

‘The Promotion Code of the Medical Devices Industry’ Terminology

Code: “Code” means a written code of behavior to which Members shall adhere. Medical device organizations in foreign countries establish a similar code.

Dealer and lease firm of medical devices: A “dealer” and a “lease firm” mean a firm granted a license for advanced control medical devices, etc. according to Article 39 of the Pharmaceutical Affairs Law, a firm that notified its control medical devices according to 3, Article 39 thereof, and a dealer and lease firm of general medical devices defined in 7, Article 2 thereof.

“Fair Competition Code”:

“The Fair Competition Code” is the industry’s voluntary rules concerning premiums offered or information to be represented and displayed by firms or trade associations under the certification of the Fair Trade Commission, as provided in Article 10 of The Act Against Unjustifiable Premiums and Misleading Representations. Marketing competition should be generally developed by quality and prices. In fact, however, once excessive offering premiums or sales activities by advertising and promotion are carried out, they are likely to spread and accelerate in the entire industry. This system is intended to remove unproductive competitiveness or mutual mistrust among firms, and to codify the common sense of the industry’s majority as “business practice” and keep it so as to prevent the escalating excessive offering premiums or unreasonable display.

In-house code: A company handling medical devices, which are engaged directly in the fundamentals of medical care, shall be highly aware of ethics. It is required to “spontaneously observe what should be observed based on one’s own sense of ethics,” and a document defining what shall be observed is an “in-house code”.

An in-house code means “specific guidelines regarding one’s own promotion” and all Members are requested to formulate it.

Manufacturer and distributor of medical devices: A “manufacturer of medical devices” means a firm granted a license according to Article 13 of the Pharmaceutical Affairs Law (Law No. 145, 1960), and a “distributor” means a firm granted a license according to Article 12 thereof.

Medical device: A “medical device” means a medical device defined in Article 2, Paragraph 4 of the Pharmaceutical Affairs Law (Law No. 145,1960) and used by a medical institution and other similar institution for the purpose of medical care.

Medical institution and other similar institutions: “Medical institution and other similar institution” means a hospital or clinic defined in 5, Article 1, of the Medical Care Act (Act No. 205, 1948), a health services facility for the aged defined in Article 6, Paragraph 4 of the Health and Medical Services Act for Aged (Act No. 80, 1982) or a pharmacy designated in Article 2, Paragraph 5 of the Pharmaceutical Affairs Law (Law No. 145, 1960).

Medical professionals: “Medical professionals” means doctors, nurses, technicians, and other personnel engaged in medical care according to doctors’ instructions.

Members: “Members” means member companies of the associations who have joined the Japan Federation of Medical Devices Associations.

Normal business practice: “Normal business practice” can also be said to be rules of common sense of the business society. Business practice, which is generally followed but is not considered to be normal practice by many firms, cannot be regarded as normal business practice.

Personnel in the field of medical care: “Personnel in the field of medical care” means the founder of a medical institution or other similar institution, its director, medical professional, or another employee.

Premiums: A “premium” is as defined in Article 2, Paragraph 1 of The Act Against Unjustifiable Premiums and Misleading Representations, and means an economic benefit provided in connection with trade as a means of inducing customers. Premiums, however, do not include economic benefits regarded as discounts, as after-sale services, or as pertaining to products, according to the Notification of Designation of Premiums (Fair Trade Notification No. 3 of the Fair Trade Commission, 1962) and in terms of normal business practice. Out of premiums mentioned herein, goods and money and the like have the following meanings:

- **Goods:** “Goods” include economic benefits except services and money and the like, as well as the provisions of attached products.

- **Money and the like:** “Money and the like” includes cash and notes, money certificates, bank deposit certificates, bond or share certificates, shopping certificates and other negotiable securities as substitutes for money, payments of travel expenses, and assumptions of monetary liabilities.

Promotion: Although the term “promotion” is not generally used in the medical devices industry, the promotion of medical devices means a proper sales promotion activity for the purpose of the adoption or use of medical devices.