

FOR CONVENIENCE ONLY

JPMA Promotion Code for Prescription Drugs

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Preamble

In recognition of the need to upgrade the dignity and fulfill the social responsibilities of the pharmaceutical industry, it is of vital importance to carry out the basic concept underlying the "Code of Practices for Pharmaceutical Industry," published in 1983 by the Federation of Pharmaceutical Manufacturers' Associations of Japan, which stipulates that "Because pharmaceuticals by their nature, have a profound impact on human lives, the pharmaceutical industry must always pay the highest respect to the dignity of human life, maintain good discipline with a spirit of modesty toward science, and respond to the expectations of society." On this fundamental concept, the Japan Pharmaceutical Manufacturers Association (hereinafter called JPMA) reviewed its "Code of Practices for Promotion of Ethical Drugs" published in 1976, and in March 1993 established a new code entitled "JPMA Promotion Code for Prescription Drugs" (hereinafter called JPMA Code) that also meets the "IFPMA Code of Pharmaceutical Marketing Practices."

It is an obligation of the pharmaceutical industry to strictly comply with the Pharmaceutical Affairs Law, the Anti-Monopoly Act, and all other

relevant laws and regulations as well as the industry's self-regulations, such as the Fair Competition Code. It is also its obligation to provide, collect, and disseminate information on pharmaceuticals as accurately and promptly as possible and with proper means. The pharmaceutical industry must refrain from any act that may distort an appropriate use of pharmaceuticals.

The JPMA Code stipulates the standards of conduct that must be adhered to by all pharmaceutical companies when conducting promotional activities of prescription drugs (hereinafter called drugs) and mandates member companies of the JPMA (hereinafter called Member Companies) to conduct their drug promotional activities in strict compliance therewith. Any and all violations of or deviations from the respective laws and regulations and the industry's self-regulations in promotional activities of drugs shall be treated as breaches of the JPMA Code, even if such violations or deviations are not specifically mentioned in the JPMA Code.

Member Companies are encouraged to formulate their own promotion codes that may include more specific requirements and additional rules for conducting their own promotional activities.

The JPMA Code shall be revised based on the establishment or revisions of the IFPMA Code of Pharmaceutical Marketing Practices, related laws and regulations and the industry's self-regulations, and in keeping with changes in promotion activities.

I. Promotion Code

1. Responsibility of Member Companies

Member Companies shall assume responsibility for all promotional activities conducted by itself and its medical representatives. In thorough recognition of this principle, Member Companies shall be required to establish an in-house system to conduct appropriate promotional activities.

Member Companies shall have their subsidiary company (a company in which the Member Companies own over 50% of the shares) in Japan adhere to the JPMA Code.

Member Companies shall also require its business partners who conduct sales and promotional activities of the Member Company's drugs in Japan to adhere to the JPMA Code.

It is essential for Member Companies to take the following actions:

- 1-1. To appoint qualified employees as medical representatives, and maintain continuous education and training programs for them.
- 1-2. To ensure that the system of remuneration of medical representatives should not be such as to induce unethical acts.
- 1-3. To provide in the most appropriate manner information such as indications, dosage and administration based on up-to-date scientific data, which should not deviate from the approved items for the drugs.
- 1-4. To collect and disseminate drug information as accurately and promptly as possible.
- 1-5. To establish in-house systems necessary to comply with all relevant laws and regulations and the industry's self-regulations.

2. Responsibility of Chief Executives of Member Companies

The chief executives of Member Companies shall undertake the following tasks with the awareness and responsibility of chief executives to meet the expectations of society as a company closely related to the lives of the people.

- 2-1. To realize that achieving the spirit of the JPMA Code is their duty, to thoroughly inform related persons as an example to others and to establish in-house systems.
- 2-2. When situations arise that contravene the spirit of the JPMA Code, to solve problems on their own responsibility, and endeavor to clarify the causes and prevent recurrences.

3. Medical Representatives' Activity Standards

Medical representatives shall fully recognize their social mission as persons who participate in health care services in conducting promotional activities on behalf of their respective companies. They shall perform the following duties in a sincere and honest manner:

- 3-1. To exert their best efforts to acquire knowledge concerning the package inserts of their drugs, as well as the medical and pharmaceutical knowledge constituting the basis thereof, and to cultivate the abilities needed to present such information correctly.
- 3-2. To conduct promotional activities according to the rules and methods established by their companies.
- 3-3. To provide drug information such as indications, dosage and administration, which does not deviate from approved items for drugs. balanced and fair information on efficacy and safety of drugs shall also be provided.
- 3-4. To collect and disseminate drug information as accurately and promptly as possible.
- 3-5. Not to slander or defame competitors or competitors' drugs.

- 3-6. To abide by rules imposed by a medical institution and maintain discipline when visiting such a medical institution.
- 3-7. To strictly abide by relevant laws and regulations and behave sensibly with full recognition of themselves as medical representatives.

4. Production and Use of Promotional Materials and Advertisements

Member Companies shall fully realize that brochures, advertisements in medical journals, Internet web-pages for the medical profession, audiovisual materials such as slides and VTR, and other promotional materials are important media in dissemination of drug information, and shall produce and use those materials in compliance with the Pharmaceutical Affairs Law and relevant self-regulations. The statements contained therein shall be correct, fair, and objective, based on scientific data.

