

PROMOTION OF PHARMACEUTICALS AND MEDICAL DEVICES
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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.
<p>The following laws and codes of practice govern the promotion and advertising of medicines and medical devices in Romania:</p> <ul style="list-style-type: none">• Act No 95/2006 on healthcare reform;• Decree of the Ministry of Health No 194/2015 on the Approval of the Norms for the Evaluation and Permitting of Human use Medicine Advertising (Decree No 194/2015);• Government Emergency Ordinance No 46/2021 on establishing the institutional framework and measures for applying Regulation (EU) 2017/745 on medical devices;• Ethics Code of the Romanian Association of International Medicine Manufacturers (affiliated to EFPIA) (ARPIM Code of Ethics);• The Ethics Code of the Romanian Association of OTC Medicines, Food Supplements and Medical Devices (affiliated to AESGP);• The Code for Commercial Communication Practice of the Romanian Advertising Council.
2. How is 'advertising' defined? If relevant in your jurisdiction, what is the difference between promotion and advertisement of pharmaceuticals? Of medical devices?
<p>Please see below the definition of 'advertising' and 'promotion' for medicines and medical devices.</p> <p>The definitions are vastly similar and the term 'promotion' is included in the definition of 'advertising', as may be seen below.</p> <p>For medicines:</p> <p>Promotion is defined as including any activity organised, carried out or sponsored by a pharmaceutical company (or with its authorisation) that stimulates the prescription, distribution, sale, administration, recommendation or use of medicines.</p> <p>Advertising is defined as including any form of informing through direct contact (door-to-door system), as well as any form of promotion intended to stimulate the prescription, distribution, sale or use of medicines; advertising for medicinal products includes in particular:</p> <ul style="list-style-type: none">• advertising for medicines intended for the general public;• advertising for medicines intended for persons qualified to prescribe or distribute medicines;• visits by medical representatives to persons qualified to prescribe medicines;• providing samples;• sponsoring promotional meetings attended by persons qualified to prescribe or distribute medicines;• sponsoring scientific congresses attended by persons qualified to prescribe or distribute medicines and, in particular, the payment of transport and accommodation expenses caused by them. <p>For medical devices:</p> <p>Advertising is defined as including any form of informing through direct contact, as well as any form of promotion intended to stimulate the distribution, sale or use of medical devices; advertising for medical devices includes in particular:</p> <ol style="list-style-type: none">a) advertising for medical devices intended for the general public;b) advertising for medical devices intended for healthcare professionals, which also includes the following forms of advertising –<ul style="list-style-type: none">• visits by medical representatives to persons qualified to recommend medical devices;• providing samples;• sponsoring promotional meetings attended by persons qualified to recommend or distribute medical devices;

<ul style="list-style-type: none"> • sponsoring scientific congresses attended by persons qualified to recommend or distribute medical devices and, in particular, payment of transport and accommodation expenses for them.
<p>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?</p>
<p>The National Agency of Medicines and Medical Devices in Romania (ANMMDR) is the competent authority for the evaluation and approval of advertising materials and any other form of advertising of medicines and medical devices.</p> <p>ANMMDR exercises its supervisory and enforcement functions as provided by the law regardless of any self-regulatory process previously conducted by a market player.</p>
<p>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?</p>
<p>No. Only medicines and medical devices fall under the applicable laws referenced in the response to Question 1, above.</p> <p>Food supplements, for example, are regulated by other laws and by the Ethics Code of the Romanian Association of OTC Medicines, Food Supplements and Medical Devices.</p> <p>Furthermore, Decree No 194/2015 prohibits including materials messages or images of campaigns in advertising regarding other types of products, such as cosmetics, food supplements, medical devices etc.</p>
<p>CONSUMER MARKETING</p>
<p>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 (advertisements) in your country and, if so, which ones?</p>
<p>Medicines</p> <p>Comparative advertisement for the general public is prohibited.</p> <p>Advertising for the general public is banned for medicines that:</p> <ul style="list-style-type: none"> • do not have a valid market authorisation in Romania; • are prescription only; • contain substances defined as narcotics or psychotropic in accordance with the legal provisions in force; • are prescribed and issued under the health insurance system, with the exception of vaccination campaigns carried out by the pharmaceutical industry and approved by the Ministry of Health. <p>Advertising for medicines for the general public must not contain any material which:</p> <ul style="list-style-type: none"> • suggests that a medical consultation or a surgical intervention is not necessary, especially through offering a diagnosis or remote treatment; • suggests that the effect of the medicine treatment is guaranteed, is not accompanied by adverse reactions or that the effect is better or equivalent to that of another treatment with another treatment or medicine; • suggests that the health of the subject may be improved by using the medicine; • suggests that the health of the subject may be affected if the medicine is not used; • addresses, exclusively or especially, children; • refers to a recommendation of scientists, health professionals or people who are not part of these categories, but whose celebrity status may encourage the use of the medicine; • suggests that the medicine is a cosmetic or relaxation product or other consumer product; • suggests that the safety or effectiveness of the medicine is due to the fact that it is natural; • may, through a detailed description or representation of a case, lead to an erroneous self-diagnosis;

