

Promotion Code Committee of Japan Dental Trade & Industry Association

I. The Pharmaceutical Affairs Law; Enforcement Regulations

- Article 66 of the Pharmaceutical Affairs Law prohibits advertising false or exaggerated contents.
- Article 67 restricts advertising the ethical drugs for specified diseases
- Article 68 prohibits advertising all the Unapproved drugs/ products in any case.
(Unapproved : MHLW of Japan has not yet been approved.)

1) Detailed explanation of the part of Article 66 of the Pharmaceutical Affairs Law

- ① **Article 66 .1** of the Pharmaceutical Affairs Law prohibits advertising false or exaggerated articles in description and dissemination regarding name, manufacturing method, efficacy, indication or performance of medical drug, quasi-drug, cosmetics and/or medical devices, whatever it may be described/presented explicitly or implicitly.
- ② **Article 66.2** prescribes that the advertising description and dissemination of articles regarding name, manufacturing method, indication including efficacy, safety or performance of medical drug, quasi-drug, cosmetics and/or medical devices, which may be misunderstood by doctors or other relevant medical parties as assurance or evidence are equivalent to "advertising false or exaggerated articles" described in Article 66.1.

2) Fair Advertising Regulation for Drugs, Etc.

(Notice No 1339, October 9, 1980, issued by the Inspection and Guidance Division of the Pharmaceutical Affairs Bureau, Ministry of Health and Welfare, Japan)

- ① The regulation prohibits expressions from assuring indication including efficacy, safety or performance.
- ② The regulation prohibits superlative expressions of indication including efficacy, safety or performance, and the expressions that have the similar effects.
- ③ The regulation prohibits the expressions of unapproved indications including efficacy.
- ④ The regulation restricts to slander and defame competitors in advertising.
- ⑤ Recommendations by relevant medical parties should be shown correctly.

3) Requirements for advertising by Pharmaceutical Affairs Law

Relevant contents of advertising for drugs, etc. in the Pharmaceutical Affairs Law (Notice 148, September 29, 1998, issued by the Inspection and Guidance Division of the Pharmaceutical Affairs Bureau, Ministry of Health and Welfare, Japan)

- ① Attracting customers or potential customers.
- ② Clarifying the trade name of Drugs for specified uses.
- ③ Recognizing to allow as advertisement by member of the public.

II. Guidelines on Medical Advertising

Notice No0330014, March 30, 2007, issued by the Evaluation and Licensing Division of the Pharmaceutical and Food Safety Bureau, Ministry of Health, Labor and Welfare, Japan

The Guidelines include the requirement for advertising the guidance for making appropriate expression of advertising regarding medical doctors or dentists, and/or hospitals or clinics.

- It may be useful to understand and know the definition of advertising and the cases that will NOT be assumed as advertising

1) Basic Concept of Guidelines on Medical Advertising

Though medical advertising had been considered to avoid other than the restricted specification approved for protecting the benefit and neutrality of patients in principle, the Guidelines may allow medical advertising in terms of supporting options of patients on condition that the medical information could be provided objectively and correctly with patients as broad spectrum as possible.

2) Basic Concept for Certain Advertising Prohibited

- Advertising including false contents (false advertising)
- Expressions of advertising are:
 - ① Comparative advertising
 - ② Puffery advertising
 - ③ Advertising not shown evidences of objective data/facts
 - ④ Advertising against public policy

3) Examples not considered as Medical Advertising

- ① Scientific articles, scientific presentations
- ② Articles in newspapers and/or public and scientific journals
- ③ Talks and notes from experiences
- ④ Bulletins/brochures to be designed to distribute information to patients and people in general.
- ⑤ Brochures and/or e-mail responding to patients on request.
- ⑥ Advertising of occupational classification made by medical facilities or institutions
- ⑦ Home page on Web-site

4) Definition of Advertising

- ① It should be intended to attract patients to come hospital/receive Treatment or therapy or to use medical devices.
- ② It should be able to specify the names of doctors/dentists and hospitals/clinic provided the specified services.
- ③ It should be allowed to recognize as an advertisement by people of the public.

