Fair Competition Regulations in the Medical Device Industry

1. Notice to the Medical Device Industry

Fully revised on August 11, 1997 by notification No. 54 of the Fair Trade Commission
Revised on November 16, 1998 by notification No. 18 of the Fair Trade Commission
Revised on March 31, 2000 by notification No. 8 of the Fair Trade Commission
Revised on March 29, 2005 by notification No. 4 of the Fair Trade Commission

A part of the restrictions (notification No. 54 of 1997 issued by the Fair Trade Commission) on the offering of premiums in the pharmaceutical product, medical device, and health laboratory industries will be revised in accordance with the provision of Article 3 of the Act against Unjustifiable Premiums and Misleading Representations (Law No. 134 enforced in 1962) as follows:

Restrictions on Matters Concerning the Offering of Premiums in the Pharmaceutical Product, Medical Device, and Health Laboratory Industries

The companies which manufacture or sell pharmaceutical products, those which manufacture or sell medical devices, and those which conduct health laboratory tests shall not offer premiums to medical institutions, etc. as a means of unjustifiably leading trade of pharmaceutical products, medical devices, or health laboratory tests by exceeding the limit that is deemed acceptable in the light of the necessary goods and services for using pharmaceutical products, medical devices, or health laboratory tests and of the normal commercial practice.

Remarks

1. Pharmaceutical products as used in this notification mean the pharmaceutical products which are used for the medical purposes at medical institutions, etc. prescribed in Article 2-1 of the Pharmaceutical Affairs Law (Law No. 145 enforced in 1960).
2. Medical devices as used in this notification mean the medical devices which are used for the medical purposes at medical institutions, etc. prescribed in Article 2-4 of the Pharmaceutical Affairs Law.
3. Health laboratory tests as used in notification mean the tests which are prescribed in Article 2-2 of the Clinical Laboratory Technicians and Health Laboratory Technicians Law (Law No. 76 enforced in 1958).
4. Medical institutions, etc. as used in this notification mean the hospitals and clinics which are prescribed in Article 1-5 of the Medical Care Law (Law No. 205 enforced in 1948), the health care facilities for the elderly requiring long-term care which are prescribed in Article 7-22 of the Long-term Care Insurance Law (Law No. 123 enforced in 1997), and the pharmacies, the companies which conduct medical care, and those which are entrusted with health laboratory testing (including their directors, medical personnel, and other employees), prescribed in Article 2-11 of the Pharmaceutical Affairs Law.

Supplementary provisions

1. This notification shall be put into effect on October 1, 1997.
2. The offering of premiums in conjunction with any trade which has ended prior to the enforcement of this notification shall comply with the prior practice.

Supplementary provisions

1. This notification shall be put into effect on April 1, 1998.
2. The offering of premiums in conjunction with any trade which has ended prior to the enforcement of this notification shall comply with the prior practice.

Supplementary provision

This notification shall be put into effect on April 1, 2000.

Supplementary provision

This notification shall be put into effect on April 1, 2005.

2. Fair Competition Regulations for Restrictions on the Offering of Premiums in the Medical Device Industry

Approved by the Fair Trade Commission on November 16, 1998 in
Notification No. 19 issued by the Fair Trade Commission on November 16, 1998
Revised (approved by the Fair Trade Commission on June 27, 2000 in
Notification No. 26 issued by the Fair Trade Commission on July 17, 2000)
Revised (approved by the Fair Trade Commission on March 14, 2005 in
Notification No. 6 issued by the Fair Trade Commission on March 29, 2005)

Article 1: Objective

The present Fair Competition Regulations (hereinafter referred to as "the Regulations") is intended to restrict the unjustifiable offering of premiums in the medical device manufacture and selling industries so as to prevent the unreasonable attraction of customers and potential customers and thereby ensure the fair competition order.

Article 2: Definitions

1. Medical devices as used in this notification mean the medical devices which are used for the medical purposes at medical institutions, etc. prescribed in Article 2-4 of the Pharmaceutical Affairs Law.
2. Medical device manufacturers as used in the Regulations mean the companies which manufacture or import and sell medical devices and abide by the Regulations.
3. Medical device sellers as used in the Regulations mean the companies which sell medical devices and abide by the Regulations.
4. Business organizations as used in the Regulations mean the medical device manufacturers, medical device sellers, and other similar companies.

