PROMOTION OF PHARMACEUTICALS AND MEDICAL DEVICES

Authors: Elisa Stefanini, Claudio Todisco and Denise Moretti

GENERAL

1. What laws and codes of practice govern the promotion and advertising of pharmaceuticals and medical devices in your jurisdiction? Please also include any relevant industry and self-regulatory codes.

The laws regulating the promotion/advertising of drugs are the following:

- Legislative Decree No 219/2006 (the 'Italian Code of Medicine'). According to settled jurisprudence, certain rules of the Italian Code of Medicine generally apply also to the promotion and advertising of medical devices (Administrative Court of Milan No 8943/2014);
- Guidelines of the Ministry of Health of 21 July 2023, on the advertising of over-the-counter drugs ('OTCs') and non-prescription drugs ('SOPs'); and
- Code of Ethics issued by Farmindustria, the main industry association of pharmaceutical companies (not legally binding and applies only to Farmindustria members, although it is a guide for companies in the sector, particularly in their relations with healthcare organisations (HCOs) and/or healthcare professionals (HCPs).

As for the regulations governing specifically the medical devices industry, we mention:

- Legislative Decree No 137 of 5 August 2022, on medical devices, adapting national legislation to Regulation (EU) 745/2017 (MDR);
- Legislative Decree No 138 of 5 August 2022, on in vitro diagnostic medical devices, adapting national legislation to Regulation (EU) 746/2017 (IVDR);
- Decree of the Ministry of Health of 26 January 2023, on cases of the advertising of medical devices that do not require ministerial authorisation;
- Guidelines of the Ministry of Health of 20 December 2017, on the advertising of medical devices;
- Guidelines of the Ministry of Health of 27 September 2017, on the use of testimonials for the advertising of medical devices;
- Guidelines of Ministry of Health of 24 October 2019, on the advertising of medical devices on Facebook; and
- Code of Ethics issued by Confindustria Dispositivi Medici, the main industry association of medical device companies (not legally binding and applies only to Confindustria members, although it is a guide for companies in the sector, particularly in their relations with HCOs/HCPs.

In addition to the aforementioned regulations, the following general rules on consumer protection apply both to the pharmaceutical and medical device industries:

- Legislative Decree No 206/2005 (the 'Italian Consumer Code'), specifically the provisions on unfair commercial practices; and
- The Advertising Self-Regulatory Code (the 'IAP Code') by the Advertising Self-Regulatory Institute (the 'Institute'), and the other specific regulations and guidelines from the Institute.

2. How is 'advertising' defined? If relevant in your jurisdiction, what is the difference between promotion and advertisement of pharmaceuticals? Of medical devices?

The Italian Code of Medicine provides for a very broad definition of 'advertising' as 'any action of information, customer research or exhortation, intended to promote the prescription, supply, sale or consumption of drugs'; it includes, in particular: (1) the advertising of drugs to the general public; and (2) the advertising of drugs to persons authorised to prescribe or dispense them.

Any activity falling within this definition is considered 'advertising' and is subject to the relevant rules, without distinction from 'promotion'.

This definition of 'advertising' is generally applied also to the medical devices sector.

3. Which are the regulatory and supervisory authorities that regulate and enforce the promotion and advertisement of pharmaceuticals and medical devices? What is the relationship, if any, between any self-regulatory process and the supervisory and enforcement function of the competent authorities?

The Italian Medicine Agency (Agenzia Italiana del Farmaco or AIFA) is responsible for the advertising of drugs to HCPs, while the Ministry of Health is responsible for advertising of drugs and medical devices to

the general public. For consumer protection, the competent authority is the Italian Competition Authority (Autorità Garante della Concorrenza e del Mercato or 'AGCM').

The additional rules provided for by the associations mentioned above (Farmindustria, Confindustria Dispositivi Medici and the Institute) are binding for members only and are enforced by associations' internal supervisory bodies and juries. There is no formal link between the authority's enforcement and the disciplinary procedures of the associations, and the two procedures may run in parallel.

