

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 promotion and advertising of pharmaceuticals and medical devices in Saudi Arabia are governed by various laws and codes of practice issued by the Saudi Food and Drug Authority (SFDA) and other relevant authorities. These include:</p> <ul style="list-style-type: none"> • The Saudi Code of Pharmaceutical Promotional Practices, which regulates the marketing activities of pharmaceutical companies and their relations with healthcare professionals (Code); • The Code of Ethics for Healthcare Practitioners, which provides ethical guidelines for healthcare practitioners in their interactions with pharmaceutical and medical device companies, insurance companies, and the public; • The Law of Medical Devices and its Implementing Regulation, which outline the requirements and procedures for the registration, marketing, and post-market surveillance of medical devices, including the approval of advertising and promotion materials (Medical Device Law); and • Requirements for Advertisement Approval and Launching Awareness and Charity Campaigns for Medical Devices (Version 3) (MDS-REQ 8), which clarifies the advertising requirements for medical devices and the submission of advertising and marketing materials to the SFDA. This document replaces Guidelines for Advertisement Approval Requirements for Medical Devices and Products – MDS-G11. <p>In addition, the promotion and advertising of pharmaceuticals and medical devices must comply with the Saudi law of Printed Materials and Publication and the Audio-visual Media Law, for example, which bans any content that violates Islamic Sharia law and public morals.</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 term ‘advertising’ is not uniformly defined in all the documents, but one definition defines advertising of medical devices as any form of information, canvassing activity, or inducement intended to promote the supply or use of medical devices.</p> <p>There is no formal distinction between ‘promotion’ and ‘advertisement’ of pharmaceuticals and medical devices, but promotion is generally a broader term that encompasses various activities and materials aimed at influencing the prescription, supply, purchase, or use of pharmaceuticals and medical devices. Examples of advertising and promotion of pharmaceuticals and medical devices include: written material (eg, newspapers, professional journals/magazines); information available on the internet; television; radio; exhibition materials; medical lectures; and seminars, as well as information available in electronic form (eg, CD).</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 primary regulatory and supervisory authority that regulates and enforces the promotion and advertisement of pharmaceuticals and medical devices in Saudi Arabia is the SFDA. The SFDA is responsible for ensuring the safety, quality, efficacy, and accessibility of human and veterinary drugs, biological products, and cosmetics, as well as medical devices, in the Kingdom of Saudi Arabia. The SFDA also approves and certifies advertising and promotional materials for pharmaceutical products and medical devices according to national laws and regulations.</p> <p>There is no mandatory self-regulatory process for the promotion and advertisement of pharmaceuticals and medical devices in Saudi Arabia. However, the Code suggests an expectation of self-regulation within the pharmaceutical sector, where companies and institutions are expected to establish internal and external rules to ensure that information and declarations conform to the principles and provisions of the Code.</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?
There are separate advertising and promotion regulations applicable to other product types, although health food supplements and special nutritional products fall under the same regulations as pharmaceuticals where they are considered health-related products subject to the drug department of the SFDA.
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>It is not possible to promote or advertise all forms of pharmaceuticals and medical devices directly to the public in Saudi Arabia, as there are various restrictions and requirements that apply to different types of products and target audiences.</p> <p>Furthermore, some products, such as prescription-only medicines or controlled substances, are banned from being advertised to the public, and can only be promoted to healthcare professionals. Similarly, some medical devices, such as those intended for professional use only, are not allowed to be advertised to the public, and must include information relevant to the professional needs of the target audience.</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>Promotion and advertising of pharmaceuticals and medical devices through the Internet and social media is regulated by the SFDA, and other relevant authorities.</p> <p>Pharmaceuticals</p> <p>For pharmaceuticals, the SFDA requires all advertising and promotional materials to be approved by the SFDA before use, and to conform to the uses approved by the SFDA. The advertisements must include trade name, generic name, company/agent details, and scientific references, and must not contain misleading claims. The advertisements must also respect Islamic Law, national laws, and societal norms.</p> <p>Medical devices</p> <p>For medical devices, MDS-REQ 8 regulates digital advertisements of medical devices, and requires obtaining prior approval from the SFDA for any advertisement material directed to the public, whether it is on a website or social media platform registered inside or outside KSA. This approval requirement applies to both individuals and establishments.</p> <p>The advertisement must be available on the website or social media platform itself and not through external links. Also, it is forbidden to provide information directed to healthcare professionals on platforms that are meant for the general public.</p> <p>If an individual intends to publish advertisements on social media platforms, the SFDA must be notified via email at least 12 hours before publication. The advertiser's name, social media account, and the date of publication must be provided as part of the notification.</p> <p>Additionally, responses to inquiries on advertisement material published on social media platforms must not include any information that has not been previously approved by the SFDA. For live video or audio advertisements, a copy of the script must be submitted as a part of the advertisement material that is to be approved by the SFDA.</p> <p>For individual advertisements, a contract must be concluded between the establishment and the individual advertiser. Further, both parties must retain a copy of the contract, and it must be included within the documents attached to the application. The contract must include the following information:</p> <ul style="list-style-type: none">• the content of the advertisement material;• the time frame of the advertisement;• the social media platform to be used;• the geographical area that the advertisement is intended for; and• the duration of the contract.