- offers, in inadequate, alarming or misleading terms, assurances regarding healing through the use of the respective medicine;
- uses, in inappropriate, alarming or misleading terms, visual representations of changes in the human body caused by diseases or injuries or actions of medicines on the human body or a part thereof.

Furthermore, the direct distribution of medicines to the population by manufacturers for promotional purposes is prohibited.

Advertising for the general public presented through social networks, mobile applications, email or mobile messaging is also prohibited.

The following are prohibited in broadcast advertising:

- advertising materials for medicines or treatments presented or recommended by health professionals, academic, scientific organisations, foundations, public, cultural, scientific, sports figures or other persons who, due to their celebrity status, may encourage the consumption of such medicines or the use of the respective treatments;
- advertising materials and teleshopping that depict health professionals recommending or medically approving medicines;
- advertising materials for medicines in children's programmes or in the advertising breaks that precede or follow such programmes;
- sponsoring of programmes or broadcasts intended for children by medicines manufacturers and distributors;
- advertising materials for medicines in which it is suggested that it is necessary for anyone to supplement their diet with vitamins and minerals or that such medicines can improve physical or mental functions, which are otherwise functioning normally.

Outdoor advertising, or any form of advertising presented on communication channels, other than pharmacies, medical offices, broadcast, print media, the internet, is prohibited.

On samples, it is prohibited to provide samples:

- for advertising purposes to the general public by market authorisation holders, as well as by any entities or persons representing them or acting on their behalf on the basis of a contract;
- for advertising purposes to the general public by companies engaged in commercial activities (authorised pharmacies or third parties);
- directly to patients through publications sent directly or by mail, or to add samples to the packaging of publications, as well as to distribute vouchers, value coupons or tickets that allow obtaining free or reduced-price medicines.

Medical devices

It is prohibited to advertise to the general public medical devices with special purposes, which are used only according to a medical recommendation.

Advertising aimed at the general public is only permitted for medical devices which are intended to be used without the intervention of qualified medical personnel for the purpose of establishing a diagnosis, recommending them, or for monitoring the treatment, with the advice of pharmacists being sufficient, if the case.

Any advertising material intended for the general public: (1) must be designed so that it is clear that the message is of an advertising nature and that the product is clearly identified as a medical device; (2) must include at least the following information – name of the medical device, a clear definition of the purpose proposed for use, information necessary for the correct use of the medical device and an explicit, legible invitation to read the instructions carefully in the user manual of the product.