4. Are there other product types that fall under the same regulations on promotion (and advertisement) as pharmaceuticals, such as food supplements, special nutritional products? If so, are there any special considerations for the promotion (and advertisement) of such other product types?

No, the rules on the advertising of drugs and medical devices do not apply to other product categories. Other products, such as food supplements, are subject to ad hoc rules on advertising and promotion.

CONSUMER MARKETING

5. Is it possible to promote (or advertise) all forms of pharmaceuticals and medical devices (eg, prescription only or professional use products) directly to the public? Are there restrictions on public promotion (advertisement) in your country and if so, which ones?

In Italy, only authorised non-prescription drugs (ie, SOPs, which include OTCs) can be advertised to the general public. Similar rules apply to medical devices because advertising to the public is prohibited: (1) custom-made devices; (2) devices to be used with the assistance of HCPs; and (3) prescription-only devices.

For products that may be advertised to the public, Italian regulations provide for several requirements and restrictions. As a rule of thumb, the advertising of both drugs and medical devices is subject to authorisation by the Ministry of Health.

Each advertisement must comply with minimum and mandatory content: in particular, it must clearly indicate the type of product (drug or medical device), its name and the name of the active substance (not required for drugs if there are two or more active substances), information on the correct use of the product and a recommendation to read the warnings in the package leaflet/instructions of use. Moreover, an advertisement for the public must not contain any element that:

- suggests that consultation with a doctor is unnecessary;
- suggests that the efficacy of the drug/device has no side effects, or is superior or equal to another treatment or another drug/device;
- suggests that the drug/device may improve the subject's normal state of good health;
- suggests that non-use of the drug/device may have a detrimental effect on the subject's normal state of good health;
- is directed exclusively or primarily at children;
- includes a recommendation by scientists, health professionals or persons widely known to the public);
- treats the drug/device in the same way as a foodstuff, cosmetic or other consumer product;
- suggests that the safety or efficacy of the drug/device is due to the fact that it is a natural substance;
- may lead to erroneous self-diagnosis;
- improperly, impressively or misleadingly refers to claims of a cure;
- makes improper, impressive or misleading use of visual representations of changes in the human body due to disease or injury, or of the action of a device on the human body or part thereof.

6. Is promotion (and advertising) of pharmaceuticals and medical devices through the internet and social media regulated in your jurisdiction? If so, what are the rules and related restrictions?

The use of the internet and social media in the advertising of pharmaceuticals and medical devices is regulated: (1) with regard to drugs, by the Guidelines of the Ministry of Health of 21 July 2023, on the advertising of OTC and SOP; and (2) with regard to medical devices, by the Guidelines of the Ministry of Health of 20 December 2017 and subsequent update dated 24 October 2019 (focusing on advertising on Facebook).

The advertising of drugs (OTCs and SOPs) and medical devices on the internet is allowed on both company and third-party websites, as long as they have obtained prior ministerial authorisation. However,

for drugs only, advertising on marketplaces is prohibited to avoid confusing consumers, as OTC and SOP drugs cannot be sold on these platforms.

The use of social media in advertising is regulated, and allowed, only on Facebook, YouTube and Instagram (as well as TikTok for drugs only). As a basic rule, the promotional messages, as approved by the Ministry of Health, must be 'static' and 'unchangeable'. As user interaction with the message could affect these requirements, functions like 'comment', 'share' and 'reactions' to messages/posts must be disabled. On social media, where the 'share' function cannot be disabled for technical reasons, the following disclaimer must be included in all messages: 'The Ministry of Health only approves the content of the advertisement. All comments are the sole responsibility of the user.'

Regarding advertising addressed to HCP's, please see the response to Question 11.

7. Must promotions (and/or advertisements) receive prior approvals from regulators before use and if so, what is the procedure (please provide a high-level description)?