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>Promotions and advertisements for pharmaceutical products and medical devices must receive prior approvals from the SFDA before use in Saudi Arabia. The procedure for obtaining prior approvals varies depending on the type of product, the target audience, and the medium of promotion or advertisement.</p> <p>Pharmaceuticals For pharmaceutical products, the SFDA requires a marketing authorisation licence for the product before any promotion or advertisement can take place. All advertising and promotional materials must also be approved and certified by the SFDA in accordance with national laws and regulations. The materials must conform to the uses approved by the SFDA and include essential information such as the trade name, generic name, company or agent's name and address, scientific references, and product usage details according to the internal leaflet. The materials must also respect Islamic Law, national laws, and societal norms, and avoid any false or misleading claims, comparisons, or statements. A medically qualified responsible person must approve all advertising materials.</p> <p>Medical devices In order to publish promotional or advertising material related to medical devices, prior approval must be obtained from the SFDA. This approval is required whether the advertisement is intended for healthcare professionals or the general public. Further, the medical device being advertised must have a Medical Device Marketing Authorisation (MDMA) obtained from the SFDA.</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>Information on unauthorised pharmaceuticals and/or off-label information cannot be promoted or advertised in Saudi Arabia. The Code states that products must have marketing authorisation before promotion and that promotional materials must conform to SFDA-approved uses.</p> <p>The Medical Devices Law and the MDS-G8 apply to medical devices; these documents require medical devices to have marketing authorisation, registration, and national listing numbers before advertising or marketing them in Saudi Arabia.</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>The Code requires that for advertisements for pharmaceuticals they must not make comparisons that are not statistically significant or medically supported. Otherwise, they can be made. However, off-label promotion is not permitted.</p> <p>For medical devices, MDS-REQ 8 states that the advertisements shall not directly or indirectly insult any other medical device. And it shall not include any comparisons to the products of other competing companies.</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>Healthcare professionals are defined differently in the regulations, depending on the context and scope of the regulation. In general, they include qualified persons who directly provide or assist in providing healthcare to patients.</p> <p>In all cases, regulations that restrict promotional (advertisement) communications directed to healthcare professionals in Saudi Arabia to those pre-approved by the SFDA.</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>There are no distinct specific rules governing promotional (and advertising) activity conducted virtually. However, the general rules and principles for pharmaceutical and medical devices promotion and advertising apply to all forms of promotion, including virtual.</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>There are some restrictions to the inclusion of endorsements by healthcare professionals in promotional (advertising) materials, depending on the type of product and the target audience.</p> <p>For pharmaceutical products, the Code regulates the use of consultants and lecturers as endorsers, as well as the disclosure of financial support from pharmaceutical companies to healthcare professionals. According to the Code, healthcare professionals who provide consulting or lecturing services to pharmaceutical companies must be reasonably compensated, have a written agreement, limit the number of consultations, maintain records of services, and disclose any previous consultations with related companies.</p> <p>For medical devices, the Medical Device Law and the MDS-G8 do not explicitly mention endorsements by healthcare professionals, but they require that advertising and marketing materials be approved by the SFDA and not be misleading or contradictory to the manufacturer's claims. Medical devices may only be advertised or promoted after obtaining approval from the SFDA, and advertisements must not contain any information that could mislead the user or contradict the claims made by the manufacturer. Advertisements directed at laypersons must avoid misleading information and must be in Arabic, while those directed at healthcare practitioners must be in English.</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>It is possible to provide healthcare professionals with samples of medicinal products or of medical devices in Saudi Arabia, but some restrictions apply.</p> <p>For pharmaceutical products, healthcare professionals may receive free samples in small quantities within the limits stipulated in Paragraph 15 of the Pharmaceutical Law. Free samples must be labelled as (free medical sample) and include the product's package leaflet. It is prohibited to provide samples of pharmaceutical products used for psychological treatment or containing narcotic substances, or any other medicinal products that the SFDA prohibits.</p> <p>Under the Code, for pharmaceutical products, monetary or material amounts must not be provided to healthcare professionals to induce them to prescribe or dispense medication. In-kind gifts to healthcare professionals are allowed in a symbolic manner, with a maximum value of SAR100 (approximately US\$27) per item and not exceeding SAR500 per year, provided they are related to the medical field or have a medical connotation that can be used in their work. In-kind gifts must bear the trade name or the generic name of the product being promoted. Healthcare practitioners can accept educational grants and financial support for training and conferences if it serves medical knowledge and the supporting company does not interfere with the scientific programme.</p> <p>For medical devices, the provision of samples to healthcare professionals is not limited but, as above, the medical devices may only be advertised or promoted after obtaining SFDA approval and in accordance with the Medical Device Law and SFDA guidance.</p>
<p>14. What rules govern the offering of hospitality to healthcare professionals?</p>
<p>The rules governing the offering of hospitality to healthcare professionals in Saudi Arabia are mainly derived from the Code. The Code applies to pharmaceutical companies and aims at ensuring ethical and professional conduct in their interactions and activities.</p> <p>According to the Code, hospitality offered by companies to healthcare professionals must be appropriate, reasonable, and proportional to the main purpose of the event, which should be scientific or educational in nature. Hospitality is limited to covering initial expenses such as tickets, meals, accommodation, and registration fees, and requires receipts as proof. Hospitality is restricted to event participants only, not their companions. The Code prohibits the inclusion of recreational events in the programme, and the use of</p>

