

# **The Promotion Code of the Medical Devices Industry**

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The Japan Federation of Medical Devices Associations

(JFMDA)

## **I. The Promotion Code of the Medical Devices Industry**

### **1. Obligations and Practices of Members**

#### **Obligations of Members**

Members shall adhere to basic philosophy which means being fully aware of the importance of social missions as a company, being engaged in medical businesses, defined in “The Code of Ethics” of the Japan Federation of Medical Devices Associations (hereinafter referred to as “JFMDA”), sharing values with society, proposing new values through their businesses and fostering a healthy and happy life.

Members shall formulate an in-house control system based on JFMDA’s “The Charter of Business Behavior” in order to properly promote it in accordance with this basic philosophy.

#### **Practices of Members**

Members shall be aware of social missions as a company handling medical devices and comply with applicable laws and regulations and adhere to ordinances. They shall also formulate a definite code of practice standards based on “The Code of Ethics” and JFMDA’s “Promotion Code” (hereinafter referred to as “Code”) and shall educate/train their employees to behave in accordance with it.

All Members shall follow the Practices shown below.

- (1) Establish an in-house control system so that proper and continuous promotion can be implemented.
- (2) Request and encourage the observance of the Code for group companies in Japan

and foreign countries.

(3) Provide, in a proper manner, medical institutions and other similar institutions with the latest data based on established scientific grounds.

(4) Aim to be an excellent company, complying with international standards for safety and taking necessary measures toward environmental issues.

## **2. Obligations of Top Management**

In order to meet the expectations and gain the confidence of society, which expects nothing less from its medical companies, top management of Members shall implement the following tasks with a high order of ethics and a strong sense of responsibility according to “The Charter of Business Behavior”:

(1) To realize this Code, top management of Members shall promote greater awareness and understanding for all parties concerned, organize an in-house system and take the lead in implementing it.

(2) In case of incidents contrary to this Code, top management of Members must promptly investigate the cause for the incident, solve the problems and make the utmost efforts to avoid recurrence at their respective organizations.

## **3. Product Development**

(1) When developing medical devices, Members shall concentrate efforts on the development of quality products by keeping abreast of scientific advances, while paying careful attention to bioethics, the preservation of environment and the protection of resources.

(2) Members shall respect know-how in the domain of medical doctors and other companies. At the same time, they shall not collect information or disclose confidential information by unfair means.

(3) Members must not use unfair means in conducting clinical studies (trials) to verify the safety and effectiveness of products.

## **4. Manufacturing and Marketing**

(1) When manufacturing and marketing medical devices, Members must strictly comply with applicable laws and regulations and make every possible effort not to violate them. They must also take appropriate action in the event the medical device which has been manufactured or marketed turns out to be defective.

(2) When manufacturing and marketing medical devices, Members shall provide medical institutions with an in-depth explanation or call their attention to applicable laws and regulations on the disposal of medical devices, while giving careful consideration to environmental protection.

## **5. Market Research**

(1) When conducting market research, Members must strictly comply with applicable laws and regulations and must not be engaged in activities using unfair means, whether directly or indirectly.

(2) Members shall handle undisclosed information as confidential, except for the information that has been disclosed, published or obtained by the legitimate means from a third party.

(3) Members shall handle any information in their domain according to The Act on the Protection of Personal Information.

## **6. Advertising /Promotion (Representations of Printed Materials and Advertisements for Promotion)**

Members shall recognize that printed materials for promotion, advertisements in specialty journals and newspapers, audiovisual materials such as websites, slides, and VTRs for medical personnel and other materials for commercial promotion give an important means to offer product information. They shall also create and use accurate, fair and objective materials based on scientific grounds according to the Pharmaceutical Affairs Law and relevant voluntary rules.

(1) Members shall not advertise the intended use and efficacy of their products out of the scope of approval or certification for manufacturing and marketing.

(2) Members shall not use false, exaggerated or misleading expressions in describing the safety and effectiveness of products.

If safety, such as “few side effects (defects)”, is to be expressed as one of the features for products, Members shall not make this claim without listing restrictions. In this case, they shall summarize and attach the data demonstrating safety.

(3) Members shall also disclose information not only on effectiveness but also on safety, including disclosing defects (side effects) on a balanced and fair basis.

(4) Members shall use objective data when comparing their products with other companies' products. In principle, they shall use generic names and not specific, identifiable names for other companies' products.

(5) Members shall not use expressions that may defame or slander other companies or their products.

(6) By picking up only exceptional data, Members shall not use descriptions that may impress people into thinking of them as general facts.

(7) Members shall not use misleading expressions, degrading photos or illustrations, etc.

(8) When emphasizing the name of a product in advertisements, Members shall make clear its information such as brand name, regulatory category, generic name, and reimbursement coverage in the medical insurance. Contact information shall also be clearly stated in response to the request for materials from outside.

(9) Members shall organize an in-house review and control committee for printed materials and advertisements. They shall use only such materials and advertisements that have passed the review of the committee.

## **7. Surveillance after Manufacturing and Marketing (Post-Marketing Surveillance)**

Members shall recognize the objective of post-marketing surveillance intended for the establishment of proper use of a medical device after manufacturing and marketing. Surveillance conducted should reflect scientific validity, comply with applicable laws and regulations, and adhere to voluntary rules. It shall not be conducted for the purpose of sales promotion.