Yes, the advertising of drugs and medical devices is subject to the authorisation of the Ministry of Health (see the response to Question 5). An ad hoc procedure is envisaged for drugs and applies to medical devices as well.

Specifically, the applicant must submit an application using the form available on the Ministry's website, providing all information relating to the company, the product being advertised, the type of advertisement and the relevant distribution medium. An application always relates to a single message, that is, a single piece of text (even if it is intended for several means of distribution, eg, printed matter at the point of sale or printed matter/street posters and billboards); however, a single message may advertise different products, provided the products are owned by the same company, or at least that the same company is responsible for placing them on the market.

If there is no refusal from the Ministry within 45 days of submission, authorisation is deemed to have been granted on the basis of tacit consent. In any case, the Ministry of Health always has the power to suspend promotional activity if it is deemed not to comply with the law.

8. May information on unauthorised pharmaceuticals and/or off-label information be promoted (advertised)? If so, in what circumstances and under which modalities?

No, both forms of advertising are expressly prohibited by law. According to the Code of Medicine, spontaneous and unsolicited requests by patients can be answered by pharmaceutical companies under very strict conditions, on the assumption that such communication does not qualify as advertising but only information.

9. What rules govern comparative advertisements? Is it possible to use another company's information (including brand name) as part of that comparison? If so, which information and under which conditions? Would it be possible to refer to a competitor's product or indication which has not yet been authorised in your jurisdiction?

Comparative advertising is prohibited for both drugs and medical devices, pursuant to the Code of Medicines. In particular, any message addressed to the general public suggesting that the efficacy of a drug/device is superior or equal to another treatment or another drug/device is prohibited.

DEALING WITH HEALTHCARE PROFESSIONALS AND HEALTHCARE INSTITUTIONS

10. How are healthcare professionals defined in your jurisdiction? Is there any regulation that restricts promotional (advertisement) communications directed to healthcare professionals? If so, what are those restrictions?

Italian law does not provide for a general definition of 'healthcare professionals', but rather defines each of the different professionals that can be qualified HCPs. By way of example, the following are considered HCPs: physicians; paediatricians; nurses; midwives; rehabilitation professionals; healthcare professionals in technical-diagnostic and technical-assistance areas; and preventive healthcare professionals.

The advertising of drugs to HCPs who are allowed to prescribe or deliver them must include certain mandatory information (summary of product characteristics, classification of the drug, sales price and the conditions for its reimbursement by the National Health Service) and the relevant materials must be submitted in advance to AIFA. Conversely, there are no specific provisions of law addressing the advertising of medical devices to HCPs, which is generally regulated at the regional level, as well as at the hospital level.

11. Are there specific rules governing promotional (and advertising) activity conducted virtually, including online interactions with healthcare professionals, virtual meetings and participation in virtual congresses and symposia?

In general, when information directed to HCPs is disseminated on the web, dedicated websites or dedicated access areas are required (for both drugs and medical devices), and messages must include a statement that the information contained therein is intended for HCPs only.

Webinars and virtual conferences are permitted, although there is no specific regulation on promotional activities addressed to HCPs carried out remotely.

12. Are there any restrictions to the inclusion of endorsements by healthcare professionals in promotional (advertising) materials? If so, which ones and how such endorsements may take place?

Italian law prohibits the inclusion of 'endorsement by scientists and healthcare professionals' in the advertising of drugs to the general public, without exception. This applies also to medical devices (see the response to Question 5). Conversely, HCPs may be involved in promotional activities addressed to other HCPs, under the condition that certain requirements are met.

13. Is it possible to provide healthcare professionals with samples of medicinal products? Of medical devices? If so, what restrictions apply? Is it possible to give gifts or donations of money to healthcare professionals? If so, what restrictions apply? If monetary limits apply, please specify.

