

Promoting Medical Products Globally

Handbook of Pharma and
MedTech Compliance

Japan



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Japan

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Introduction

As stated below, there are multiple regulations which govern advertising and promotional activity in the pharmaceutical drug and medical device industries in Japan. Medical product companies must ensure that they understand the details of these rules and regulations.

Advertising

With regard to advertising regulations, there are a lot of rules, including, but not limited to, the Pharmaceutical Affairs Act, the Advertisement Adequacy Standards and the Promotion Code. Pharmaceutical drug and medical device companies should have adequate procedures to ensure compliance with the multiple rules and regulations.

Off-label promotion by pharmaceutical companies is gradually becoming an issue, and industry groups (e.g., the Japan Federation of Pharmaceutical Organizations (“JFPO”)) are requesting that companies establish adequate rules to regulate it. For example, the JFPO has expressed the view that some companies convey off-label information under the pretense of press releases, articles containing interviews with doctors, and disease education advertisements. Pharmaceutical drug companies should heed the current movement to strengthen control of off-label promotion.

Promotional Activities

With regard to promotional regulations, it is worth noting that a great deal of public concern and attention has recently been focused on improper interactions between pharmaceutical or medical device companies and healthcare practitioners (“HCPs”). In order to respond to this severe public concern, the pharmaceutical and medical device industries have been strengthening their self regulatory codes (i.e., the Fair Competition Code). For example, the pharmaceutical industry group has decided to adopt a new rule which stipulates clear limits on the prices of meals and receptions that may be provided to HCPs¹. The medical device industry group has decided to adopt similar rules². Both industry groups have become more strict in their treatment of violations of the Fair Competition Code.

Given these circumstances, companies involved in these industries should pay keen attention to the latest laws and regulations regarding interactions with HCPs and should abide by every rule in order to avoid public censure and damage to reputation.

The Regulatory Framework

Relevant Regulations

In Japan, there is no law that generally applies in regard to advertising medicines and medical devices. The following laws and rules individually/independently regulate advertising and promotional activities.

¹ For example, meals provided to HCPs in connection with a lecture must cost less than JPY20,000, meals provided in connection with the provision of medical information to HCPs must cost less than JPY5,000 and light meals provided during explanatory meetings must cost less than JPY3,000 under the new Fair Competition Code rules for the Ethical Pharmaceutical Drug Marketing Industry.

² For example, meals provided to HCPs in connection with a lecture must cost less than JPY20,000, meals in connection with the provision of medical device information to HCPs must cost less than JPY10,000 and light meals provided during explanatory meetings less than JPY3,000 under the new Fair Competition Code rules for the Medical Device Industry.

General Regulations Regarding Advertising

- The Pharmaceutical Affairs Act (Prohibition on misleading advertising and others, restriction on advertising medicines for specified diseases, prohibition on advertising prior to approval)
- Order for Enforcement of the Pharmaceutical Affairs Act

Administrative Guidance Related to Advertising

- Appropriate Advertising Standards for Pharmaceuticals, etc.³

Industry Self-Regulation Related to Advertising and Promotion of Medicines

- Promotion Code of Ethical Pharmaceutical Drugs⁴ (Japan Pharmaceutical Manufacturers Association)
- Entry Guideline for Outlines of Ethical Pharmaceutical Drugs Information
- Fair Competition Code in Ethical Pharmaceutical Drugs Marketing Industry (Based on Article 11 of the Act against Unjustifiable Premiums and Misleading Representations)

Industry Self-Regulation Related to Advertising and Promotion of Medical Devices

- Promotion Code in the Medical Devices Industry⁵ (The Japan Federation of Medical Devices Association)
- Fair Competition Code for the Medical Devices Industry (Based on Article 11 of the Act against Unjustifiable Premiums and Misleading Representations)

Laws Related to Corruption and Bid Rigging

- Penal Code
- Antimonopoly Act
- National Public Service Ethics Act
- National Public Service Ethics Code

Definition of Advertisement

The Ministry of Health, Labour and Welfare has officially given notice that “advertisement” is defined by the following three characteristics: there is a clear intent to stimulate customers’ desire to purchase products or services; names of specific pharmaceutical products and the like are clearly revealed; and the general public may perceive it.⁶

General Requirements

The key rules on advertising medicines and medical devices are described below.

