Promotion Code of the Medical Device Industry

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The Japan Federation of Medical Devices Associations
(JFMDA)

I. Promotion Code of the Medical Device Industry

1. Responsibilities and the Standards of Conduct of Member Companies

Responsibilities of Member Companies

Member companies' basic principles of the business activities is to realize people's healthy and happy life by acknowledging strongly the social mission and significance as a health care related company set forth in the "Code of Ethics" of Japan Federation of Medical Devices Associations (hereinafter referred to as "JFMDA"), sharing values with society, and proposing new values through their businesses.

Member companies must establish their internal administrative system based on the "Charter of Business Behavior" of JFMDA to conduct appropriate promotion according to these basic principles.

Member companies' standards of conduct

Member companies must acknowledge the social mission as a company which handles medical devices and observe the relevant statute or laws and regulations, as well as to create the specific standards of conduct based on the "Code of Ethics" and "Promotion Code of the Medical Device Industry" (hereinafter referred to as "Code") and educate and train their employees to act according thereto.

Each member company will perform the following standards of conduct;

(1) to establish the company administrative system for making it possible to execute appropriate and consistent promotion,
(2) to request and enlighten related/affiliated companies, etc. which handle medical devices as well regardless at home or abroad to observe this Code,
(3) with regard to providing information on medical devices to medical institutions and other organizations, to collect the latest data based on clear scientific grounds and provide it promptly in an appropriate method, and
(4) to take into account the safety that meets international standards and environmental issues and aim at becoming an excellent company.

2. Responsibilities of High-level Management

High-level management of member companies performs the following matters with their high level of ethical view and strong sense of responsibility based on the "Charter of

Business Behavior" to meet social expectations and trust as a health care related company;

(1) aiming at the realization of this Code, to raise awareness to relevant persons and prepare a proper company system, and take action to become a role model on its own initiative, and

(2) in case of any event that is likely to be against this Code, to address the problem-solving at its own responsibility and authority and do its best for prompt diagnosis and the prevention of recurrence.

Product Development

(1) For the development of medical devices, member companies must take into account the bioethics and environmental preservation, and the protection of resources and make an effort to realize excellent products along with the advance of science.

(2) Member companies must respect the know-how of doctors or other companies, etc. and neither collect information, etc. by using unfair means nor leak any secret.

(3) Member companies must not use unfair means for the performance of clinical trial to verify the usefulness such as efficacy and safety.

4. Manufacturing/Marketing

(1) For manufacturing/marketing of medical devices, member companies must observe related legislation and take all possible measures not to violate it. If any fault in the medical devices manufactured/marketed is found, member companies must take measures immediately.

(2) For manufacturing/marketing of medical devices, member companies must take into account environmental protection and give sufficient explanation or call attention on the disposal, etc. of such medical devices for medical institutions.

5. Market Research

(1) For the market research, member companies must observe related legislation, etc. and not conduct, directly or indirectly, any activities using the unfair means.

(2) Member companies must handle non-public information with due care and must not leak it externally other than released information, public information, and information duly obtained from a third party.

(3) With regard to the handling of personal information obtained, member companies must handle it based on "the Act on the Protection of Personal Information" (Personal Information Protection Act).

6. Advertisement (Printed Material for Promotion and Display of Advertisement, etc.)

Member companies must acknowledge that any printed material for advertisement, advertisement on any specialist magazine, homepage for medical staffs, audiovisual for advertisement such as slides/VTR and other materials for advertising and selling are important means to provide product information and, for such creation and use thereof, member companies must observe the Act on Ensuring Quality, Efficacy and Safety of Pharmaceuticals and Medical Devices, etc. (hereinafter referred to as "Act on

Pharmaceuticals and Medical Devices") and related self-imposed norm, etc. and make the contents precise, fair and objective based on scientific grounds.

(1) For the description of effects or performance, purposes of use, etc., do not deviate from the scope to which marketing approval or certification for marketing has been given.
(2) With regard to efficacy/safety, do not use false, exaggerated or misleading expression. When describing safety as one of characteristics, such as "side effects (nonconformity) are rare", the description should have a supplementary note of abstract of data that forms the grounds, not using without limited requirement.
(3) Fairly note information on safety such as nonconformity and do not incline toward efficacy.
(4) The comparison with other products should be conducted based on objective data by using general name without using any proper noun in principle.
(5) Do not have the description or expression that slanders other companies and products of other companies.
(6) Do not take up exceptional data and give an impression as if it is a general fact in their expression.
(7) Do not use misleading expressions, or pictures or illustration, etc. which would lose dignity.
(8) For advertisement mainly composed of product name, to state clearly brand name, regulation classification, general name, the handling on reimbursement of medical insurance.
In addition, to state clearly the contact point to request materials of such product so that the request of materials from outside can be responded.
(9) For the printed material for advertisement and advertisement, etc., to establish the screening administration system and use the contents after passing such screening.

7. Implementation of Post-marketing Surveillance, etc.

Post-marketing surveillance of medical devices means use-results survey or post-marketing studies conducted for the collection, detection, confirmation or verification of information on quality, efficacy and safety, etc. of medical devices ("Ministerial Ordinance concerning Good Post-marketing Study Practice for Medical Devices" (Ministry of Health, Labour and Welfare ordinance No. 38 of 2005)). With the accurate acknowledgement of this purpose, the surveillance is governed by scientific validity and implemented in accordance with the related statute and self-imposed norm, not for the purpose of sales promotion.