5. Medical institutions, etc. as used in the Regulations mean the hospitals and clinics which are prescribed in Article 1-5 of the Medical Care Law (Law No. 205 enforced in 1948), the health care facilities for the elderly requiring nursing care and the companies which provide medical care service, which are prescribed in Article 7-22 of the Long-term Care Insurance Law (Law No. 123 enforced in 1997), including their directors, medical personnel, and other employees).
6. Premiums as used in the Regulations mean the goods, money, and other economic interest which business organizations give away to customers or potential customers in any manner as a means of attracting them in association with any trade of medical devices supplied by such business organizations, including but not limited to:
   (1) Goods, land, buildings, and other constructions;
   (2) Money, cash vouchers, deposit certificates, certificates with winning money, bonds and debentures, stock certificates, gift certificates, and other securities;
   (3) Entertainments (including invitations or complimentary tickets to movies, theater, sports event, travel, and other events)
   (4) Benefits, labor, and other services.

   However, premiums as used in the Regulations do not include economic interest which is deemed as markdown or after-sales service or as coming with the medical device in the light of the normal commercial practice.

Article 3: Principle for Restrictions on the Offering of Premiums
No business organizations shall offer any premium to medical institutions, etc. as a means of unjustifiably leading any trade of medical devices.

Article 4: Instances Where Offering is Restricted
The offering of premiums which violates the provision of Article 3 is instantiated below:
   (1) Money or goods, invitation to travel, entertainment, benefit, labor, etc. is offered to any physicians, dentists, or other medical personnel who belong to medical institutions, etc. as a means of leasing the choice or purchase of medical devices, or
   (2) Any medical device, benefit, labor, etc. is offered free of cost to medical institutions, etc. as a means of leading the choice or purchase of medical devices.

Article 5: Instances Where Offering Is NOT Restricted
The offering of premiums which does not violate the provision of Article 3 is instantiated below:
   (1) Goods, benefits, or other services which are necessary for the proper use of the company's own medical device or any emergency action are offered;
   (2) Medical information on medical devices, documents, explanatory material, etc. on the company's own medical devices are offered;
   (3) Medical devices for trial use are offered in accordance with the requirements set forth in the Enforcement Regulations;
   (4) Consideration and expenses for post-marketing surveillance studies for medical devices, clinical trials, and other researches and studies for medicine and medical devices, which have been requested to medical institutions, are paid; or

(5) Goods or services which are neither luxurious nor extravagant and offered at lecture meetings, etc. held for medical institutions on the company's own medical device or the expenses for attending such meetings are born by the company.

Article 6: Restrictions on the Offering of Premiums to Medical Device Sellers

No manufacturers for medical devices shall offer premiums to any medical device sellers by violating the provision of Article 19: Prohibition of Unfair Trading Method in the Act Concerning Prohibition of Private Monopoly and Maintenance of Fair Trade (Law No. 54 enforced in 1947).

Article 7: Fair Trade Council

1. In order to achieve the objective of the Regulations, the Fair Trade Council of Medical Device Industry (hereinafter referred to as "the Fair Trade Council") shall be set up.
2. The Fair Trade Council shall be comprised of business organizations which abide by the Regulations and the groups organized by such business organizations.
3. The Fair Trade Council shall undertake the following activities:
   (1) Ensuring that the Regulations are strictly observed;
   (2) Providing services for consultation, guidance, and complaint handling in relation to the Regulations;
   (3) Conducting investigations on any suspected violation of the Regulations;
   (4) Taking action for any business organization which has violated any provision of the Regulations;
   (5) Publicizing the Act against Unjustifiable Premiums and Misleading Representations and the other laws and ordinances related to fair trade and preventing any violation of them;
   (6) Making communication with the authorities concerned; and
   (7) Taking any other action in enforcing the Regulations.

Article 8: Business Organizations' Obligation for Cooperation

The business organizations shall cooperate with the Fair Trade Council in order to ensure the efficient implementation of the Regulations.

Article 9: Investigations on Violations

1. If the Fair Trade Council suspects that there is an event which violates the provision of Article 3, the Fair Trade Council may summon the persons concerned, inquire about the necessary information from such persons, seek opinions from witnesses, and otherwise conduct the necessary investigation on such event.
2. The business organizations shall cooperate with the investigation which is conducted by the Fair Trade Council pursuant to the provision of Article 9-1.
3. The Fair Trade Council shall warn, in writing, any business organization which does not cooperate with the investigation conducted pursuant to the provision of Article 9-1 about the obligation to cooperate with such investigation. If such business organization fails to comply with such warning, the Fair Trade Council may impose a penalty in an amount of no more than ten thousand (100,000) yen or remove such business organization from a list.