Advertising for medical devices for the general public must not contain any material which:

- suggests that a medical consultation or a surgical intervention is not necessary;
- suggests that the diagnosis, the result of the determination established with a medical device is guaranteed, cannot be accompanied by errors or that the effect of the treatment with a medical device is guaranteed, is not accompanied by adverse reactions or that the effect is better or equivalent to that of another treatment with another medical device or medicine;

- suggests that the health of the subject may be affected if the medical device is not used;
- is addressed exclusively at children;
- refers to a recommendation by scientists, health professionals or people who are not part of these categories, but whose celebrity status may encourage the use of the medical device;
- suggests that the medical device is a cosmetic or relaxation product or other consumer product;
- suggests that the safety or effectiveness of the medical device is due to the fact that it is natural;
- may, through a detailed description or representation of a case, lead to an erroneous self-diagnosis;
- offers, in inadequate, alarming or misleading terms, assurances regarding healing through the use of the respective medical device;
- uses, in inappropriate, alarming or misleading terms, visual representations of changes in the human body caused by diseases or injuries or actions of medical devices on the human body or a 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?

As noted in the response to Question 5 above, the promotion and advertising of medicines through social media is prohibited.

Internet advertising of medicines is allowed through web pages, email, forums, blogs or any other forms of electronic support, other than social networks or mobile applications such as Android, iOS or any other type of application.

Internet advertising for Rx medicines is permitted towards healthcare professionals under certain conditions.

Internet and social media promotion and advertising are not specifically regulated for medical devices.

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)?

Medicines

The ANMDMR monitors medicine advertising, as follows: (1) for OTC medicines – advertising materials for the general public are subject to the prior approval of the ANMDMR; (2) for all medicines – advertising materials intended for healthcare professionals are analysed by the ANMDMR after dissemination, via a survey or as a result of notifications.

Prior ANMDMR approval is required for: (1) all educational materials for patients; and (2) all educational materials for healthcare professionals.

Medical devices

The documentation for advertising a medical device intended for the general public must be submitted to the ANMDMR for approval by the manufacturer, importer or distributor of the medical device and disseminated only after obtaining the advertising permit.

The ANMDMR analyses legal violations and orders the appropriate sanctions, in response to the distribution of advertising materials intended for healthcare professionals and other forms of advertising regarding medical devices, through self-reporting, or as a result of notifications made by natural or legal persons.

However, advertising of medical devices intended for healthcare professionals, when categorised as medical devices with a high degree of risk to the health of the population according to specific legal definitions, must be notified urgently, in advance, by the manufacturer, importer or distributor of the medical device to the ANMDMR.

When it finds that the advertising material violates the provisions of the law, the ANMDMR orders the cessation of advertising if the advertising material has already been published or its prohibition if the advertising material has not yet been published.

8. May information on unauthorised pharmaceuticals and/or off-label information be promoted (advertised)? If so, in what circumstances and under which modalities?
<p>No, information on unauthorised pharmaceuticals and off-label information cannot be promoted or advertised.</p> <p>All information contained in advertising materials for a given medicine must correspond to the information listed in the summary of product characteristics.</p> <p>Information on off-label indications of a given medicine may only be provided in response to a properly documented request from a healthcare professional.</p> <p>For medical devices, all information contained in the advertising material must correspond to the information found in the instructions/user manual of the product.</p>
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?
<p>Medicines</p> <p>Comparative advertising for the general public is prohibited.</p> <p>Comparative advertising aimed at healthcare professionals is prohibited if:</p> <ul style="list-style-type: none"> • the comparison is misleading; • the brand name of a competitor is used – only the mention of international non-proprietary names is permitted; • medicines that have different therapeutic indications or different pharmaceutical forms are compared; • one or more essential, relevant, verifiable and representative characteristics of a certain medicine are not objectively compared, among which the price may be included; • confusion is created on the market between the advertiser and a competitor or between the different trademarks, international non-proprietary names or other distinctive signs of the advertiser and those belonging to a competitor; • the trademark, international common name, other distinctive signs, activities or any other characteristics of a competitor are discredited or denigrated; • it unfairly takes advantage of the reputation of a trademark, the international non-proprietary name, the distinctive signs of a competitor or any other characteristics of a competitor without having evidence to support the claims. <p>Medical devices</p> <p>There are no specific provisions on comparative advertisement for medical devices.</p>
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?
<p>Decree No 194/2015 defines healthcare professionals as medical doctors, dentists, pharmacists and medical or pharmacy assistants.</p> <p>Please see our answer above on the main conditions in which promotional/advertisement communications may be directed at healthcare professionals and the related restrictions.</p>
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?
<p>No specific rules on virtual promotional activities, such as online interactions, virtual meetings, congresses or symposia apply.</p> <p>General rules regarding offline interactions with healthcare professionals apply accordingly.</p>