## **8. Marketing Activities**

(1) Ensuring fair competition and fair trade

Members shall carry out sales activities and transactions of medical devices with a high order of ethics. At the same time, they shall comply with The Antimonopoly Act (Act Concerning Prohibition of Private Monopolization and Maintenance of Fair Trade (Act No. 54, 1947)) and other applicable laws and regulations.

- Members shall positively and strictly adhere to “The Fair Competition Code Concerning Restriction on Premium Offers in the Medical Devices Industry” (The Fair Competition Code of the Medical Devices Industry in Japan (April, 2005, hereinafter referred to as “Fair Competition Code”)) formulated under The Act Against Unjustifiable Premiums and Misleading Representations.

- Members shall organize and put in place an in-house control system to ensure fair and free competition, whereas JFMDA and its member associations shall set up an adequate committee for guidance and enlightenment.

(2) Prohibiting slanderous or defamatory acts

Members shall not slander or defame other companies or their products.

(3) Prohibiting the preparation of unfair comparison tables

Members shall prepare comparison tables for products based on objective data. They shall not use any unfair method.

(4) Offering services

Members shall not offer personnel in the field of medical care or medical institutions and other similar institutions benefits, labors and/or other services that may infringe on applicable laws and regulations and the “Fair Competition Code” except when they are reasonably justified.

(5) Offering goods

Members shall comply with applicable laws and regulations when offering personnel in the field of medical care and medical institutions or other similar institutions some goods. Those goods shall not adversely affect the adoption or proper use of the offerer’s medical devices and shall be socially acceptable in light of normal business practices.

(6) Offering money or the like

①Members shall not offer personnel in the field of medical care or medical institutions and other similar institutions money or the like that may adversely affect the adoption or proper use of the offerer’s medical devices, whether directly or indirectly.

②Members shall take precautions so that money or the like is not beyond a socially acceptable level, even if they can offer it to personnel in the field of medical care or medical institutions and other similar institutions.

(7) Offering sample medical devices

Members shall restrict the quantity of sample medical devices which are supplied to medical professionals as a means to furnish information. The quantity shall be kept to a minimum level necessary to help medical professionals confirm and evaluate appearance features, quality, effectiveness and safety for such devices.

(8) Offering medical devices on loan

Before making loan of medical devices to medical institutions or other similar institutions, Members shall confirm the terms and conditions of the loan in writing,

including items such as purpose, reason, number of cases (minimum), period, etc.

(9) Confidentiality of information on customers and like persons

Members shall not disclose personal information of patients or persons involved in clinical studies or entrusted research, etc., nor any internal information on customers which they have come to know through business, to any third party or utilize it for sales promotion without prior consent in accordance with The Act on the Protection of Personal Information.

(10) Concluding agreements in writing

① Members shall conclude a written agreement prior to transactions with customers as well as prior to entrustment or requests to medical institutions and doctors for research, surveys or lectures, in order to make the terms and conditions of transactions clear and to carry out business activities in a safe, smooth and transparent manner.

② Members shall comply with applicable laws and regulations in transactions with public institutions and operate business activities following their rules, if any.

## **9. Holding Seminars**

When holding a seminar on product explanations for medical professionals, Members shall take reasonable care not to take advantage of scientific opportunities by providing the attendants with professional information. When Members host social gatherings or receptions, or present some gifts, they shall adhere to the “Fair Competition Code”.

## **10. Scientific Display of Unapproved Medical Devices**

When displaying unapproved medical devices, only those that have been requested from and permitted by the chair of a medical conference for the purpose of enhancement and advances in scientific research shall be allowed.

In this case, Members shall adhere to the industry’s voluntary standard, “Guideline Concerning the Display of Unapproved Medical Devices, etc.” issued by JFMDA in August, 1990. (Note 1)

Important provisions of the Guideline are excerpted below.

① It shall be clearly stated that approval by the Pharmaceutical Affairs Law of Japan of the device concerned is pending and that this product is not for sale.

② The brand name planned for such device shall not be displayed or announced.

(Note 1) See Appendix 3 for the “Guideline Concerning the Display of Unapproved

Medical Devices, etc.”

### **11. Promotion in Foreign Countries (Provision of Information on Medical Devices in Foreign Countries)**

Members shall provide information on medical devices to medical professionals in foreign countries, whether directly or indirectly, by following applicable laws and regulations and industry’s voluntary standards pertaining to each country.

### **12. Relationship between this “Code” and the “Fair Competition Code”**

Violation of the “Fair Competition Code” means violation of this “Code.” Some acts, however, which do not violate the “Fair Competition Code,” may violate this “Code.”

## **II. Management of this Code**

1. This Code shall be managed by the Corporate Business Ethics Committee of JFMDA.
2. The Corporate Business Ethics Committee shall be made up of committee members and academic experts and placed under the supervision of the JFMDA Chair.
3. The Corporate Business Ethics Committee shall conduct an investigation and hearing when it receives a complaint about a matter that may infringe on this Code or when it itself considers a matter to be questionable, it may then take the following action:  
In the event an act is considered to infringe on this Code, the Corporate Business Ethics Committee shall carry out activities to raise the awareness in each member company.
4. Members shall cooperate with the Corporate Business Ethics Committee in conducting investigation.
5. Provisions relating to organization, members and administration of the Corporate Business Ethics Committee shall be separately defined.

## **III. Revision of this Code**

1. This Code shall be reviewed and revised to ensure its validity as needed.
2. The revision of this Code shall be approved by the Board of Directors, JFMDA.