Article 10: Action for Violation

1. If the Fair Trade Council finds that there is any misconduct violating the provision of Article 3, the Fair Trade Council may warn, in writing, the relevant business organization about the obligations to take the necessary action to eliminate such misconduct, not to repeat the same or any similar kind of such misconduct, and carry out the related activities.
2. If the Fair Trade Council finds that the business organization which has been warned pursuant to the provision of Article 10-1 fails to comply with the warning, the Fair Trade Council may impose a penalty in an amount of no more than one million (1,000,000) yen upon such business organization, remove such business organization from a list, or ask the Fair Trade Commission to take the necessary action.
3. If the Fair Trade Council issues a warning, imposes a penalty, or removes the name of the violating business organization from a list pursuant to the provision of Article 9-3, 10-1, or 10-2, the Fair Trade Council shall immediately notify, in writing, the Fair Trade Commissions that such action has been taken.

Article 11: Decision in Relation to Violation

1. If the Fair Trade Council is taking action (except for issuing a warning) pursuant to the provision of Article 9-3 or 10-2, the Fair Trade Council shall prepare a draft for the action which should be taken (hereinafter referred to as "the Action Plan") and send such draft to the violating business organization.
2. The violating business organization may raise an objection, in writing, to the Fair Trade Council within ten (10) days after receiving the Action Plan.
3. If such objection is raised pursuant to Article 11-2, the Fair Trade Council shall give the violating business organization a chance to make any additional assertion and submit evidences. The Fair Trade Council shall further review the violation based on such additional material and decide on action accordingly.
4. If no objection is raised pursuant to the provision of Article 11-2, the Fair Trade Council shall immediately make a decision similar in intent to the Action Plan.

Article 12: Establishment of Enforcement Regulations

1. The Fair Trade Council may establish enforcement regulations for the matters related to the enforcement of the Regulations.
2. If the enforcement regulations are being established or revised, a prior approval shall be obtained from the Fair Trade Commission.

Supplementary Provisions:

1. The Regulations shall be put into effect on April 1, 1999. However, the provisions of Articles 7 (except for Articles 7-3-3 and 7-3-4) and Article 12 shall be put into effect on the day when the Fair Trade Commission gives notice of its approval.
2. If the system for the supply of medical devices in the medical care under insurance is altered, the Regulations shall be immediately reviewed from the viewpoint of ensuring fair competitions in the medical device industry.

Supplementary Provision:
The revision of the Regulations shall be put into effect on the day when the Fair Trade Commission give notice of its approval (July 17, 2000).

Supplementary Provision:
The revision of the Regulations shall be put into effect on April 1, 2005.

3. Enforcement Regulations for Fair Competition Regulations for Restrictions on the Offering of Premiums in the Medical Device Industry

Approved by the Fair Trade Commission on December 12, 1998
Revised (approved by the Fair Trade Commission on March 14, 2005)

Article 1: Terminology
The terms as used in the Fair Competition Regulations for Restrictions on the Offering of Premiums in the Medical Device Industry (hereinafter referred to as "the Regulations" and the present Enforcement Regulations are defined as follows:

(1) The products which are used for the medical purposes by medical institutions, etc. regardless of whether the medical insurance is applicable for such products shall be included in the medical devices as used in the Regulations.
(2) "Other similar companies" as used in Article 2-4 of the Regulations mean the companies which agree to comply with the Regulations and sell medical devices manufactured by a subcontractor or a vendor under their own brands or names and those which agree to comply with the Regulations, have exclusive distributorship or any other special contractual relationship with any medical device manufacture, and are deemed as carrying out practically the same business as that of such manufacturer (distributors, etc.)
(3) "Medical institutions, etc." as used in Article 2-5 of the Regulations include the physicians, dentists, pharmacists, and other medical personnel who belong to medical institutions, etc.; the directors and employees of medical institutions, etc.; and the persons who are involved in the choices and purchase of medical devices at medical institutions, etc. (medical service personnel).
(4) "Economic interest which is deemed as after-sales service in the light of the normal commercial practice" in the conditional clause of Article 2-6 of the Regulations mean the goods, benefits, and other services that are necessary for the trade or use of medical devices (e.g., handling within the warranty period, explanations of operations, maintenance, and repairs).
(5) "Economic interest which is deemed as coming with the medical device in the light of the normal commercial practice" in the conditional clause of Article 2-6 of the Regulations means the goods, benefits, and services which are structurally and functionally integral to medical devices (e.g., installation of, setup of, wiring for, and operational adjustments for medical devices, and storage containers).

Article 2: Medical Devices for Trial Use

The offering of medical devices for trial use pursuant to Article 5-3 of the Regulations shall be carried out as follows:

(1) Definition of medical devices for trial use

Medical devices for trial use mean the medical devices that are offered free of cost to medical institutions, etc. so that medical personnel can check the visual properties such as the shapes or access the efficacy and safety through trial use prior to the purchase of such medical devices.

(2) Requirements for offering

a. The medical devices for trial use shall be marked so that they can be identified from commercial products.

b. The medical devices for trial use shall be offered in the minimal quantity necessary for the purpose of the check or assessment prescribed in Article 2-(1).

c. If the medical devices for trial use are being used clinically, they can only be offered when a prior written request is made by a physician, etc.