12. Are there any restrictions to the inclusion of endorsements by healthcare professionals in promotional (advertising) materials? If so, which ones and how may such endorsements take place?
As noted above, advertising of both medicines and medical devices may not refer to a recommendation of scientists, health professionals or people who are not part of these categories, but whose celebrity status may encourage the use of the medical device. Furthermore, broadcasting of advertising materials and teleshopping that depicts health professionals recommending or medically approving medicines is banned.
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.
<p>Medicines</p> <p>Samples of medicines may be granted for free to healthcare professionals to familiarise themselves with and gain experience of the product.</p> <p>It is not permitted to provide, offer or promise any gift, pecuniary advantage or benefit in kind to healthcare professionals for the purpose of prescribing, purchasing, supplying, selling or administering a medicine.</p> <p>It is permitted to provide or offer promotional items to healthcare professionals, only if they have a minimal value (maximum RON150 approx. €30 including VAT before personalisation) and are relevant to the practice of medicine or pharmacology.</p> <p>Promotional objects can only be inscribed with:</p> <ul style="list-style-type: none"> • the name and logo of the pharmaceutical company; • the name of the medicine or its international non-proprietary name, if any, or the trademark; • the concentration, the pharmaceutical form and, possibly, a simple statement of the indications to designate the therapeutic category of the medicine. <p>The ARPIM Code of Ethics provides that a limited number of medical samples may be supplied on an exceptional basis and for a limited period and that a reasonable interpretation of such a provision is that each healthcare professional should receive, per year, not more than four medical samples of a particular medicine that they are qualified to prescribe for two years after the healthcare professional first requested samples of each particular medicinal product (ie, the '4x2' standard).</p> <p>Medical devices</p> <p>Samples to healthcare professionals are permitted as a means of advertising for medical devices, but no further specific provisions are stipulated.</p>
14. What rules govern the offering of hospitality to healthcare professionals?
<p>Decree No 194/2015 provides that hospitality for healthcare professionals during scientific/professional events is permitted provided that the hospitality is limited to the main objective of the meeting, without being able to be extended to other people who are not healthcare professionals or for whom the scientific field that is the subject of the meeting has no professional relevance.</p> <p>The ARPIM Code of Ethics further provides certain guidelines (in line with those of EFPIA) on hospitality and events, such as: (1) the fact that all events must be held in 'appropriate' locations and venues that are conducive to the main purpose of the event, avoiding those that are 'renowned' for their entertainment facilities or are 'extravagant'; (2) hospitality extended in connection with events must be limited to travel, meals, accommodation and genuine registration fees; (3) all forms of hospitality offered to healthcare professionals must be 'reasonable' in level and strictly limited to the duration and main purpose of the event.</p>
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?
Sponsoring promotional meetings attended by healthcare professionals and sponsoring scientific congresses attended by healthcare professionals and, in particular, the payment of transport and accommodation expenses are expressly provided as forms of advertisement under Decree No 194/2015.

