hospitality for accompanying spouses or other guests; and travel, lodging, hospitality and meals must be reasonable and can be offered only for the duration of the scientific event attended by the HCP.

Hotel services must be in hotels with a maximum rating of four stars and air travel must be in economy class only, excluding intercontinental flights. The Competition Authority, in its communication of May 2011, noted the illegitimacy of the ABM and Farmindustria Codes in so far as it prohibits the organization of conferences in five-star hotels on a basis other than the prices they

may charge. This provision is detrimental to competition, to the benefit of lower-category hotels.

Following the communication of the Competition Authority on June 2014, Assobiomedica and the Italian Hotels Association executed a memorandum of understanding according to which the prohibition on the organization of congresses and events in five-star hotels does not apply to those five-star hotels that agree to comply with the moderation requirements indicated above. Conversely, the Farmindustria Code of 2015 ignores the communication of the Competition Authority and persists in maintaining the prohibition, since the luxurious image given by five-star hotels is against the principle of moderation on which the Farmindustria Code is based.

Entertainment

No specific laws or regulations regulate this aspect, apart from the abovementioned rules regarding bribery of public officials and the pecuniary advantage offered to HCPs. However, under the Farmindustria and ABM Codes, on the occasion of conferences and workshops, recreational activities should not prevail over the content of the technical-scientific event and must be characterized by moderation.

Sponsorship for Training, Research, Employee Positions or Events

The Eucomed Code sets forth the following principles concerning sponsorship for training, research, employee positions or events:

- Training − Medical device companies are encouraged to make product education and training available to facilitate the safe and effective use of medical technology.
- Research − Companies may provide funds to support genuine independent medical research, provided that it is not viewed as a price concession, reward or incitement to commit acts contrary to law, that appropriate documentation is maintained and that the recipients are entitled to receive grants under local

rules. Research grants to support customer-initiated studies may be permitted for programs involving clinical or non-clinical research in areas of legitimate interest to the company in question. All requests for research grants must be in writing from the requestor stating the nature and objective of the research activity, and no support should be provided until a written agreement providing for adverse event reporting is signed by both parties. Full disclosure of the award should be made to the healthcare professional's hospital, superior or employer, and the recipient of the grant must acknowledge the sponsorship of the research in all oral or written presentations of the results.

- Employee Positions − Companies may also provide educational grants to training or healthcare institutions or professional societies for medical education programs by providing financial support for fellowships and similar scholarship awards. However, the selection of the grantee should be within the discretion of the institution at which they are enrolled or the teaching institution at which they will be trained, rather than the company sponsor. Grants must be provided to the teaching or professional institution, not to individual fellows, save for the prior written request of the institution. In no way should the funding be tied to an institution's purchase of a company's products, or otherwise based on an institution's past or potential future use of the company's products or services.

- Events − Medical device companies are entitled to provide financial support to cover the cost of third-party educational conference attendance of individual healthcare professionals. Such financial support must be limited to the conference registration fee and reasonable travel, meals and accommodation costs relating to the attendance of the event. Companies must ensure they comply with local rules surrounding such sponsorship, such as disclosure

requirements. In this respect, we note that the Farmindustria Code implements the EFPIA Code also in relation to disclosure of transfers of value from pharmaceutical companies to healthcare professionals and healthcare organizations. Particularly, pharmaceutical companies must annually publish either individual or aggregate data in relation to these transfers of value on their website.

Equipment

The companies marketing medicines and medical devices are authorized to provide equipment to hospitals free of charge if permissible under tender regulations.

Medical device companies are also allowed to enter into charitable donations with hospitals. However, according to the ABM Code, charitable donations entered into with public hospitals and entities should be documented in writing.

Contracts with Healthcare Professionals and Medical Institutions

According to Section 53 of Legislative Decree No. 165 of 30 March 2001, HCPs who work for a public hospital or entity must be authorized by their employer before entering into contracts with private companies (e.g., consulting agreements or research and development agreements). The authorization of the employer is not required for agreements concerning attendance at conferences and seminars (e.g., speaking agreements) and for articles to be published in scientific reviews. That said, following the entry into force of Law No. 190 of 6 November 2012, which amended Section 53 above, private companies must communicate to the concerned public administration the amount paid to the public employee within 15 days from the relevant payment.

According to Section 6 of Law No. 240, dated 12 December 2010, as amended by Law Decree No. 5 of 9 February 2012, university professors and university researchers (a rank below full professors) are no longer requested to obtain the employer's authorization to sign

agreements related to occasional lessons and seminars, scientific and consultancy activities, and dissemination of scientific material.