Article 3: Consideration, etc. for Case Report

Consideration and expenses for post-marketing surveillance studies as prescribed in Article 5-(4) shall be offered in accordance with the following requirements:

(1) Case reports mean reports which physicians, etc. prepare, at the request of a medical device manufacturer, by filling out a specified research form to provide some information on the efficacy, safety, and quality of a specific kind of post-marking medical device that was actually used for patients.

(2) No money shall be offered as a means of leading the choice or purchase of the manufacturer's medical device by camouflaging such means through the payment of consideration for making a case report. For this purpose, the following requirements shall be met:

a. No case report shall be requested under the condition of continuing the choice and purchase of the medical device under investigation or increasing the purchase quantity.

b. The number of patients to be included in the investigation shall be reasonable in the light of the purpose and other details of the investigation.

c. Case reports shall be requested to medical institutions, etc. which can fully achieve the purpose of the investigation.

d. Case reports shall not be requested excessively to a specific area or specific kinds of medical institutions, etc. in the light of the purpose and other details of the investigation.

e. Case reports shall not be requested in any excessive number disproportionate to the number of patients who were treated by medical institutions, etc. or physicians, etc.

f. Case reports shall be requested in writing.

g. The amount of consideration for a case report shall not exceeds a reasonably calculated amount.

Article 4: Lecture Meeting for Manufacturer's Medical Device

The offering of premiums at lecture meetings, etc. for the manufacturer's own medical device as prescribed in Article 5-5 of the Regulations shall meet the following requirements:

(1) Lecture meetings, etc. mean meetings which are intended for giving explanations about the manufacturer's own medical device for multiple medical institutions, etc. regardless of whatever names such as explanatory meetings and seminars are given.

(2) In order to prevent such lecture meetings from being misunderstood as invited travel or entertainment, care must be taken for the venues, locations, and arrangements.

(3) The permissible payment of expenses, etc. for attendance shall meet the following requirements:

a. The consideration and expenses for lecturers, etc. requested for lecture meetings shall be paid within the socially accepted limits.

b. The traveling expenses paid to the attendees other than lecturers, etc. shall be minimal.

c. Entertainment, if provided in conjunction with lecture meetings, etc., shall be neither luxurious nor extravagant.

Article 5: Offering of Modest Premium

The offering of the following economic interest does not violate the provision of Article 3 of the Regulations even of such economic interest is deemed as premium:

(1) Premium which has only a small value and does not exceed the socially acceptable limits that are duly reasonable in the light of the normal commercial practice.

(2) Gifts and entertainment which are offered at conventionally held convivial meetings to the extent that is neither luxurious nor extravagant.

(3) Gifts and entertainment which are offered at conventionally held memorial events for persons or medical institutions, etc. to the extent that is neither luxurious nor extravagant.

Article 6: Detailed Regulations

In order to implement the Regulations and the Enforcement Regulations, the Fair Trade Council may establish detailed regulations for operation requirements or procedures by notifying the Fair Trade Commission.

Supplementary Provision:

The Enforcement Regulations shall be put into effect on the effective day of the Regulation (April 1, 1999).

Supplementary Provision:

The revision of the Enforcement Regulations shall be put into effect on the effective day of the revision of the Regulation (April 1, 2005).

Form 1

Application Form for Trial Use of Medical Device for Clinical Trial

Date:

To: _____

Location:

Name of medical institution:

Name of department:

Name:

Product name and description	Quantity for trial use	Number of days (frequency) for trial use	Number of patients

Enforcement Regulations & Operation Standard for Fair Competition Regulations

Definition of medical devices for clinical trials: These medical devices mean the ones that are intended for use in clinical trials by medical personnel in order to assess their efficacy and safety prior to the use of such medical devices.

Fair Trade Council of Medical Device Industry

Form 3

Voucher for Lending of Medical Devices

Date:

Lent by:
Location:

Lent to:
Location:
Returned on:
Name of responsible person for management:

Purpose of lending

☐ Demonstration ☐ Clinical trial (assessment of efficacy, safety, operability, etc.) ☐ Use in emergency or at disasters ☐ Accident or failure
☐ Training ☐ Study or public research activity ☐ Delayed delivery ☐ Others

Product name, manufacturer's name, and description	Q'ty	User's name/installation site	Period	Number of patients

Costs to be born during the lending period

Lender | Borrower

1. Installation of the lent medical device
2. Removal
3. Maintenance and service charge
4. Consumables
5. Other cots

The medical device shall be immediately returned to the lender after the expiration of the lending period.

Fair Trade Council of Medical Device Industry