- With regard to medicines intended to treat cancer, sarcoma and leukemia and identified by government ordinances (i.e., Enforcement Order of Pharmaceutical Affairs Act), advertisements are only permitted to target medical personnel and not the general public pursuant to Article 67-1 of the Pharmaceutical Affairs Act and Article 64 of the Order for Enforcement of the Pharmaceutical Affairs Act.

³ 9 October 1980, *YakuHatsu* No. 1339, Notice by Chief of Pharmaceutical Bureau, Ministry of Health, Labour and Welfare to Governors of all Administrative Division (*todofuken*), Amendment 28 March 2002 *IYakuHatsu* No. 0328009

⁴ Japan Pharmaceutical Manufacturers Association, “Promotion Code in Ethical Pharmaceutical Drugs,” Amended 19 March 2008 (Implemented 23 May 2008).

⁵ The Japan Federation of Medical Devices Association, “Promotion Code in the Medical Devices Industry,” Amended 30 June 2010 (Implemented 1 October 2010).

⁶ *Iyakukan* Notification No. 148 dated September 29, 1998 issued by Director of Compliance Department, Pharmaceutical and Medical Safety Division, the Ministry of Health and Welfare to health directors of prefectural governments.

- With regard to medicines that require a prescription, advertisements may only target healthcare professionals under the Appropriate Advertising Standards No. 3-5.
- With regard to medical devices that are intended to be used by healthcare professionals and that may cause harm when used by general public, advertisements may only target healthcare professionals under the Appropriate Advertising Standards No. 3-5.
- Article 66 of the Pharmaceutical Affairs Act prohibits advertising, writing or circulating false or misleading articles regarding the name, manufacturing methods, efficacy/effectiveness and nature of any medicines and medical devices. Additionally, Article 66 of the Act prohibits advertising, writing or circulating articles that misleadingly convey that some doctors or healthcare practitioners have certified the efficacy/effectiveness and nature of certain medicines or medical devices. Furthermore, it prohibits the usage of words or pictures that are obscene or suggest abortion.
- Article 68 of the Pharmaceutical Affairs Act prohibits advertising the name, manufacturing methods, efficacy/effectiveness and nature of any unapproved medicines.
- The expressions and contents of advertisements for the general public and promotional materials for medical personnel must follow Promotion Codes, Entry Guideline for Outlines of Ethical Pharmaceutical Drugs Information, and other relevant self-regulations.

Permitted and Prohibited Practices – Advertisements

Advertisements for Drugs

Ethical Pharmaceutical Drugs (Require a Prescription)

- Advertisements for ethical pharmaceutical drugs that require a prescription are not permitted to target the general public.
- Promotional materials for pharmaceutical professionals must follow the Promotion Code of Ethical Pharmaceutical Drugs. The main points of the Promotion Code are as follows:
 - The expressions of efficacy/effectiveness, nature, dose and dose regimen of drugs shall not go beyond the scope for which approval was obtained.
 - Use of false, excessive or misleading expressions regarding safety and efficacy is not allowed.
 - Along with information on efficacy, information on the side effects and others related to the safety of the drugs must also be noted as well.
 - Comparison with other drugs must be based on objective data, and in principle, should use generic names.
 - Defamation of other companies or their products is not allowed.
 - Giving the wrong impression by conveying exceptional data as if it represents a common fact is not allowed.
 - Use of photographs or illustrations that would mislead and hurt the dignity of the drug is not allowed.
 - Advertisements that are mainly constituted by the name of the product must mention the name (used for distribution), the efficacy classification names, regulatory classifications, generic name, contact information for requests for more informational materials, and whether the advertised drug is covered by the Japanese social health insurance.
- More specific methods of writing promotional materials of ethical pharmaceutical drugs must follow the Entry Guideline for Outlines of Ethical Pharmaceutical Drugs Information and other relevant self-regulations, and must be scientifically objective, fair and accurate.

Advertisements for OTC Drugs

Advertisements of OTC drugs intended for the general public must follow the Appropriate Advertising Standards for Pharmaceuticals, etc. The main points of the Appropriate Advertising Standards are as follows:

