

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>Pharmaceuticals The Law on Medicines and Medical Devices (the LMMD) and the Rulebook on the Advertisement of Medicines or Medical Devices (the Rulebook on the Advertisement of Pharmaceuticals) govern the advertising of pharmaceuticals and veterinary medical devices.</p> <p>Medical devices The Law on Medical Devices (the LMD) and the Rulebook on the Advertisement of Medical Devices (the Rulebook on the Advertisement of Medical Devices) govern the advertising of medical devices for human use.</p> <p>The adoption of separate regulations on medical devices for human use first occurred in 2017 and 2018. Subsequently, the provisions on medical devices for human use and their advertising in the LMMD and the Rulebook on the Advertisement of Pharmaceuticals ceased to apply. However, these regulations still apply to veterinary medical devices.</p> <p>General advertising The Law on Advertising (the LA) contains rules protecting children from inappropriate advertisements that involve the use of pharmaceuticals in ads or recommendations of pharmaceuticals before, during, and after the broadcasting of children's programmes. The LA also regulates displaying statements on health, healing, and nutritive features of products and services.</p> <p>Self-regulatory (pharmaceuticals) The INOVIA Association Code of Practice (the INOVIA Code) contains rules on prescription pharmaceuticals promotion. The INOVIA Association of Manufacturers of Innovative Pharmaceuticals adopted the INOVIA Code as a collection of ethical rules on prescription pharmaceuticals promotion obligatory for all members. Other pharmaceutical companies may decide to abide by the INOVIA Code.</p>
2. How is 'advertising' defined? If relevant in your jurisdiction, what is the difference between promotion and advertisement of pharmaceuticals? Of medical devices?
<p>The advertisement of pharmaceuticals and medical devices encompasses every dissemination towards the general and professional public of accurate information about pharmaceuticals to encourage their prescribing, supply, sale, and consumption.</p> <p>Types of advertisement include:</p> <ul style="list-style-type: none">• advertisements through the media, including – the internet, advertisements in public areas, and other forms of advertisement (mail, visits, etc.);• promotion at professional conferences, in professional journals, and in other forms of promotion to health professionals who prescribe pharmaceuticals;• giving free samples to the professional public;• sponsoring scientific and promotional meetings that involve the professional public (by paying travel expenses, accommodation, food, and the costs of mandatory participation). <p>Promotion versus advertisement The promotion of pharmaceuticals and medical devices is recognised as a type of advertising by providing information to healthcare professionals (HCPs) at professional conferences, in professional journals, or through comparative promotions. The promotion of pharmaceuticals via HCPs must incorporate basic information about a pharmaceutical from the marketing authorisation (the MA) or the information consistent with the summary of product characteristics (SmPC) and the information on the prescription regime. Such information needs to be accurate, updated, confidential, and sufficiently complete to enable the recipient to form an opinion on the therapeutic value of a pharmaceutical, including the date they were compiled or last reviewed.</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>The Medicines and Medical Devices Agency of Serbia (ALIMS) is the regulatory authority in charge of authorising the use of promotional materials and other documentation concerning the advertisement of pharmaceuticals and veterinary medical devices, which must align with the SmPC and the package leaflet ('Instructions for Use') that ALIMS also pre-approved.</p> <p>The Ministry of Health (the MoH) Inspectorate for Pharmaceuticals and Medical Devices supervises the advertisement of pharmaceuticals and veterinary medical devices. In addition, at MoH's request, the ALIMS controls the promotional materials concerning medical devices for human use.</p> <p>The INOVIA Association of Manufacturers of Innovative Pharmaceuticals is a typical example of the introduction of self-regulatory processes through the INOVIA Code, which demands that its members comply with rules regulating the advertisement of pharmaceuticals. However, the competent authorities, such as ALIMS and the MoH, do not have any supervisory and enforcement functions in this respect.</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>Products such as food supplements fall under the category of consumer goods. The advertisement of consumer goods is not within the scope of regulations on the advertisement of pharmaceuticals. Instead, it is subject to special rules on advertisement of food.</p>
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 (advertisements) in your country and, if so, which ones?
<p>Advertisements to general public (pharmaceuticals)</p> <p>The LMMD strictly bans the advertising of certain forms of pharmaceuticals to the general public, including prescription pharmaceuticals, pharmaceuticals administered at the expense of health insurance, pharmaceuticals containing opiates or psychotropic substances, pharmaceuticals for tuberculosis, sexually transmitted diseases, infectious diseases, chronic insomnia, diabetes, and other metabolic diseases. In addition, the advertising of pharmaceuticals for the treatment of children to the general public by directly addressing children is forbidden, as well as dispensing free samples of pharmaceuticals to the general public.</p> <p>The advertising of non-prescription pharmaceuticals to the general public is permitted via media and other means or to provide information on their effects under the SmPC. Advertising non-prescription pharmaceuticals to the general public must be objective and avoid misleading claims. The ALIMS determines the list of non-prescription pharmaceuticals eligible for advertisement to the general public.</p> <p>The principal rule of the LMD is that it permits the advertising of medical devices (whether to the general public or the HCPs) only of registered medical devices or medical devices if they conform with essential requirements. The advertisement of medical devices administered at the expense of health insurance to the general public is not permitted. In addition, the Minister of Health has the authority to extend the advertising ban to any other medical devices in the interest of protecting public health.</p>
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?
<p>Rules on the advertisement of pharmaceuticals and medical devices via the internet are relatively concise and do not address social media in particular as a potential advertising channel. According to the Rulebook on the Advertisement of Pharmaceuticals and the Rulebook on the Advertisement of Medical Devices, when advertising a pharmaceutical or medical device on the internet, the information on the pharmaceutical or medical device must be integrated in the initial or home page of the online message or advertisement, instead of a linking page or page referencing to the home page.</p>
Internet advertising in the Law of Advertising