8. Sales Activities

(1) Securing Fair Competition and Fair Trade
For the trade of medical devices, member companies will conduct the sales activities based on the high level of ethical view. Member companies will observe related legislation such as Anti-Monopoly Act (Act on Prohibition of Private Monopolization and Maintenance of Fair Trade (Act No. 54 of 1947)).
- To observe "Fair Competition Code on Restriction of Premiums Offering in

Medical Device Industry" (Fair Competition Code of the Medical Device Industry (April 2005, hereinafter referred to as "Fair Competition Code")) developed based on Act against Unjustifiable Premiums and Misleading Representations positively and strictly.

- To prepare the internal administrative system for fair and free competitions, and JFMDA and member associations thereof will establish committees, etc. to conduct the enlightenment and training.

(2) Prohibition of Slander Act

Do not slander other companies and products of other companies.

(3) Prohibition of Creation of Unfair Comparison Table

A Product comparison table shall be created based on objective data without using an unfair method.

(4) Offering of Services

Member companies shall not offer benefit, labor or other services which is likely to be in conflict with related legislation and "Fair Competition Code" to healthcare professionals or medical institutions and other organizations, excluding the case that reasonable grounds are given.

(5) Offering of Articles

Articles which member companies may offer to healthcare professionals or medical institutions and other organizations must be those which are in conformity with legislation, regulations, etc., not likely to pose a risk to have an influence on the adoption or appropriate use of medical devices and socially accepted in light of normal business practice.

(6) Offering of Cash and Cashable Articles

1. Member companies shall not offer, directly or indirectly, the cash and cashable articles which are likely to have an influence on the adoption or appropriate use of medical devices to healthcare professionals or medical institutions and other organizations.
2. Member companies must pay attention for the cash and cashable articles not to exceed over a socially accepted idea, even if the cash and cashable articles are allowed to offer to healthcare professionals or medical institutions and other organizations.

(7) Offering of Medical Device Samples

The offering of medical device samples used as a means of information provision for medical staffs must keep to a bare minimum necessary to be used as an aid to confirm and evaluate exterior features or quality, efficacy and safety, etc.

(8) Medical Equipment Loan

In medical equipment loan to medical institutions and other organizations, member companies must confirm the purpose, grounds, the minimum number/period of cases, etc. by written documents in advance.

(9) Personal Information Protection and Confidentiality

Member companies shall not use the personal information of patients or the examinees of clinical study, contract research, etc. without approval of the applicable person based

on “the Act on the Protection of Personal Information” (Personal Information Protection Act). Member companies shall not disclose the inside information of customers obtained through their business to any third party.

(10) Execution of Written Agreement

1. Upon contracting or requesting medical institutions or doctors to research, investigate, giving a lecture, not to mention having trades between customers, member companies must dispel the ambiguity of the terms of trade by exchanging documents such as contracts and conduct business activities by safe and smooth methods with the high level of transparency.
2. For the transactions with public institutions, etc., member companies must observe related legislation and deal with the business according to regulations set forth by such public institutions, etc., if any.

9. Holding Lectures/Seminars.

Lectures/Seminars on products held by member companies for medical staffs shall be academic for providing technical information to the attendees. If offering a social event or gifts accompanying to lectures/seminars, “Fair Competition Code” must be observed.

10. Academic Exhibition of Unapproved Medical Devices

For the purpose of the improvement and progress of academic research and only for those which the chairman of such academic conference granted permission for the request of exhibition, the exhibition of unapproved medical devices is permitted.

Upon exhibition, “Guideline Bylaws on the Exhibition of Unapproved Medical Appliances, etc.” * which are industry voluntary standards issued by Japan Medical Devices Relevant Group Council (current JFMDA) on August 1990 shall be observed.

The followings are important rules in the Bylaws.

1. To be marked clearly as that such medical devices are unapproved and cannot be sold nor given.
2. Not to profess the intended brand name.

* Refer to Material 3 for “Guideline Bylaws on the Exhibition of Unapproved Medical Appliances, etc.”

11. Promotion outside Japan (Provision of Medical Devices Information outside Japan)

With regard to medical devices information given to medical staffs outside Japan, regardless of directly or indirectly, member companies will provide according to legal restrictions or industry voluntary standards of the relevant country.

12. Relationship of “this Code” and “Fair Competition Code”

The violation of “Fair Competition Code” will be deemed as the violation of “this Code” at the same time and on the other hand, any act which is not deemed as violation in light of “Fair Competition Code” may violate “this Code”.

II. Administration of this Code

1. The administration of this Code will be conducted by Business Ethics Committee established in JFMDA.
2. Necessary matters regarding the organization, structure and operation of Business Ethics Committee will be determined separately.
3. In case that a claim on the case which may be contrary to this Code has been made or at the independent discretion, Business Ethics Committee will conduct investigation and examination and take the following measures.
   If any act which is contrary to this Code is found, awareness activities will be taken to stimulate self-awareness of each member company for the purpose of this Code.
4. Member companies must assist with the investigation conducted by Business Ethics Committee.

III. Revision of this Code

1. With regard to the revision of this Code, it must be reviewed as the need arises to secure its efficacy.
2. For the revision of this Code, the approval must be obtained from the board of JFMDA directors.