Promotion Code of the Medical Device Industry

Revised on March 10, 2021

Japan Federation of Medical Devices Associations

<Revision History of the Promotion Code of the Medical Device Industry>

- Established on January 28, 1997, implemented on February 20, 1997
- Revised on June 22, 2000, implemented on July 1, 2000
- Revised on July 29, 2003, implemented on October 1, 2003
- Revised on March 25, 2005, implemented on April 1, 2005
- Revised on June 30, 2010, implemented on October 1, 2010
- Revised on November 1, 2015, implemented on November 1, 2015
- Revised on March 10, 2021, implemented on April 1, 2021

I Promotion Code of the Medical Device Industry

1. Objective, Scope, etc.

1-1 Objective

The objective of the Promotion Code of Medical Device Industry (hereinafter, “this Code"), which sets forth the code of conduct to be observed by Member Companies of the Japan Federation of Medical Devices Associations (hereafter, "the JFMDA") in their promotional activities for medical devices, is to maintain and improve the public trust in the medical device industry through conducting transparent corporate activities of all Member Companies rooted in compliance with a high ethical view while giving the highest priority to their contribution to the health and welfare of patients as members of the life science industry.

1-2 Scope

This Code applies not only to the promotional activities for medical devices but also to all relationships (transactions, information provision, interactions, etc.) between Member Companies and medical institutions, healthcare professionals, and researchers, etc.

Member Companies shall create internal regulations targeting all the officers and employees based on this Code and comply with this Code. In addition, Member Companies shall always make judgment based on whether their actions are in accordance with the purport of this Code regardless of the presence or absence of specific descriptions in this Code.

1-3 Definition of promotion

In this Code, "promotion" refers not only to so-called sales promotion but also to the provision, collection, and communication of information on medical devices to medical institutions, healthcare professionals, etc. to ensure proper and safe use of medical devices.

2. Responsibilities of Member Companies

The basic philosophy of corporate activities of Member Companies is to strongly recognize their social mission as life science companies, share their values with the society, propose new values through their corporate activities, and contribute to the realization of healthy and happy lives of people.

Member Companies shall establish an internal system for proper promotion based on this basic philosophy, be aware that they are fully responsible for the promotional activities conducted by their employees, and implement the following:

(1) To conduct highly transparent corporate activities by taking the utmost care to ensure the efficacy and safety of products and securing fair and free competitions.
(2) To accurately provide the latest data in an appropriate manner based on clear scientific evidence when providing information on medical devices to medical institutions, etc.
(3) To provide continuous education and training to the officers, employees, etc. to implement proper promotion.
(4) To establish an internal system to comply with the relevant laws and regulations and the voluntary code of conduct.

3. Responsibilities of High-level Management

The high-level management of Member Companies performs the following matters with a high level of ethical view and strong sense of responsibility to meet social expectations and trust as a life science company.

(1) To take initiative in complying with this Code, consider the actions of all the officers, employees, etc. as the responsibility of the top management, thoroughly inform the concerned parties, and improve the internal system.
(2) In case of any event that is likely to be against the spirit of this Code, to address the problem-solving at its own responsibility and do its best for prompt diagnosis and the prevention of recurrence.
(3) The divisions in charge of products other than medical devices shall also make efforts to conduct corporate activities while respecting the spirit of this Code.
(4) To make efforts to ensure the subsidiaries that manufacture and sell medical devices in Japan also comply with this Code.
(5) To express its stance to comply with this Code to affiliated companies and business partners who manufacture and sell medical devices in or outside Japan and strive to ask for their understanding.

4. Relationship with Medical Institutions/Healthcare Professionals

The relationship between Member Companies and medical institutions/healthcare professionals shall aim to contribute to the advancement of life science such as medical science and medical engineering and the improvement of public health and shall focus on the provision of information on medical devices, the academic exchanges on medical science and healthcare, and the research support. Even when promoting industry-academia collaboration, Member Companies shall also establish relationships of trust with researchers and healthcare professionals for the development of medical devices and advancement of medical science and healthcare.