According to the ABM Code, consulting agreements entered into between medical device companies and HCPs who work for public hospitals and entities must meet the following conditions: the agreement must be documented in writing; the fees paid to HCPs must be reasonable and closely connected to the service performed by the HCPs; the agreement must be entered into only if bearing a legitimate purpose for performing the services; the consultant must be chosen for his qualification and expertise; and if the consultant is engaged for research and development, a research protocol must be approved by the public hospital or entity where the HCP works.

Promotional Practices

As already underlined, according to the applicable laws and regulations on advertising of medical devices, advertising to the general public of categories of medicines and medical devices sold only after a physician's prescription or requiring a physician or other medical professional intervention is forbidden.

As a general rule, the advertising of medicines and medical devices, with very few exceptions, is authorized by the MoH. For that purpose, a specific Advisory Board has been established within the MoH with the aim of evaluating all advertising requests and ensuring full compliance with all applicable laws governing the advertising of medicines and medical devices. In applying for such authorization from the MoH, the manufacturing company or the party responsible for placing the medicine or the device on the market must file all the relevant information regarding the product, the kind of advertising and the relevant means of communication chosen.

Supply of Scientific Data and Literature

In Italy, applicable regulations on medical device advertising do not provide any specific provisions regarding the supply of scientific data and relevant scientific literature. However, the general principles and

rules on advertising medicinal products to HCPs are deemed applicable also to medical devices, in line with the trend to regulate the promotion of medicinal products and medical devices to HCPs in the same manner.

Pursuant to Article 120, paragraph 3 of LD 219, all the information contained in the promotional documentation shall be accurate, up-to-date, verifiable and sufficiently complete to enable the recipient to form his or her own opinion of the therapeutic value of the medicinal product concerned. According to paragraph 4 of the abovementioned article, quotations as well as tables and other illustrative matters taken from medical journals or other scientific works for use in the documentation shall be faithfully reproduced and the precise sources indicated.

Promotional Messages Addressed to the Public

Direct advertising to the general public of medical devices for which a medical prescription is required, or for which a physician or other medical assistance is necessary, is forbidden. It is only permissible to advertise to the public those medicines and medical devices for which a physician's prescription or other medical assistance is not required, provided that the promotional messages were authorized by the MoH.

There are no specific legal provisions with regard to the kind of language to be used in the advertising of medicines or medical devices with the general public, for example, regarding the use of expert terminology. For the categories of medical devices that need to be authorized, the claims need to be approved by the Advisory Board of the MoH.

In Italy, there are no specific provisions forbidding the display of prices in advertising materials.

According to the guidelines provided on the MoH website regarding the application for advertising authorization, in addition to other information, the company must indicate the means of communication chosen for the advertising campaign. The listed means of

communication include TV and movie shorts, radio communications, general press and newspapers, advertising materials for retail shops (such as flyers, brochures, displays and shop windows) and others. Furthermore, on 28 March 2013, the Circular's new guidelines were issued containing clarifications on the permitted contents and methods for the dissemination of advertisements relating to medical devices through new means of delivery (toll-free numbers, web, SMS, MMS, email).

In Italy, there are no specific regulations regarding the use of testimonials to promote medical products. However, according to Section 114 of Legislative Decree 219/2006 on advertising of pharmaceutical products, the principles of which also apply to medical devices, advertising of medicinal products must encourage the rational use of the medicinal product by presenting it objectively and without exaggerating its properties. Moreover, in publications, radio or television broadcasting, or in any non-promotional messages to the general public, it is prohibited to mention the name of a medicinal product in a context where this results in the promotion of the consumption of the product.

With regard to the permission to offer contests, raffles or other procedures where results are determined by chance to consumers who purchase medical devices, the applicable laws and regulations on medical device advertising do not provide any specific provision. However, considering the general trend of regulating the promotion of medicinal products and medical devices in the same manner, Article 5, paragraph 3 of Legislative Decree No. 223/2006, which forbids the organization of contests and competition concerning medicines, may apply.

According to Article 3, paragraph 2 of MD, the advertising of medical device manufacturing or distribution companies is allowed if no additional information regarding the characteristics of such devices is provided. This type of advertising is referred to as institutional and is in accordance with the abovementioned dispositions. No authorization of the MoH is required for it. The same conclusions must be reached

with respect to institutional advertisement of pharmaceutical companies.

Section 113 of LD 219 defines advertising as any form of information, activity or inducement designed to promote the prescription, supply, sale or consumption of medicinal products. In light of such broad definition, a patient information session organized to inform patients about the characteristics and the properties of a company's medical devices would be considered as a way to promote such products.