- Advertisement using misleading expressions that may suggest false information regarding the efficacy/effectiveness and safety of the drugs is not allowed.
- Using expressions guaranteeing the efficacy/effectiveness, nature and safety of drugs is prohibited.
- Noting the efficacy/effectiveness, etc., of drugs that is not acknowledged as innate is prohibited.
- Encouraging overdose or abuse of the drugs is prohibited.
- Defaming other companies' products is prohibited.
- Mentioning that medical personnel or another similar professional recommends a product is prohibited.
- Excessive prizes that would appeal to gambling tendencies is prohibited. In principle, advertisements shall not state that medicines are given out as prizes or promotional gifts. Advertisements shall not convey that medicines will be handed out in exchange for containers, wrappers, etc., of drugs.
- Using expressions that may convey discomfort, concern and fear is prohibited. Advertisements shall also not create discomfort, nuisance, etc.
- When advertising through emails:
 - show contact information (email address, etc.) of the distributor, etc., of the drug;
 - the subject line of an email with the advertisement must indicate that it is an advertisement if the email was sent unilaterally without the request or consent of the consumer; and
 - the advertisement email must set forth an option and procedure to refuse further advertisement emails, and such refusal request must be followed.
- In sponsored programs on television or radio, people on the programs may not comment on or suggest certain drugs' quality, efficacy, safety and other related qualities. Advertisements for sponsored programs for children require special attention not to induce wrong perception of the drugs.
- Advertisements should not encourage relaxed usage of medicines by emphasizing the methods of cosmetic use or consumption as foodstuff, or methods of using medical equipment as cosmetic equipment or health equipment.
- Advertising that significantly lacks integrity or misleads as to the nature of medicines is prohibited.

Advertisements for Medical Devices

If the medical device is intended to be used by healthcare professionals and may cause harm when used by the general public, then it shall not be advertised to the general public.

Applicable regulations are the same as that of medicines (as described above).

Permitted and Prohibited Practices – Other Promotion

Promotion to National Public Servants

The Penal Code prohibits bribing government employees. If a healthcare professional is a government employee (e.g. a doctor at a national hospital), a bribe cannot be given to that medical personnel. A "bribe" is defined as a certain amount of benefit that may satisfy one's need or desire.

Furthermore, pursuant to the National Public Service Act, the National Public Service Officials Ethics Code and relevant regulations prohibit national public servants from receiving benefits from stakeholders. For example, the National Public Service Officials Ethics Code regulates the relationship between stakeholders and national public servant as follows:

- National public servants are not permitted to attend receptions, games, golf, or trips (unless for official business) with stakeholders.
- As an exception, national public servants may be provided with meals in buffet meetings and refreshments at meetings for official business. Also, national public servants may accept promotional samples and commemorative gifts that are widely distributed to the public as gifts.

Fair Competition Code in Ethical Pharmaceutical Drugs Marketing Industry

The Fair Competition Code in Ethical Pharmaceutical Drugs Marketing Industry prohibits marketers from offering premiums to medical institutions, etc., that unjustifiably induce transactions of medical devices. Primary regulations are described below.

Gifts

Gifts given as social courtesy (mid-year and year-end gifts, calling gifts, etc.) are permitted; however, any lavish, extravagant gifts are prohibited. Marketers may provide commemorative gifts at a memorial event. The monetary value of such gifts given at a memorial event that is directly related to a company's own medical device, e.g., a gift commemorating the anniversary event of the launch of particular medical device, should generally not exceed JPY5,000 to be considered appropriate. Goods distributed to the attendees of lecture meetings (held strictly for the purpose of offering guidance on the use of a particular medical devices) may be permitted. In this context, gifts with a monetary value of JPY3,000 or less are generally considered appropriate.

Drug Samples

Drug samples may be offered free of charge only if they are in accordance with the following purposes:

- Presentation samples to enable healthcare professionals to confirm the outward characteristics of the relevant ethical pharmaceutical drugs.
- Clinical testing samples to enable physicians to confirm and evaluate the quality, efficacy and safety of the drugs.

Drug samples shall always be accompanied by information on the relevant ethical pharmaceutical drug. The quantity offered shall be the necessary minimum in accordance with the purpose of presentation or clinical testing samples. The Fair Competition Code provides specific amounts that constitute "the necessary minimum." Moreover, the samples shall not be recurrently offered or offered to medical institutions that have already adopted the relevant ethical pharmaceutical drugs.

Entertainments and Meals

Entertainment and meals offered as a form of reception (provided for facilitating communication amongst the attendees of commercial negotiations or meetings) are permitted; entertainment and meals provided solely for leisure pursuits and dining opportunities that are beyond the scope of such as reception (as described above) are prohibited. Furthermore, lavish and extravagant recreational activities and meals are prohibited. Recreational activities such as social gatherings and dining and other meals offered as social courtesy are permitted if not lavish and extravagant.

