

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>In the Republic of Korea ('South Korea'), the Act on Fair Labelling and Advertising, the Medical Devices Act, and the Pharmaceutical Affairs Act generally govern the matters related to the promotion and advertising of drugs and medical devices.</p> <p>Other than the above, the Fair Competition Code issued by the Korea Medical Devices Industry Association (KMDIA) and Korea Pharmaceutical and Bio-Pharma Manufacturers Association (KPBMA) and approved by the Korea Fair Trade Commission applies to the promotion and advertising to medical service personnel.</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>Advertising means informing or publicising the products (eg, medical devices and drugs) to consumers through statutorily defined media such as newspapers, broadcast or periodicals.</p> <p>Other than the term 'advertisement', the applicable laws do not define the term 'promotion'. However, the term generally refers to the activity of encouraging the sale of products other than by advertising.</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 Ministry of Food and Drug Safety (MFDS) regulates and enforces the promotion and advertisement of drugs and medical devices.</p> <p>The KMDIA and KPBMA may investigate and supervise a violation of the Fair Competition Code. However, the supervision of the KMDIA and KPBMA are separate from that of the MFDS in that the associations supervise their member companies. If the associations determine that their members have violated the Fair Competition Code, they have autonomy to impose sanctions such as fines and removal of members. Other than the foregoing, the associations may request the MFDS or relevant authorities to take necessary measures.</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>In South Korea, Health Functional Food is defined as food including ingredients which provide beneficial functions to human body and are not defined as drugs under the Pharmaceutical Affairs Act.</p> <p>The Act on Fair Labelling and Advertising regulates the advertisement and promotion of Health Functional Food as well, and the structure of regulation for Health Functional Food is not significantly different from that of the drugs or medical devices. However, in general, the relevant authorities more strictly regulate drugs and medical devices than Health Functional 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>Under the Pharmaceuticals Affairs Act, APIs and prescription drugs may only be advertised through professional medical media targeting professionals in medicine and pharmacy. However, relevant laws do not restrict public advertising of over-the-counter drugs or medical devices.</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?

The laws on advertisements equally regulate the advertisements carried out through the internet and social media as those are included in the definition of the term 'advertisement'.
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)?
The advertisement for drugs or medical devices shall be subject to the pre-review of the KPBMA and KMDIA In principle, there is no regulation requiring pre-review related to promotion activities that are not advertisements.
8. May information on unauthorised pharmaceuticals and/or off-label information be promoted (advertised)? If so, in what circumstances and under which modalities?
Advertisement of unauthorised drugs or medical devices are prohibited.
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 advertisements are not prohibited per se. However, advertisements that criticise the products of other companies by emphasising their disadvantages are banned even if the comparative advertisements are based on facts. Further, explicitly or implicitly mentioning the names of other companies' products is discouraged as it may constitute a slanderous advertisement. On the other hand, while there is no clear law on whether comparative advertisement against unauthorised drugs is permitted, it is highly likely that such an advertisement will not be allowed as it may mislead the consumers regarding the effects of the drugs.
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?
Under the Framework Act on Health and Medical Services, the term 'healthcare professional' means persons who acquire qualifications, licences, etc or are allowed to engage in providing health and medical treatment services under statutes related to health and medical services. However, healthcare professionals subject to advertising regulations may differ depending on the individual statutes. The Pharmaceutical Affairs Act and the Medical Devices Act forbid the provision of economic benefits (ie, illegal rebates or kickbacks) to healthcare professionals or medical institutions for the promotion of drugs or medical devices. These statutes comprehensively prohibit the provision of economic benefits, but make some exceptions for the following if they meet statutory qualifications: providing samples, sponsoring a symposium, supporting clinical trials, product demonstrations, product discounts, or post-market surveillance. The Fair Competition Code of the KPBMA and KMDIA identically regulates the promotions for healthcare professionals.
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?
We are of the view that if economic benefits are not provided, the virtual promotional and advertising activity is likely to be permitted.
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?
Such advertisement or promotion activity is prohibited.
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>Samples may be provided to medical institutions for no consideration if the term ‘sample’ is indicated on the minimum packaging that shows the characteristics of the drug or medical device. However, medical institutions may not sell or use the samples on patients.</p> <p>Gifts or donations are subject to anti-kickback regulations as described in the response to Question 10, above. In principle, donations shall be made by specifying the purpose and scale of the donation on the form prescribed by the KPBMA and KMDIA, and by requesting the KPBMA and KMDIA for the selection of the recipient (ie, medical research institutions or academic associations). The donor shall subsequently make the donation following the decision of the KPBMA and KMDIA. Alternatively, if the medical research institution/academic association requests the KPBMA and KMDIA for donations in order to carry out projects such as academic awards, campaigns, etc, the donor may directly make donations in accordance with the Fair Competition Code. However, other than the foregoing, the donor is banned from directly donating to medical institutions or healthcare professionals.</p>
14. What rules govern the offering of hospitality to healthcare professionals?
<p>There is no specific regulation governing the offering of hospitality to healthcare professionals, but the provision of economic benefits is prohibited.</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?
<p>The relevant laws do not ban the advertisement of donations. However, it is necessary that consumers are not misled about the efficacy of drugs or similar products due to such advertising.</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>Supporting of scientific or educational meetings must be conducted in accordance with the requirements of the relevant laws and the Fair Competition Code. Under the Code, the regulation applies not only to the entity engaging in drug or medical device business but also to its domestic and foreign head office, branches, and related companies providing economic benefits. Therefore, we are of the view that the regulation will equally apply to pharmaceutical laboratories or medical device manufacturers or their licensees.</p>
17. Please provide an overview of the rules around the industry and patient organisations' relationships, including funding.
<p>There are no separate rules regulating the industry and patient organisations' relationships.</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>It is possible to delegate the promotion to a third party or proceed with co-promotion. However, the applicable laws must be followed at all times as the delegator or the promoter may become legally liable for the delegate or co-promoter's violation of laws.</p>
19. Is it mandatory in your country to report transfers of value made by permit/authorisation holders to healthcare professionals?
<p>Transfers of value (ie, provision of economic benefits) must be reported to KPBMA and KMDIA even when such provision of economic benefits are permitted under the Fair Competition Code.</p>
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?
<p>In the event of breach of the Pharmaceutical Affairs Act or the Medical Devices Act, the violator may be subject to criminal penalties or administrative sanctions such as suspension of business for a certain period or revocation of permits and licences.</p> <p>The supervising authority often investigates potential violation of advertising laws and takes measures to impose criminal penalties or administrative sanctions. However, the details of the penalties or sanctions generally are not disclosed.</p>

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 MFDS or the administrative agency having jurisdiction over the relevant business is responsible for enforcement. The administrative sanctions are strictly enforced since the relevant laws and regulations describe very specific sanctions to various violation cases.

Competitors may directly report the violation of advertising regulations to the MFDS or investigative authorities or may directly file a criminal complaint to the investigative authorities for the violation.

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 has not been any significant developments in the field of pharmaceutical or medical device promotion (advertising) to date.