- 4-1. Statements regarding indications, dosage and administration, and any other statements, shall not deviate from the approved items. When scientific data are presented at international scientific meetings based on the attached guidelines, such statements can also refer to unapproved drugs (except for drugs not approved in any country).
- 4-2. No false, exaggerated or misleading expression shall be used regarding efficacy and safety. Advantageous claims relating to safety such as "there are few adverse reactions" shall not be cited without qualification and must be supplemented with a summary of data on which such claims are based.
- 4-3. Fair statements shall be made by presenting both efficacy data and safety data, including adverse reactions.
- 4-4. Comparisons with other drugs shall be based on scientific data and, in principle, shall be made using their generic names.

- 4-5. Competitors or competitors' drugs shall not be slandered or defamed.
- 4-6. Extraordinary data shall not be presented by using an expression that may give an impression that the data represent a universal fact.
- 4-7. Misleading or indecent photos, illustrations, etc., that are not suitable to the socially respected role of drugs shall not be used.
- 4-8. When an advertisement is aimed mainly to promote only the name of a drug, the statements in such advertisement shall include the name (brandname), therapeutic category (product abbreviation), regulatory classification, generic name, and status of NHI drug price listing. The contact and address for more detailed information shall be given.
- 4-9. Member Companies shall appoint a Management Representative, etc. for promotional materials and advertisings and establish an in-house auditing system so that only audited promotional materials and advertisements are used.

5. Post-Marketing Surveillance

Member Companies shall properly recognize the objectives of post-marketing surveillance (PMS), that is, the establishment of the appropriate usage of marketed pharmaceuticals, and shall conduct such PMS activities on a scientific basis, in strict compliance with relevant laws and regulations as well as relevant self-regulations. These activities shall not be misused as a means of promotion.

6. Supply of Samples

Samples are a way of providing drug information and may be supplied

to the medical profession to show the physical appearance of drugs or to help them evaluate and confirm the quality, efficacy, safety and other claims. In view of this purpose, Member Companies shall always supply clinical samples only in the minimum quantity necessary, together with related drug information.

7. Seminars and Study Meetings

Seminars and study meetings organized by Member Companies to present their drugs to the medical profession shall be academic events where scientific information is provided to attendants.

When social events and gifts incidental to such seminars and study meetings are offered, such events and gifts shall not be luxurious or expensive and shall be in good taste.

8. Gifts

Member Companies shall not offer to the medical profession etc. any gift that could potentially affect the appropriate use of drugs or any gift that is not in good taste.

9. Financial Inducement

Member Companies shall not offer, either directly or indirectly, a pecuniary benefit or its equivalent to medical institutions, etc., for the purpose of potentially influencing the appropriate use of drugs.

Even where Member Companies are permitted to offer a pecuniary benefit or its equivalent to medical institutions, etc., Member Companies shall take care to ensure that the amount that may be offered does not exceed a socially acceptable level.

10. Relation with the Fair Competition Code Concerning Restrictions on Premium Offers in the Ethical Pharmaceutical Drugs Manufacturing Industry

Member Companies shall proactively and strictly comply with the Fair Competition Code Concerning Restrictions on Premium Offers in the Ethical Pharmaceutical Drugs Manufacturing Industry, based on high ethical standards.

11. Promotional activities outside Japan

11-1. Dissemination of information on drugs in overseas

To the medical profession overseas, Member Companies shall provide, either directly or indirectly through local agents, information on drugs globally consistent, and in accordance with relevant pharmaceutical affairs laws, regulations, and promotion codes applicable in such countries.

11-2. Subsidiary companies overseas

When an overseas subsidiary company of a Member Company (a company in which the Member Company holds over 50% of the equity or shares) conducts promotional activities, the Member Company shall ensure that the subsidiary will adhere to the promotion code established by the national organization of pharmaceutical companies of the country, or, if no such local code exists, to the IFPMA Code of Pharmaceutical Marketing Practices.

11-3. Overseas licensees and agents

Member Companies entering into licensing and agency agreements shall require their licensees and agents to respect the promotion code established by the national organization of pharmaceutical companies of the country or the IFPMA Code of Pharmaceutical Marketing Practices.

11-4. Activities overseas for the Japanese medical profession

When Member Companies undertake activities aimed at the Japanese medical profession overseas by holding seminars or study meetings or at scientific meetings overseas, they shall comply with the JPMA Code.

11-5. Activities in Japan for the overseas medical profession

When Member Companies invite the overseas medical profession to seminars or study meetings in Japan, they shall comply with the promotion code established by the national organization of pharmaceutical companies of the country, or, if no such local code exists, to the IFPMA Code of Pharmaceutical Marketing Practices.

II. Administration of the JPMA Code

1. JPMA Code shall be administered by the promotion code committee established by the JAPMA (the Code Committee hereinafter).
2. The Code Committee shall consist of twelve members, at most, who represent JPMA Committees relating to drug promotional activities and three members, at most, who are outside experts. The president of JPMA shall nominate the Code Committee members.
3. The Code Committee shall carry out necessary procedures according to the separately established "Procedures for Inquiries and Complaints Relating to the JPMA Code", in response to the relevant inquiries and complaints, and shall take action to ask Member Companies voluntary amelioration, according to the separately established "Rules of Actions against Breach of the JPMA Code", when the JPMA Code is judged to have breached.
4. Necessary provisions relating to the organization and operation of the Code Committee other than those stipulated in JPMA Code shall be separately established.

Supplementary Provision

The JPMA Code revision was adopted by the General Assembly of JPMA at the meeting held on January 7, 2004. The revised JPMA Code shall come into force on April 1, 2004.