Free samples of drugs may be provided only to HCPs who are authorised to prescribe the relevant products on written and dated request filed by the HCP concerned and must be delivered only through medical representatives (together with the summary of product characteristics).
Medical representatives may provide each doctor with no more than two samples per visit of each strength or pharmaceutical form of a medicinal product during the 18 months following the date on which the product was first placed on the market, subject to a maximum of eight samples per year of each strength or form. Further, after the first 18 months of marketing, medical sales representatives may provide each doctor with no more than four samples per visit, subject to a maximum of ten samples per year. Samples must be marked 'free sample - not a sale' or similar.
Apart from samples of drugs, it is forbidden to give doctors or pharmacists any 'financial or non-financial advantage', unless it is of 'negligible value' and related to the professional activity. In any case, donations of money to HCPs must be considered prohibited.
For medical devices, there are no regulations governing the provision of free samples and gift/donations, but rules similar to those related to drugs are generally applied also to medical devices in accordance with the ethical provisions of the Code of Ethics of Confindustria Dispositivi Medici.

14. What rules govern the offering of hospitality to healthcare professionals?

Hospitality provided by companies to HCPs is regulated by the Italian Code of Medicine and only permitted in the context of scientific congresses and events, which must be restricted to qualified professionals and cannot be extended to potential guests. In addition, hospitality is limited to 12 hours before and 12 hours after the event.
Further and more specific rules on hospitality are provided in the Codes of Ethics of Farmindustria and Confindustria Dispositivi, among which we report the following:

- hospitality must be limited to economy class air travel (with some exceptions for international congresses and flights longer than six consecutive hours) and stays in hotels with a maximum of four stars;
- the same HCP may not be invited to events (with related hospitality) by the same company more than twice a year, with some exceptions, for example, for speakers and event moderators (for drugs only);
- providing hospitality in facilities such as resorts, health clubs and wellness centres is forbidden (for drugs only); and
- hospitality may also include meals and drinks up to a limit of €60 per meal for each HCP (for drugs only).

15. Are donations made by permit/authorisation holders to healthcare institutions or organisations considered a promotional (advertising) tool? Is there a special regulation on donations?

According to the ethical rules set out in the Codes of Farmindustria and Confindustria Dispositivi Medici, donations of money and goods should be made in response to a specific request from HCOs (while donations to professionals are prohibited, see the response to Question 13). In general, HCOs have specific internal procedures for managing donations from companies.

16. Can pharmaceutical laboratories or medical device manufacturers or their licensees support scientific or educational meetings? If so, is there any difference between these two sectors from the perspective of rules on the promotion of products?

Yes, pharmaceutical laboratories or medical device manufacturers may support and/or help organise scientific or educational meetings.

Specific rules and restrictions apply to the support provided by pharmaceutical companies to events on topics related, directly or indirectly, to the use of the drugs they market. In these cases, companies must obtain prior authorisation from the AIFA by submitting the relevant request, indicating, among other things, the place, date and subject of the event, the speakers involved and their professional qualifications, as well as an analytical estimate of the expenses incurred.

On the other hand, medical device legislation does not provide for a specific procedure/authorisation for companies supporting congresses and events.

17. Please provide an overview of the rules around the industry and patient organisations' relationships, including funding.

National legislation does not address the relationship between companies and patient organisations. However, for drugs only, the Code of Ethics of Farmindustria provides for some general rules for the industry, stating that any financial support from companies to patient organisations should be transparent and without promotional purpose, and should be governed by a written agreement specifying the amount of financial support and its purpose. Moreover, companies should not be the only source of financial support for a patient organisation.

18. Is it possible to delegate promotional (advertising) activities to a third party through a service agreement? If so, under which conditions? Is co-promotion regulated in your jurisdiction and if so, how?

The advertising of drugs and medical devices to the general public may be physically delegated to a third-party provider (eg, a digital media agency), although the responsibility remains with the pharmaceutical company.