In regard to ethical pharmaceutical drugs, the Fair Competition Code likely will be amended as follows:

- Meals offered at a lecture meeting or other social event shall not exceed JPY20,000.
- Lunch boxes (bento) and snacks offered at a product explanatory promotion conducted by MR shall not exceed JPY3,000.
- Meals offered at a meeting for organizers to plan a lecture meeting, held in relation to the entrustment of research, etc., shall not exceed JPY20,000.
- Meals offered to a speaker who was invited to an in-house study group shall not exceed JPY20,000.
- Meals that go with a product explanatory activity shall not exceed JPY5,000.

Donations

Donations for the purpose of serving the public interest are generally permitted. Such donations should be made to serve the interests of society as a whole, and should not be made for commercial purposes. Donations made for the purposes of funding a health care provider's individual research or a medical institution's ordinary services are not considered as donations made for the purposes of serving the public interest and are therefore prohibited.

The following are considered as means of unjustifiably inducing transactions, and are prohibited:

- Donations in the form of an agreement to assume expenses to be disbursed by medical institutions (for purposes of purchasing goods, renovating facilities, supplementing administrative funds or otherwise used to serve the interest of the medical institution receiving the donation)
- Offering of cash (or other value) in consideration of ordinary medical practices conducted by the medical institution
- Cases where it has been promised that marketers will receive advantageous treatment in return for donations
- Donations that are deemed excessive from standards of social acceptability
- Cases where a marketer was induced to give donations in consideration of possible consequences on future transactions

Lecture Meeting or Seminar About Product

The place, facility and other means of holding such meeting must not represent an invited trip or entertainment. The place, facility, date and schedule shall not depart from the purpose of a lecture meeting held to explain the offerer's products. Reception must neither lavish nor excessive, e.g. a buffet meeting, held in connection with the meeting is permitted.

Permitted payments for the cost of attending the meetings are as follows:

- Fees and expenses may be offered to a speaker if they are deemed appropriate by standards of social acceptability.
- The necessary minimum travel expenses may be offered to a non-speaker.

Fair Competition Code for the Medical Devices Industry

Gifts, samples, entertainment/meals, donations, and lecture meetings are regulated in the same manner as pharmaceuticals, above. In addition, the Fair Competition Code for the Medical Devices Industry provides regulations specifically for medical devices.

Lending

Medical devices shall not be loaned to assume expenses to be disbursed by medical institutions. Described below are the standards (not regulations) on lending medical devices:

- Lending for demonstration shall not exceed one month. The same medical device may be loaned to the same hospital department only once.
- Lending for trial use shall not exceed six months. The same medical device may be loaned to the same hospital department only once.
- Lending for research purpose shall not exceed 12 months.
- Lending in response to accidents and malfunctions shall not exceed the warranty period or the time it that would normally take to fix the device.
- Lending for training shall not exceed one month.

Attendance (“Tachiai”)

“Attendance” refers to visiting a medical institution to offer labor benefits and information regarding the medical devices. However, attending with the intent to sell medical devices and assume expenses to be disbursed by medical institutions is not permitted. In principle, attendance is permitted to ensure the safe operation of medical devices or offer supplemental explanations to the content of package inserts, etc. However, the attendance offered for free beyond the provided standard of the Code is prohibited as it falls within the scope of unjustifiably inducing transactions.

Public Procurement and Fraud

In principle, contracts for the state, local governments and incorporated administrative agencies must employ general competitive bidding. Thus, general competitive bidding is employed in national public hospitals (including national university hospitals) to purchase supplies.

- Bid rigging is prohibited. Under the Antimonopoly Act, a concerted action with shared intent among the bidders with mutual restraints and actually restricts competition constitutes unjust restraint on trade. Moreover, the Penal Code crime of offering of bribes applies to bid rigging with the purpose of unjustly gaining profit or affecting fair price.
- An act of offering a bribe to a national public servant in order to acquire inclusion in the bid constitutes the crime of offering of bribes in the Penal Code.

Consequences of Breach

Breach of the Pharmaceutical Affairs Act

A breach of Article 66 (prohibition of misleading advertisements) or Article 68 (prohibition of advertisements prior to approval) of the Act shall be punished by imprisonment with work for not more than two years, or a fine of not more than JPY2,000,000.

A breach of Article 67 (restriction on advertising medicines for specified diseases) Act shall be punished by imprisonment with work for not more than one year, or a fine of not more than JPY1,000,000.

Crime of Offering of Bribes in the Penal Code

The crime of offering of bribes is punishable by imprisonment with work for not more than three years, or a fine of not more than JPY2,500,000. A crime of bid rigging is punishable by imprisonment with work for not more than three years, or a fine of not more than JPY2,500,000.