When interacting with medical institutions/healthcare professionals, Member Companies shall comply with the "Fair Competition Code of the Medical Devices Industry" (hereafter, "FCC") and shall not conduct corporate activities which are likely to inappropriately influence their decisions to use or select medical device products.

4-1 Written agreement

Upon not only outsourcing operations such as research, survey or lectures to medical institutions/healthcare professionals but also having transactions with Customers, Member Companies must dispel the ambiguity of the terms of trade by exchanging documents such as written contracts and conduct corporate activities by safe and smooth methods with the high level of transparency.

For the transactions with the public offices, Member Companies must observe the related legislation and deal with the business according to the regulations set forth by the public offices, if any.

4-2 Outsourcing

Member Companies may outsource operations such as research, clinical studies, post-marketing surveillances, consultations/technical guidance, participation in meetings, writing/supervising articles, acting as chairpersons or speakers at lecture meetings, and giving training instructions to medical institutions/healthcare professionals and pay remunerations/expenses based on legitimate needs. When outsourcing these operations, however, a contract must be singed and meet all of the following criteria;

(1) A written contract specifying the purpose of the operation and the remunerations/expenses for the operation should be signed.
(2) The legitimate need for the operation should be clearly identified before outsourcing.
(3) The contractor of the operation should have its specialty directly related to the identified need and reasonable

reasons to be selected, like based on its expertise needed for the operation.

(4) The number of contractors of the operation should be reasonable to achieve the identified need.

(5) It should not be intended to inappropriately induce to use, select, prescribe, purchase and/or recommend medical device products or accept contract offer for medical device control operations (hereafter, collectively, "Adoption of medical devices") should not be wrongly induced.

(6) The remuneration for the operations should be appropriate as a consideration for the outsourced operations.

4-3 Offering of cash or cash equivalents, goods, and services

(1) Member Companies shall not offer, directly or indirectly, cash or cash equivalents, goods or services, which are likely to have an influence on the Adoption of medical devices, to medical institutions/healthcare professionals.

(2) Member Companies may provide cash or cash equivalents, goods or services to an appropriate extent in light of normal business practices in accordance with the related laws and regulations and the FCC with respect to academic research, education, and activities to improve public health conducted by medical institutions/healthcare professionals.

4-4 Securing transparency

Member Companies are required to have a high ethical view as life science companies and need to appropriately fulfill the accountability to the society concerning their ethical and sincere relationships with medical institutions/healthcare professionals and researchers. Member Companies must ensure the transparency of corporate activities under the "Transparency Guidelines for the Medical Device Industry and Its Relationships with Medical Institutions and Other Organizations" of the JFMDA and their own guidelines developed based on the Transparency Guidelines.

In addition, the guidelines for the management of conflict of interest (COI) established by medical institutions and other organizations such as academic societies must be understood and respected.

4-5 Relationship with Officials

When entrusting operations or providing cash or cash equivalents, goods or food/drink to national, local governments or deemed civil service officials (hereafter, "Officials "), Member Companies must understand and respect the National Public Service Ethics Act, the related laws and regulations such as the National Public Service Ethics Code, and the in-hospital ethics code established by public medical institutions.

5. Environmental Conservation

In all their corporate activities including development, manufacturing, and sales of medical devices, Member Companies shall comply with the environment-related laws and regulations and proactively work on environmental preservation as well as resource protection.

6. Protection of Information

6-1 Protection of confidential information

Member Companies must not obtain confidential information from customers, business partners or other third parties (hereafter, "Customers") in an unfair manner. Member Companies must manage and handle confidential information obtained from Customers in an appropriate and safe manner.

6-2 Protection of personal information

Member Companies must manage and handle the personal information of patients, examinees of clinical study or contract research, Customers, and business partners obtained through their business in an appropriate and safe manner in accordance with “the Act on the Protection of Personal Information” (Personal Information Protection Act).

7. Research and Development

7-1 Bioethics

Member Companies must give full consideration to bioethics in their activities such as development of medical devices.

7-2 Clinical research

When conducting clinical or other type of research, Member Companies shall comply with the "Clinical Research Act", the "Ethical Guidelines for Medical and Health Research Involving Human Subjects", and other related laws, regulations, and guidelines.