Co-promotion is specifically addressed by the Italian Code of Medicine, which states that the promotion of drugs to HCPs may be carried out by a pharmaceutical company other than the marketing authorisation holder, alone or jointly with the marketing authorisation holder, on the basis of a written agreement between the parties. The law specifies that the marketing authorisation holder is, in any case, responsible for the promotional activities carried out by its commercial partner.

No specific provision on this topic is provided for by legislation on medical devices.

19. Is it mandatory in your country to report transfers of value made by permit/authorisation holders to healthcare professionals?

Recently, Law No 62/2022 (the so-called Sunshine Act) introduced the obligation for all companies marketing goods and services in the healthcare sector to disclose all agreements and payments made to HCOs and HCPs in a public electronic register held by the Ministry of Health. However, this legislation is not yet applicable because the necessary implementing measures are still lacking and the public registry is not yet operational.

In the meantime, pharmaceutical and medical device companies are subject to the rules on transparency and disclosure of direct and indirect 'transfers of value' to HCOs and HCPs set out in the Codes of Ethics of Farmindustria and Confindustria Dispositivi Medici, which derive from the rules established at the European level by the European Federation of Pharmaceutical Industries and Associations (EFPIA) Code.

ENFORCEMENT

20. What penalties and other sanctions are associated with violations related to product promotion (advertisement)? Do supervisory authorities actively impose penalties and other sanctions? Are these penalties and other sanctions announced publicly?

For both drugs and medical devices, the Ministry of Health may order the immediate cessation of advertising and impose administrative fines ranging from €2,600 to €15,600 for failure to comply with the rules on advertising to the general public.

The AIFA can also impose fines ranging from €2,600 up to €15,600 for violations of the rules on advertising of drugs to HCPs.

In addition, for drugs only, it is specifically provided that: (1) the competent authority may also order the dissemination, at the offender's expense, of 'correction and clarification' notice regarding unlawful advertising; (2) in the case of drugs reimbursed by the national health system, the violation of the rules on advertising to HCPs may also lead to suspension of the drug's reimbursement for between ten days and two years, depending on the seriousness of the offence.

Finally, the violation of the rules on the advertising of drugs or medical devices could also result, depending on the case, in: (1) the issuance by the AGCM of fines ranging from €5,000 to €10m for the violation of the provision on unfair commercial practices set forth in the Italian Consumer Code, in addition to an order to immediately cease the practice and the publication of the relevant decision; and (2) an order by the Giurì of the IAP to immediately cease advertising and disclose the relevant measure.

21. Who is responsible for enforcement, and how strictly are the rules enforced? To what extent may competitors take direct action through the courts in relation to promotion (advertising) infringements?

The authorities responsible for enforcement are the Ministry of Health, the AIFA and the AGCM for violations of advertising and consumer protection laws, as well as competition rules.

In terms of possible actions by competitors, Article 2598 of the Italian Civil Code allows competitors to take direct action against the company and claim damages for unfair competition, including the case of false advertising. In this regard, the Court of Milan, in its judgment of 24 July 2017, No 8240, found that a pharmaceutical company that advertised its products in breach of the applicable laws violated the unfair competition rules and issued a cease-and-desist order to stop further publication.

FUTURE DEVELOPMENTS

22. Are any significant developments in the field of pharmaceutical or medical device promotion (advertising) expected in the next year or so? Are there any general practice or enforcement trends that have become apparent in your jurisdiction over the last year or so?

Based on recent trends, it can be expected that, as the use of digital media for advertising becomes more widespread, more attention will be paid to these phenomena, which will increasingly be taken into account in the drafting of laws and guidelines by legislators and authorities (as evidenced by the recent Ministerial Guidelines on the promotion of OTC and SOPs, which introduced a set of brand new rules for the social media 'Tik Tok').

In addition, we expect that the future implementation of the Sunshine Act's transparency requirements will have a significant impact on companies' activities in the health sector (see the response to Question 19).