Liability Under Criminal and Civil Law and the Applicable Codes of Conduct

Companies that violate the provisions of Italian law regarding the promotion of medical devices are punished with administrative fines between EUR2,582.28 and EUR15,493.71. Moreover, unless the MoH decides to proceed by its own initiative, the MoH can order the immediate cessation of the advertising and the dissemination at the expense of the infringing party, or a notice to rectify or clarify the advertising in accordance with the instructions provided by the MoH.

In the case of misleading advertising, the Italian Antitrust Authority may order the infringing party to stop any illegal activity, order rectifying statements to be published at the expense of the infringing party and issue administrative fines between EUR5,000 and EUR500,000.

As for pharmaceutical products, in case of any violation of the rules on advertising to the general public, Article 118 of the Code provides that the MoH can order the immediate cessation of the advertising and the dissemination at the expense of the violator, or a notice to rectify or clarify the advertising in accordance with the instructions provided by the Ministry, unless the Ministry decides to proceed by its initiative. The company is also subject to a pecuniary fine ranging from EUR2,600 to EUR15,600, pursuant to Article 148 of the Code.

In accordance with Articles 127 and 148 of the Code, the same sanctions apply in case of a violation of the requirements set forth for the advertising to persons qualified to prescribe or supply medicinal products. For products that are reimbursed by the National Health Care Service, the violation shall also be punished with the suspension of the medicinal product from the reimbursement regime for a period ranging from 10 days to two years. The suspension is adopted after the notification of the violation to the holder of the marketing authorization that has the right to file its observations within 15 days from the notification.

Article 148 of the Code provides other penalties in case of violation of the requirements for publications, radio and television broadcasting, and messages that do not have promotional content (administrative fine from EUR10,000 to EUR60,000), for free samples of medicinal products (for instance, an administrative fine from EUR5,000 to EUR30,000 for samples that do not bear the "not for sale" marking) and for the scientific service (administrative fine from EUR50,000 to EUR300,000).

Moreover, both the ABM Code and the Farmindustria Code provide that in case of findings of violations of the relevant provisions — including those on advertisement and promotion of medicines and medical devices — the following sanctions can be applied:

(a) warning and request to immediately cease the wrongful behavior;

(b) written reprimand;

(c) temporary suspension from the association; and

(d) exclusion.

In addition, pecuniary fines adjusted according to the seriousness of the violation and the publication in a national newspaper of the decisions taken against the company may also be imposed.

A further potential area of liability for pharmaceutical and biomedical companies stems from Legislative Decree no. 231 of 2001, under which companies will be criminally liable for crimes committed, for the benefit or the advantage of the company, by its representatives (i.e., directors, managers, and other employees). Companies may avoid this liability by implementing the 231 Model, an internal organizational model that sets specific procedures to be followed by managers and employees in order to avoid or to reduce the risk of committing crimes, appoints referents to be informed with regard to the activities carried out by the company and appoints an independent supervisory body that ensures the enforcement of the model.

Recommendations

Stringent laws apply to the promotional activities of medicine and medical devices, and in case of infringement of such rules, the MoH may institute an administrative proceeding and impose sanctions.

Strict compliance with the above-explained administrative rules and self-regulation is are surely the most effective ways a company may minimize the risk of infringing any of the laws governing direct advertising of medicines and medical devices to the general public in Italy.

In Italy, stringent laws and regulations govern the promotion of medicine and medical devices to HCPs and even more so to consumers. These requirements are enforced by the MoH and the AIFA, which have the power to initiate administrative proceedings and impose sanctions in case of noncompliance. Companies wishing to promote medicine and medical devices in Italy need to be aware of existing and proposed rules, as well as the industry's best practices like those promulgated by Farmindustria, Eucomed and Assobiomedica, and implement a regime that ensures the compliance of their employees and their contractors to avoid the risk of serious penalties.

Finally, it is recommended to adopt and implement the 231 Model, including the appointment of a supervisory body with the task of ensuring its enforcement, to avoid the risk of criminal liability in case of crimes committed by directors, managers or other employees.

This third edition of "Promoting Medical Products Globally. Handbook of Pharma and MedTech Compliance" is intended to provide an overview of the applicable compliance laws governing the cooperation between the medical industry and physicians in Europe, North America, Latin America and the Asia Pacific region. It highlights the legal framework within which medical device and pharmaceutical companies cooperate with health care professionals. It deals with common sponsoring practices such as invitations, conferences and financial grants for research, personnel and equipment as well as other promotional activities such as the giving of gifts, samples and other items and services which are of interest to health professionals. We trust that the third edition is a useful resource for lawyers, compliance officers, managing directors and managers in marketing and medical departments of the medical industry to assess the legal impact on their promotion and marketing activities involving healthcare professionals or medical institutions.

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