<p>The LA defines online advertising as advertising on an internet presentation, social network, application, or through another form of internet communication, if the advertising message undoubtedly targets recipients in Serbia, who can buy or receive the advertised goods or service in the territory of Serbia. Online advertising uses banners, contextual messages and menus, specialised online magazines etc. Presentation on one's own internet domain (internet page) is not considered to be advertising. All restrictions deriving from the LA concerning the advertising of pharmaceuticals and medical devices apply to online advertising. These are:</p> <ul style="list-style-type: none"> • Advertising messages must not contain an image of a child¹ without parental supervision in possession or near pharmaceuticals as hazardous substances. • Advertising or recommending pharmaceuticals and medical devices (and food supplements) during a children's programme and at least ten minutes before or after a children's programme is banned. • Product placement involving pharmaceuticals and medical devices is strictly prohibited in children's fiction films, television movies, fiction series, sports and entertainment programmes. • Advertising containing claims about the health, healing or nutritional properties of the advertised goods or services (health or nutritive features statement), must be based on scientific or professional findings.
<p>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)?</p>
<p>The ALIMs must authorise the use of promotional materials and other documentation concerning the advertisement of pharmaceuticals and veterinarian medical devices (Authorisation Approval). Such promotional materials must align with the SmPC and the Instructions for Use that ALIMs also pre-approved. Materials for the promotion of medical devices for human use are not subject to Authorisation Approval. The ALIMs only controls such materials following the MoH's request.</p> <p>The by-laws governing the advertisement of pharmaceuticals and medical devices do not outline a procedure for obtaining an Authorisation Approval, which is why the ALIMs adopted professional instructions concerning the transfer of a market authorisation to another holder and variations in the SmPC and the Instructions for Use.</p> <p>In case of an MA transfer to another marketing authorisation holder (an MAH or MAHs), and where the new MAH wishes to use previously approved promotional materials for the advertisement of pharmaceuticals, the new MAH must submit a request for the approval of promotional materials, including such revised promotional materials, a revised SmPC and the Instructions for Use with any amendments.</p> <p>Regarding SmPC and package leaflet variations, in the case of permanent MA, the Authorisation Approval ceases to be valid if changes to the pharmaceutical's safety, efficiency, or quality occur and directly influence the promotional material's content. The new MAH must request approval of promotional material, including such revised promotional materials, a revised SmPC, and the Instructions for Use with amendments.</p>
<p>8. May information on unauthorised pharmaceuticals and/or off-label information be promoted (advertised)? If so, in what circumstances and under which modalities?</p>
<p>No.</p>
<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>
<p>Comparative advertisements aimed at the general public Using another company's information (including its brand name) to compare its products against an advertised product is not possible. According to the applicable regulations, it is not permitted to lead the general public to a conclusion that: (1) a certain or recommended pharmaceutical/veterinarian medical device is better than or replaceable with another such product; and (2) a certain or recommended medical device for human use is the best, or better than other such products, or replaceable with another such product.</p>