venues known for their entertainment. The Code also provides a definition of ‘reasonable’ hospitality, which is linked to any applicable charters.
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?
Yes, they would be considered a form of promotion and they must comply with the Code, as detailed in response to other questions in this survey.
For example, grants from pharmaceutical companies can be provided to government or private hospitals, not to individuals, in the form of assistance to furnish a department or purchase a device. Books, scientific references, anatomical structures, or other educational materials of moderate value may be presented to healthcare professionals if they serve a purely educational purpose.
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 or medical device manufacturers or their licensees can support scientific or educational meetings in Saudi Arabia, as long as they comply with the relevant regulations and ethical guidelines. For pharmaceutical laboratories, the same rules apply as to other pharmaceutical companies, as set out in the preceding questions. For medical device manufacturers, the same rules apply as to other medical devices companies, as set out in the preceding questions.
17. Please provide an overview of the rules around the industry and patient organisations' relationships, including funding.
The Code and other advertising/promotion regulations also apply here.
Patient organisations must be accredited by the Ministry of Health and must be focused on providing patient education or support and may not be created for commercial or marketing purposes.
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?
It is possible to delegate promotional (advertising) activities to a third party through a service agreement, but the delegating party must ensure that the third party complies with the same ethical and regulatory standards as the delegating party.
For example, the third party must be familiar with relevant charters, laws, and regulations, and must provide accurate and non-misleading information about the products they promote. The delegating party must also have a mechanism to monitor breaches of the code and report them to the SFDA.
Co-promotion is not explicitly regulated in the documents, but it can be inferred that any co-promotion activities would need to follow the same principles and guidelines as any other promotional activities, ensuring accuracy, balance, and disclosure of financial support.
19. Is it mandatory in your country to report transfers of value made by permit/authorisation holders to healthcare professionals?
According to the documents, it is mandatory in Saudi Arabia to report transfers of value made by permit/authorisation holders to healthcare professionals in some cases. For example, the Code states that financial support details exceeding SAR100 per item or SAR500 per year must be disclosed to the SFDA.
Similarly, the Code of Ethics for Healthcare Practitioners requires healthcare professionals to disclose any financial or material benefits they receive from pharmaceutical companies or other sources which may affect their professional judgement or integrity.
Furthermore, the Medical Device Law obliges manufacturers, authorised representatives, and distributors to keep records of all transactions and activities related to medical devices, and to provide them to the SFDA on request.
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?