7-3 Clinical study (clinical trial)

Studies and research activities such as clinical studies (clinical trials and post-marketing clinical studies) must have highly ethical and legitimate scientific objectives in compliance with the laws and regulations and the ethical guidelines provided by the government for each stage.

7-4 Animal welfare

Member Companies must promote further improvement of the research and development system for laboratory animals necessary for the development of safer and more effective medical devices by ensuring appropriate voluntary management from the viewpoint of animal welfare.

8. Manufacturing/Marketing

8-1 Compliance with the relevant laws and regulations

For manufacturing/marketing of medical devices, Member Companies must observe the related legislation and give full consideration to the efficacy and safety.

8-2 Stable supply

Member Companies must make efforts to ensure stable supply of medical devices approved (certified, notified) for marketing.

8-3 Quality control

The marketing authorization holder must identify opportunities for improvement and refinement of medical devices based on the information from the market through operations such as manufacturing control, quality control, and post-marketing safety management and make efforts to improve and refine the medical devices from the standpoint of users while ensuring quality.

9. Market Research

For the market research, Member Companies must observe the related legislation, etc. and not conduct, directly or indirectly, any activities using the unfair means.

10. Post-marketing Surveillance

The objective of post-marketing surveillance, which is establishment of a proper use method of medical device after marketing, must be accurately recognized. The surveillance must be conducted in accordance with the scientific validity and in compliance with the related laws and regulations and the self-regulations and must not be conducted for the purpose of sales promotion.

11. Handling of Reportable safety information (adverse events and malfunctions, etc.)

If any information on adverse events, malfunctions, infections or research reports related to a medical device manufactured and marketed by a Member Company or the regulatory measures such as discontinuation of manufacturing, recall, and disposal in foreign countries (hereafter, collectively, "Reportable safety information") is obtained, the company must promptly take actions.

The Reportable safety information obtained from medical institutions, etc. must be promptly reported to the Pharmaceuticals and Medical Devices Agency (PMDA) based on the "Act on Securing Quality, Efficacy and Safety of Pharmaceuticals and Medical Devices, etc." (hereafter, "PMD Act").

12. Preparation and Use of Promotional Materials

Promotional materials prepared by Member Companies or prepared by third parties with involvement of Member Companies must be recognized as important means to provide information on medical science, healthcare, and medical devices. When preparing and using promotional materials, ensure the contents are accurate, fair, and objective based on scientific grounds in accordance with the PMD Act, the Standard for Adequate Advertisement of Pharmaceutical Products, etc. and related voluntarily established standards.

(1) In promotional materials developed by Member Companies, the brand name, the regulation classification, the general name, and the handling of reimbursement of medical insurance shall be specified. In addition, the contact point to request materials of such product must be clearly stated so that the request of materials from outside can be responded.

(2) The description and phrasing of efficacy and performance or purpose of use must not deviate from the scope of marketing approval, certificate or notification.

(3) Do not use the maximum expression, false or exaggerated expressions or possibly misleading indications, layout or expressions for the quality, efficacy or safety. Description of safety as one of the characteristics, such as "the occurrence of adverse events or malfunctions are rare", should not be used without a defined condition and should be accompanied by a supplementary note of abstract that forms the grounds.

(4) Fairly note information on safety such as adverse events and malfunctions, etc. and do not incline toward efficacy.

(5) Do not take up exceptional data and give an impression as if it is a general fact in their expression.

(6) Do not have the description or expression that slanders other companies and products of other companies.

(7) The comparison with other products should be conducted based on objective data by using general name without using any proper noun in principle.

(8) Do not use misleading expressions or expressions, pictures or illustrations that injure the manufacturer’s dignity.

(9) The internal screening system for Promotional materials must be established by the Member Companies and Promotional materials must be used after passing its screening system.

13. Corporate Information Dissemination Activities

Member Companies must comply with the legal regulations and the voluntary code of conduct by reviewing the contents starting in the planning stage even in activities to disseminate information such as press release, introduction of corporate activities such as company's prospectus, provision of disease information to the public or patients, and information provision to investors so that the activities will not be suspected to be advertising activities for medical devices or advertising to recommend unapproved medical devices or off-label use.