¹ A child is deemed to be a person under 12, and a minor is a person of at least 12, but under 18.

<p>Comparative advertisements aimed at HCPs</p> <p>A similar ban applies if comparative advertisements target HCPs. It is not permitted to:</p> <ul style="list-style-type: none"> • incite HCPs that a pharmaceutical/medical device for human use is replaceable with another one from the same therapy group without a clear medical indication; • diminish the therapy values of another pharmaceutical with a MA/registered medical device for human use, or cast doubt on that product's value in any other way; • use copyrighted materials or materials protected under any other type of intellectual property rights without the owner's previous consent (eg, registered trademarks or brand names).
<p style="text-align: center;">DEALING WITH HEALTHCARE PROFESSIONALS AND HEALTHCARE INSTITUTIONS</p>
<p>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>
<p>The definition of an HCP differs depending on whether it refers to pharmaceuticals and veterinary medical devices or medical devices for human use.</p> <p><i>Pharmaceuticals and veterinary medical devices</i> HCPs are health and veterinary workers prescribing pharmaceuticals and veterinary medical devices, pharmacists and other professionals in manufacturing and wholesale and the retail of pharmaceuticals and veterinary medical devices, as well as professionals in a mandatory health insurance organisation.</p> <p><i>Medical devices for human use</i> HCPs are health workers prescribing and using medical devices for human use, professionals in manufacturing and wholesale and the retail of medical devices for human use, as well as professionals in a mandatory health insurance organisation.</p> <p>The LMMD and LMD set out extensive restrictions regarding the advertisement of pharmaceuticals and medical devices to HCPs, including:</p> <ul style="list-style-type: none"> • The promotion must contain basic information about a pharmaceutical/medical device from the MA or information consistent with the SmPC and the information on the prescription regime. • The information needs to be accurate, updated, confidential, and sufficiently complete to enable the recipient to form an opinion on the product's therapeutic value, including the date they were compiled or last reviewed. • If seeking to inform HCPs on the characteristics of a new product in the market, giving one smallest possible package of the new product to the HCP is allowed, if the package indicates 'Free Sample – Not for Sale'. • Advertisement materials for HCPs must be marked 'for healthcare professionals only'. • Visiting HCPs is permitted exclusively at the time and in the place ordered by the director of the organisation employing HCPs. • HCPs are prohibited from soliciting or receiving any material or intangible benefits as an incentive for prescribing, dispensing, procuring or using a pharmaceutical/veterinary medical device.
<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>
<p>No.</p>
<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?</p>
<p>HCPs should not endorse pharmaceuticals or medical devices in promotional (advertising) materials.</p>
<p>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>
<p>Providing free samples to HCPs is permitted and is classified as a type of advertisement. If seeking to inform HCPs of the characteristics of a new product in the market, they may give one smallest possible package of the new product to the HCP, if the package clearly indicates 'Free Sample – Not for Sale'. An</p>

HCP may submit a written request to receive a free sample. HCPs may use free samples to promote the product to the general public within their employer. Dispensing free samples is subject to several conditions:

- the pharmaceutical must have an MA and the medical device must be registered;
- the quantity of free samples must be limited to one smallest possible package of the new pharmaceutical per calendar year and disseminated exclusively to HCPs who prescribe or apply them;
- the quantity of free samples of single-use medical devices must be limited to 15 samples per calendar year, or one sample per calendar year for multi-use medical devices and disseminated exclusively to HCPs who prescribe or apply them;
- the free sample of a pharmaceutical must not contain intoxicating drugs or psychotropic substances;
- a copy of the SmPC and the Instructions for Use must accompany each free sample of a pharmaceutical and medical device.