<p>No form of sponsorship of healthcare professionals must be linked to the name of a medicine, regardless of its status at release, ie, with or without a medical prescription.</p> <p>Sponsorship actions must not involve direct or indirect promotional messages for medicines, regardless of their status at release, with or without a medical prescription.</p> <p>The ARPIM Code of Ethics further provides that donations and sponsorships (in cash or in kind or otherwise) to healthcare organisations and/or patient organisations are only permitted if:</p> <ul style="list-style-type: none"> • they are made for the purpose of supporting healthcare, research or education; • they are documented and kept on record by the donor/grantor; • they do not constitute an inducement to recommend and/or prescribe, purchase, supply, sell or administer specific medicines; and • are specifically based on an unsolicited request from the respective organisation.
<p>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?</p>
<p>Yes, such companies can support scientific or educational meetings through donations or sponsorships and, as detailed above, are considered forms of advertisement.</p>
<p>17. Please provide an overview of the rules around the industry and patient organisations' relationships, including funding.</p>
<p>Educational materials for patients and patients' organisations/associations are a form of advertising.</p> <p>The industry may provide sponsorships or grants to patients' organisations/associations, under reporting obligations, similar to those made to healthcare professionals.</p> <p>The ARPIM Code of Ethics also provides that when member companies provide financial support, significant indirect support and/or significant non-financial support to patients' organisations, they must have a written agreement in place. This must state the amount of funding and also its purpose (eg, unrestricted grant, specific meeting or publication, etc). It must also include a description of significant indirect support (eg, the donation of public relations agency's time and the nature of its involvement) and significant non-financial support. It will be considered as significant, financial or non-financial, if any support exceeds a value of RON150 (approx. €30).</p>
<p>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?</p>
<p>Yes, for example, Decree No 194/2015 defines an 'agent/advertising agency' as any person (natural or legal) designated by a pharmaceutical company to provide advertising services for its benefit, based on an agreement.</p> <p>Decree No 194/2015 further specifically states that its rules apply not only to pharmaceutical companies themselves, their subsidiaries or representatives but also to any other partners (agents, agents, representatives of market authorisation holders) with whom a contractual relationship exists in order to carry out any type of medicinal advertising.</p> <p>Furthermore, pharmaceutical companies and their representatives are responsible for complying with applicable regulatory obligations, even when ceding to third parties promotional, advertising or implementation activities, or undertaking, on their behalf, actions of advertising regulated by the above-specified rules.</p> <p>Pharmaceutical companies must also ensure that any third parties to whom they have assigned the activities of advertising medicines comply with the provisions of Decree No 194/2015.</p> <p>No specific regulations on co-promotion apply, but the provisions of Decree No 194/2015 referenced above should apply.</p>
<p>19. Is it mandatory in your country to report transfers of value made by permit/authorisation holders to healthcare professionals?</p>
<p>Yes, manufacturers, market authorisation holders or their representatives in Romania, as well as wholesale and retail distributors of medicines, have the obligation to declare to the ANMDMR, by 31</p>

March of the given year, all sponsorship activities, as well as any other expenses incurred in the year prior to reporting, for healthcare professionals, professional organisations, patient organisations and any other type of organisation carrying out activities related to human health, healthcare or pharmaceuticals.

Such an obligation also applies to the beneficiaries of sponsorship activities, medical doctors, nurses, professional organisations, patient organisations and any other type of organisations that have activities related to human health, medical or pharmaceutical assistance.

Templates for reporting are provided in the annexes of Decree No 194/2015 and the reports are published on the ANMDFM website.

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 non-compliance with the provisions of Decree No 194/2015 on medicines advertising, the ANMDFM may apply fines between RON5,000–10,000 (approx. €1,000–2,000).

For non-compliance with the applicable provisions on medical device advertising, the ANMDFM may apply fines between RON10,000–20,000 (approx. €2,000–4,000) and request the termination of the given advertising.

To our knowledge, the ANMDFM monitors the advertising market and imposes sanctions, as needed.

The penalties are announced publicly on the ANMDFM website for both medicines and medical devices.

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 ANMDFM is responsible for enforcement and to our knowledge, the rules are strictly enforced.

Natural or legal persons (including competitors) that have a legitimate interest in the prohibition of any form of advertising may notify the ANMDFM in this regard, which will typically respond to notifications within 30 days.

After notifying the ANMDFM, and depending on how and whether they respond, the option of court action becomes available.

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?

No significant developments are expected in the near future, nor have any significant general practice or enforcement trends become apparent in Romania.