14. Information Provision and Sales Activities

Member Companies shall proactively and strictly comply with the Antimonopoly Act, the related laws and regulations such as the PMD Act, and the FCC in the information provision and sales activities for their medical devices. Any divisions may take these regulatory actions whether it is a sales division or not.

Member Companies shall establish an internal management system to ensure fair and free competitions. The JFMDA and its member associations shall also establish each committee, etc. to raise awareness and provide guidance.

14-1 Holding and supporting lecture meetings and briefings

Member Companies may hold or support lecture meetings, workshops, product briefings, and proper use training sessions for the purpose of providing specialized, academic, and scientific information on medical science and healthcare and medical devices and information for disease awareness.

Appropriate places/venues must be selected for these meetings. Remunerations, travel expenses (transportation, accommodation, etc.), food/drink must be provided to persons involved in lecture meetings by complying with the FCC and the related laws and regulations.

14-2 Offering of medical device samples

Medical device samples are means of providing information on the company's medical devices to medical institutions/healthcare professionals and to be used as an aid to confirm and evaluate the appearance features or quality, efficacy and safety, etc. Medical device samples shall be provided with relevant information, which must be kept to the minimum.

14-3 Medical equipment loan

Member Companies may "loan out" their medical devices to medical institutions/healthcare professionals for the purpose of checking the appearance and the basic performance, clinical research to evaluate the product efficacy and safety or contract/joint research on their medical devices.

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.

14-4 On-site service for medical device operation

Member Companies may provide the minimum necessary "on-site service" to medical institutions/healthcare professionals to ensure proper and safe use of their medical devices.

When the on-site service is provided to the medical institution free of charge, the frequency and duration must be

determined in compliance with the FCC, and the service must be reviewed based on a document of the details of the service provided. Member Companies must not conduct any acts that conflict with the relevant laws and regulations in the course of on-site service.

14-5 Offering of articles

Articles Member Companies may offer to medical institutions/healthcare professionals 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 accepted in light of normal business practice.

14-6 Offering of services

Member Companies shall not offer benefit, labor or other services, which is likely to be in conflict with the related legislation and the FCC, for free to medical institutions/healthcare professionals without rationale.

15. Unapproved Medical Devices

15-1 Provision of information on unapproved medical devices

Member Companies may not provide information on unapproved medical devices for the purpose of sales promotion without request from doctors, etc. However, the information may be provided upon request from doctors, etc. if evidence is available in scientific and technical sentences describing the medical device, such as publicly known literature and papers, and within the range of academic research reports.

In lecturers on unapproved medical devices given by doctors at joint seminars hosted by academic societies and Member Companies, the slides and the abstracts must state unapproved contents are included.

15-2 Exhibition of unapproved medical devices

Exhibition of unapproved medical devices shall be permitted only if it is requested and approved by the exhibition manager of the exhibition.

15-3 Provision of unapproved medical devices

When providing unapproved medical devices to medical institutions for clinical use, comply with the related laws and regulations such as the Clinical Research Act.

16. Promotion Outside Japan (Provision of Medical Devices Information Outside Japan)

With regard to medical devices information given to healthcare professionals outside Japan, regardless of directly or indirectly, Member Companies will provide according to legal restrictions or industrial voluntary codes of the relevant country.

17. Administration and Revision/Abolition of This Code

(1) The administration of this Code will be conducted by Business Ethics Committee established in the JFMDA. Necessary matters regarding the organization, structure and operation of Business Ethics Committee will be determined separately.

(2) The Business Ethics Committee shall, when a complaint is filed for a case suspected to violate this Code or when it is deemed necessary based on a voluntary decision, deliberate and investigate the complaint. Member Companies shall assist with the investigation conducted by the Business Ethics Committee.

(3) Regarding the preceding paragraph, the Business Ethics Committee may conduct activities to raise awareness among Member Companies and take other measures to prevent recurrence if any act violating this Code is recognized. Matters necessary for responding to complaints shall be separately stipulated.

(4) The Business Ethics Committee shall review this Code as necessary to ensure its effectiveness.

(5) To revise or abolish this Code, an approval of the JFMDA board of directors must be obtained.