Giving gifts or monetary rewards, giving presents or granting and enabling any kind of financial, material or intangible benefits and other advantages, giving or promising privileges and prices to HCPs with the intent to incite prescribing, dispensing, procuring, endorsing or purchasing pharmaceuticals and medical devices is strictly forbidden.

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

Hospitality to HCPs is limited to necessary travel expenses, accommodation and alimentation costs, and the costs of mandatory participation at events, including registration fees, professional publications, expenses for the lease of premises where the event takes place, and the costs directly connected with the organisation of such events. It is permitted to sponsor the costs of participation at events only for their duration and a maximum of two more days for arrival and departure from the event location. Sponsoring any accompanying events such as tourist travels, sports, and similar activities is forbidden. The INOVIA Code sets a limit for meal value to €60. Hospitality at events is restricted to the main event of the meeting and must not include persons who are not HCPs.

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?

Donations by MAHs and holders of medical device registrations to healthcare institutions or organisations are not deemed to be promotional (advertising) tools. Accordingly, they are regulated under the Law on Donations and Humanitarian Aid. State-owned healthcare institutions can receive donations from donors in Serbia and abroad in goods (excluding tobacco and tobacco products, alcohol, and travel vehicles), services, money, securities, proprietary and other rights. Donations to a supervisory body, inspection organ, or an organ deciding on the donor's rights, obligations, and interests or entering in any way into a business or other relationship with the donor are prohibited. The director of state-owned healthcare institutions decides on donation acceptance and management.

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?

Pharmaceutical laboratories and medical device manufacturers may sponsor events for HCPs, including lectures, congresses and seminars if they qualify as the *advertisers* within the meaning of the applicable regulations.

Advertiser of pharmaceuticals/veterinarian medical devices

According to the Rulebook on the Advertisement of Pharmaceuticals, an advertiser of pharmaceuticals/veterinarian medical devices is an MAH, the holder of a veterinarian medical device registration, a legal entity and natural person involved in the wholesale and retail of pharmaceuticals and veterinarian medical devices.

Advertiser of veterinarian medical devices for human use

According to the Rulebook on Medical Devices, an advertiser of medical devices for human use is a manufacturer or its authorised representative, and a legal entity and natural person involved in the wholesale and retail of medical devices for human use. Therefore, pharmaceutical laboratories or medical device manufacturers can support scientific or educational meetings as advertisers and no differences apply between these two sectors from the perspective of product promotion rules.