Antimonopoly Act

An unjust restriction on a transaction shall be punished by imprisonment with work for not more than five years or a fine of not more than JPY5,000,000 for an individual, and a fine of not more than JPY500,000,000 for a company.

Appropriate Advertising Standards

The Appropriate Advertising Standards are administrative guidance, which means that there are no penal provisions.

Promotion Code

Companies that breach the Promotion Code of Ethical Pharmaceutical Drugs may face the following measures:

- “Recommendation for improvement,” “warning” or “severe warning” may be given depending on the degree of breach.
- Dismissal or suspension of membership from the Japan Pharmaceutical Manufacturers Association.

The Promotion Code in the Medical Devices Industry corporate ethics committee in the Japan Federation of Medical Devices Association will decide on an appropriate correction plan that may include announcing the breach within the association.

Fair Competition Code

For a breach of the Fair Competition Code in the Ethical Pharmaceutical Drugs Marketing Industry, the Fair Trade Counsel of the Fair Competition Code may warn the offender in writing, such as through a cease and desist order, not to repeat the same or similar breach, etc. The marketer who fails to comply with the warning shall be liable to a penalty charge of not more than JPY1,000,000 or dismissal from the Fair Trade Counsel. Furthermore, the Fair Trade Counsel then may ask the Japan Fair Trade Commission to implement necessary remedial measures. If the Counsel conducts any of the measures listed above (warning, penalty charge, or dismissal), then it must file a report with the Japan Fair Trade Commission.

A breach of the Fair Competition Code in the Medical Devices Industry is treated in the same manner as above.

Contracts with Healthcare Professionals and Medical Institutions

Contracts with healthcare professionals and medical institutions in post-marketing surveillance (“PMS”), entrustment of research, etc., are subject to the regulations of the Fair Competition Codes.

Fair Competition Code in the Ethical Pharmaceutical Drugs Marketing Industry

- PMSs or entrustments of research that are mere pretexts and actually correspond to means of unjustifiably inducing transactions of the offerer’s pharmaceutical drugs, are restricted under the Code.
- The amount of remuneration for a case report must not exceed the limit beyond which the remuneration corresponds to a means of unjustifiably inducing transactions. Normally, the total amount of remuneration shall not exceed JPY10,000.
- Requests for entrustments of surveillances and research shall basically be agreed with the medical institution in writing, and reports of the results of the requested surveillances and researches must also be received in writing.

- Entrustment of surveillance and research to a specific healthcare professional in a medical institution requires the permission from the medical institution to participate in such researches.

Fair Competition Code in the Medical Devices Industry

Same as pharmaceuticals, above.

Recommendations

The following considerations should be noted in conducting advertising and promotional activities:

- Establish a structure to follow the relevant advertising regulations (the Pharmaceutical Affairs Act, the Appropriate Advertising Standards for Pharmaceutical Affairs Act, Promotion Codes, the Entry Guidance for Outlines of Ethical Pharmaceutical Drugs Information, etc.).
- Pay attention to information offered to the general public in disease education activities, provisions of information to patient groups and open public seminars in order to follow the relevant advertising regulations.
- Formulate internal rules on the scope of providing off-label use information.
- Establish a corruption prevention policy. Such policy must encompass relationships with third parties (such as distributors, agents and consultants), including executing contracts containing adequate anti-bribery clauses as well as provide anti-corruption training.
- Provide internal rules related to offering receptions, gifts, meals, etc., to health care professionals.
- Provide internal rules related to offering donations to medical institutions, health care professionals, etc.
- Provide internal rules related to making PMSs and entrustments of research contracts with health care professionals, etc.

This third edition of “*Promoting Medical Products Globally. Handbook of Pharma and MedTech Compliance*” is intended to provide an overview of the applicable compliance laws governing the cooperation between the medical industry and physicians in Europe, North America, Latin America and the Asia Pacific region. It highlights the legal framework within which medical device and pharmaceutical companies cooperate with health care professionals. It deals with common sponsoring practices such as invitations, conferences and financial grants for research, personnel and equipment as well as other promotional activities such as the giving of gifts, samples and other items and services which are of interest to health professionals. We trust that the third edition is a useful resource for lawyers, compliance officers, managing directors and managers in marketing and medical departments of the medical industry to assess the legal impact on their promotion and marketing activities involving healthcare professionals or medical institutions.