III. Voluntary Restraint Criteria of Medial Advertising for related Parties

- The Japan Federation of Medical Devices Association (JFMDA)
 - "Promotion Code for Medical Device Industry"
(revised on March 25, 2005)
 - "Guidelines on Appropriate Advertising for Medical Device Industry"
(issued on October 24, 2006)
- The Japan Dental & Trade Industry Association
 - "Advertisement Comparing Products of Other Manufacturers"
(issued originally on December 10, 2003, and revised on June 1, 2005)
 - "Recommendations by Relevant Medical Parties"
(issued originally on December 10, 2003, and revised on September 1, 2005)

1) The Promotion Code of the Medical Devices Industry

- ① Obligations and Practices of Members
- ② Obligations of Top Management
- ③ Product Development
- ④ Manufacturing and Marketing
- ⑤ Market Research
- ⑥ Advertising and Promotion
- ⑦ Surveillance after Manufacturing and Marketing
(Post-Marketing Surveillance)
- ⑧ Marketing Activities
- ⑨ Holding Seminars
- ⑩ Scientific Display of Unapproved Medical Devices
- ⑪ Promotion in Foreign Countries
- ⑫ Relationship between this "Code" and the "Fair Trade Competition Code"

(1) Advertising and Promotion

- ① Member companies (hereafter 'Member) shall not advertise the intended use and efficacy of their product out of the scope of approval or certification for manufacturing and marketing.
- ② Members shall not use false, exaggerated or misleading expressions in describing safety and effectiveness of products.
- ③ Members shall describe information not only on effectiveness but also on safety, adverse events including side effects on a fair basis.
- ④ Members shall use objective data when comparing their products with competitors' products. They shall use generic names and not specific identifiable name for other companies' products in principle.
- ⑤ Members shall not use expressions that may defame or slander other companies or their products.

- ⑥ Member shall not use descriptions that may impress people into thinking of them as general facts by picking up only exceptional data.
- 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 a 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 establish an in-house review organization and control for printed materials and advertisements. They shall use only those that have passed the review of the organization.

(2) Marketing Activities

- ① Ensuring fair competition and fair trade
- ② Prohibiting slanderous or defamatory acts
- ③ Prohibiting the preparation of unfair comparison tables
- ④ Offering services
- ⑤ Offering goods
- ⑥ Offering money or the like.
- ⑦ Offering sample medical devices
- ⑧ Offering medical devices on loan
- ⑨ Confidentiality of information on customers and possible customers
- ⑩ Concluding a written agreement

3) Voluntary Restraint Criteria of the Japan Dental Trade & Industry Association

(1) Advertisements Comparing Products of Other Manufacturers

- ① In case of advertisements comparing products, it shall be expressed to compare products with those manufactured *by the same company*, in principle. When comparing with the products of competitors, comparative data, published by a specialist of a third party in official journals of the scientific society or commercial journal of the scientific publisher, can be included.
- ② When citing data or using in an abstract, the exact content of the author shall be accurately informed. In this case, the company shall take appropriate procedures to transfer from copyright holder.

(2) Recommendations by Relevant Medical Parties

- ① In advertisement on case studies and their use in pamphlets and dental show, only objectively verified and validated facts shall be indicated (1. Results obtained by trials, studies, or surveys, 2. Professional views by specialists, professional group, or scientific organizations, or scientific articles). In this case, the names of medical doctors, dentists, universities, and hospitals (including photos) are permitted to use.

- ② The Promotion Code Committee of JDTA is able to seek the submission of documents on the request of member or under its authority. The Committee will file a complaint to the competent authority against malicious cases.
- ③ "Recommendations by medical doctors" shall not be able to include. The articles containing interview with doctors should be submit to the committee prior to advertising, in order to determine whether it is appropriate or not.

IV. The Reported Violation in the recent Dental Shows

- Superlative Expressions

Ideal, waxed-up revolution, revolution of casting titanium, top-of-the line ring fairness, very low level of curing shrinkage, state of the art nanotechnology, most reliable in the world, miracle features of physics, similar hardness of dentine and outstanding ability of cutting, super technology of fitting various dental plaster, most suitable treatment for pediatric dentistry and geriatric dentistry

- Recommendation by medical parties

"Medical devices approved by MHLW", "Permission Number authorized by MHLW"

- Assuring expression of indication including efficacy

All the clinicians in the world have been recognized the effectiveness and esthetics of fiber post.

- Comparative Advertising

Comparing data of featuring physics with competitors (Own companies' data)

V. Superlative expressions to lead misunderstanding

- innovative, best-seller, treasure trove, miracle drug, arcanum, emperor, the finest, essence of something, leading authority in the world, very strong effects, the strongest digestive ability, wonder, top of the world, representative, known as synonymous with xxx, super effectiveness, excellent effectiveness, most advanced, most reliable, best one, ideal, dreamy, topical, strong and powerful man, special selection of selling incredibly, gaining the spotlight

- overwhelmed, eternal effect, most popular, much-awaited(longed for), valuable, God-given, revolution of xxx, gain reputation predominantly, secular, super-eminent, miraculous, on a nationwide scale, as a measure of last resort, destroy dramatically, safe absolutely, have no side effects

VI. Summary

- No advertisements comparing products of other manufacturers without availability of data published in scientific articles
- Not using superlative expressions
- Not indicating recommendations by medical doctors
- Observing the related articles of Pharmaceutical Affairs Law carefully
- Not using expressions assuring indication including efficacy and/ or safety