<p>Rules governing sponsoring events involving pharmaceuticals and medical devices are the same and include, among others:</p> <ul style="list-style-type: none"> • Sponsors must not condition support of events with requesting or giving any material or intangible counter-favours from HCPs. • Sponsoring HCPs should not influence the unbiased professional conduct of HCPs. • Events must be educational and in accordance with scientific achievements and should not serve solely to advertise products. • Sponsors cannot influence the content of the events that HCPs organise, but they are entitled to advertise their products on specially designated locations or places outside of the main event location.
<p>17. Please provide an overview of the rules around the industry and patient organisations' relationships, including funding.</p>
<p>Patient organisations in Serbia operate as non-profit organisations. The relationships between industry and patient organisations in the context of the advertisement of pharmaceuticals and medical devices are outside of the applicable regulations' scope. Therefore, general rules on contractual obligations govern agreements between industry stakeholders and patient organisations. In addition, when dealing with patient organisations, companies in the Serbian pharmaceutical and medical devices market abide by industry codes established by the European Federation of Pharmaceutical Industries and Associations (EFPIA) or local industry codes such as the INOVIA Code.</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>MAHs may promote pharmaceuticals with or through: (1) another chosen legal entity, by engaging their employees; or (2) another natural person. A common way to delegate promotional activities to third parties is by entering into service agreements. In such cases, the MAH must maintain records of the legal entities and their employees, and natural persons doing comparative promotion, including the legal entity's business name and seat, information about the persons doing the comparative promotion, their profession and job title, the amount of funds and compensation to the legal entity, or the natural person engaged for comparative promotion. The same rules apply to medical devices.</p>
<p>19. Is it mandatory in your country to report transfers of value made by permit/authorisation holders to healthcare professionals?</p>
<p>MAHs and other legal entities or natural persons involved in the wholesale and retail of pharmaceuticals and medical devices as advertisers have the continual obligation to publish information about professional conferences they have sponsored, and the total amount of funds allocated for such sponsorships during the current and previous calendar year. The platform for publishing is the advertiser's website in Serbia, or its official website abroad, or another appropriate website – while the MoH holds information about the websites used for publication. The advertisers should keep records on any transfer of value, including information on the title of the professional conference, its duration (start and end date), method of sponsoring, total amount of sponsored funds, individual amounts for sponsoring the participation of HCPs and information on any sponsored HCPs. Advertisers must deliver this information to the MoH on request.</p>
<p>ENFORCEMENT</p>
<p>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?</p>
<p><i>Commercial offences (pharmaceuticals)</i></p> <p>The non-compliant advertisement of non-prescription pharmaceuticals and infringing rules on the advertisement of pharmaceuticals to the general public constitutes a commercial offence punishable by a fine ranging from RSD800,000 (approx. €6,800) to RSD2,000,000 (approx. €17,000) for the company and RSD80,000 (approx. €680) to RSD150,000 (approx. €1,290) for the responsible individual in the company. In addition, a company may incur a ban on carrying out business activities for three to ten years. The same applies to noncompliant advertisements of veterinary medical devices.</p> <p><i>Commercial offences (medical devices for human use)</i></p> <p>The noncompliant advertisement of medical devices for human use constitutes a commercial offence punishable by a fine ranging from RSD1,500,000 (approx. €12,800) to RSD3,000,000 (approx. €25,650) for the company and RSD100,000 (approx. €850) to RSD200,000 (approx. €1,700) for the responsible individual in the company. In addition, a company may incur a ban on carrying out business activities for three to ten years.</p>

Misdemeanour (medical devices for human use)

The noncompliant advertisement of medical devices for human use by entrepreneurs constitutes a commercial offence punishable by a fine of RSD 300,000 (approx. €2,550) to RSD 500,000 (approx. €4,250), including a potential ban on carrying out business activities for six months to three years.

The Inspectorate for Pharmaceuticals and Medical Devices has the authority to ban the infringing advertising to all involved legal entities or individuals, including ordering a ban on the deployment of promotional materials and other documentation for advertising. This body initiates court proceedings against companies and entrepreneurs violating the advertising rules of the LMMD and LMD, which may ultimately result in court conviction and subsequent sanctions.

Penalties and other sanctions are not publicly announced. However, the public Register of Unpaid Fines enables access to information on imposed penalties.

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 enforced collection of adjudicated penalties and sanctions falls within the jurisdiction of the National Bank of Serbia. The National Bank of Serbia receives enforceable court adjudications immediately on the deadline for voluntary payment of the fine expiring and proceeds with the enforced collection of all outstanding amounts from the debtor's bank accounts. Direct activities of competitors through the courts in relation to promotion infringements are limited. If they do decide to take action against such infringements, competitors may report violations of advertisement regulations to the Inspectorate for Pharmaceuticals and Medical Devices, which proceeds with further steps at its own discretion.

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?

There are no significant indications suggesting fresh developments in the field of pharmaceutical or medical device promotion (advertising) in the next year or so, nor any general practice or enforcement trends which have become apparent over the past year.