Penalties and other sanctions associated with violations related to product promotion vary depending on the type and severity of the violation, as well as the authority that oversees the regulation of the product.

For pharmaceutical products, the SFDA may take action against violations, but the Code does not enumerate these. We envision that the SFDA is likely to turn to the Pharmaceutical Law, wherein, without prejudice to any more severe punishment provided for in any other law, everyone who violates the provisions of this law may be punished with one or more of the following penalties:

- a fine of at least SAR10,000 and not greater than SAR100,000;
- closure of the violating company for no more than 60 days; and
- licence withdrawal, and the licensee may not apply for a new licence until after at least two years as of the effective date of the withdrawal decision.

Disciplinary penalties for professional violations may include:

- a warning;
- a fine not exceeding SAR10,000; and
- revocation of the licence to practice healthcare and the striking of the name from the registry of licensees. In case of revocation of the licence, reapplication for a new licence may not be filed until at least two years from the date of revocation.

We would not expect a substantive risk of receiving the most severe of these penalties, provided there is compliance with the Code.

For medical devices, the Medical Devices Law and the MDS-G8 provides that penalties can include fines, temporary or permanent closure of the establishment, suspension or revocation of marketing authorisation or licence, prevention from practicing any activity related to medical devices, imprisonment, and/or destruction of the medical device. The penalties can be doubled in cases of repeated violations within one year.

The SFDA may also take preventive and precautionary measures, such as seizing the medical device, issuing and publishing a safety alert, banning its circulation, or ordering its destruction. The SFDA may publish the operative part of the judgment or decision imposing the penalty at the expense of the violator in a local newspaper or other appropriate means. Persons affected by any violation have the right to claim compensation for the damage caused by such violation before the competent court.

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 responsibility for enforcement of the rules related to promotion (advertising) of medical devices in Saudi Arabia lies mainly with the SFDA, which is the competent authority for regulating medical devices and pharmaceuticals.

The SFDA has the power to inspect, confiscate, seize, suspend, revoke, or ban medical devices that violate the law or the regulations, as well as to impose fines and other penalties on the violators.

The SFDA can also refer severe cases, such as adulteration or use of false information to promote medical devices, to the Public Prosecution and the competent court for investigation and legal proceedings. Moreover, the SFDA can take precautionary measures if there is a belief that there is damage, misleading claims, or an impact on the safety, performance, or adequacy of medical devices.

Competitors or any other affected parties may take direct action through the courts in relation to promotion (advertising) infringements, as the law grants them the right to claim compensation for damage caused by such violations.

Other authorities or bodies, such as the Saudi Commission for Health Specialties or the Chamber of Commerce and Industry, also may have a role in enforcing or monitoring the rules relating to the promotion (advertising) of medical devices or pharmaceuticals.

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?

N/A
