

## **JPMA Promotion Code for Prescription Drugs**

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### ***Japan Pharmaceutical Manufacturers Association (JPMA)***

#### **[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, member companies of the Japan Pharmaceutical Manufacturers Association (hereinafter called "JPMA") (hereinafter referred to as "member companies") 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 Promotion Code") that also meets the "IFPMA\* Code of

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\* IFPMA: International Federation of Pharmaceutical Manufacturers & Associations

Pharmaceutical Marketing Practices" (hereinafter called "IFPMA Code").

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 of the Ethical Drug Manufacturing Industry (hereinafter referred to 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 the appropriate use of pharmaceuticals.

The JPMA Promotion 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 Promotion Code, even if such violations or deviations are not specifically mentioned in the JPMA Promotion 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 Promotion Code shall be revised based on the establishment or revisions of the IFPMA Code, 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

Promotion Code.

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

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

- (1) To appoint qualified employees as medical representatives, and maintain continuous education and training programs for them.
- (2) To ensure that the evaluation/remuneration system of medical representatives should not be such as to induce unethical acts.
- (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.
- (4) To collect and disseminate drug information as accurately and promptly as possible.
- (5) To establish in-house systems necessary to comply with all relevant laws and regulations and the industry's self-regulations.

## **2. Responsibility of the Top Management of Member Companies**

The top management of member companies shall undertake the following tasks with the awareness and responsibility as the top management, to meet the expectations of the society as a company closely related to the lives of people.

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

## **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:

- (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.

- (2) To conduct promotional activities according to the rules and methods established by their companies.
- (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.
- (4) To collect and disseminate drug information as accurately and promptly as possible.
- (5) Not to slander or defame competitors or competitors' drugs.
- (6) To abide by rules imposed by a medical institution and maintain discipline when visiting such a medical institution.
- (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, website targeting at healthcare professionals, audiovisual materials such as slides and VTR, and other promotional materials are important media for the dissemination of drug information, and shall produce and use those materials in compliance with the Pharmaceutical Affairs Law and relevant self-regulations such as the Guidelines for Specifying Product Information Summaries for Prescription Drugs. The statements contained therein shall be correct, fair, and objective, based on scientific data.

- (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, such statements can also be referred to unapproved drugs, when based on the attached guidelines. (except for drugs not approved in any country).
- (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.
- (3) Fair statements shall be made by presenting both efficacy data and safety data, including adverse reactions.
- (4) Comparisons with other drugs shall be based on scientific data and, in principle, shall be made using their generic names.

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

#### **5. Post-marketing safety control operations and post-marketing surveillance**

Member companies are required to properly understand the purpose of establishing proper usage of the drug after marketing and shall carry out post-marketing safety control operations and post-marketing surveillance based on scientific fairness in compliance with related laws and regulations and self-regulations, and should not use these activities as a sales promotion tool.

#### **6. Supply of Samples**

Samples are a way of providing drug information and may be supplied to the healthcare professionals 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 held by member companies about their drugs for healthcare professionals are to be academic events where scientific information is supplied.

Such seminars are to be held in an appropriate venue conducive to the purpose in principle in Japan.

If food and drinks or any social-gathering event or gift is offered in association with a seminar, they shall not be extravagant and shall not tarnish the dignity of pharmaceutical companies.

Payments in cash or cash equivalents are to be limited to the travel expenses (transportation expenses, accommodation expenses) and the remuneration for the lecturer, when holding a seminar.

Individuals accompanying invited healthcare professionals shall not participate in the social-gathering event and shall not receive travel expenses.

## **8. Gifts**

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

## **9. Provision of cash or its equivalents**

Member Companies shall not offer, either directly or indirectly, any cash or its equivalents to medical institutions, etc., for the purpose of potentially influencing the appropriate use of drugs.

## **10. Relation with the Fair Competition Code of the Ethical Drug Manufacturing Industry**

Member companies must actively and strictly follow the Fair Competition Code of the Ethical Drug Manufacturing Industry based on high ethical awareness.

## **11. Promotional activities outside Japan**

### **(1) Dissemination of information on drugs in overseas**

To the overseas healthcare professionals, 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.

### **(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.

### **(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.

(4) Activities overseas for the Japanese healthcare professionals

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

(5) Activities in Japan for healthcare professionals from overseas

When Member Companies invite healthcare professionals from overseas 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.

## **II. Administration of the JPMA Promotion Code**

(1) Revision or abolition of the JPMA Promotion Code shall be resolved by the General Assembly of JPMA.

(2) The management of the JPMA Promotion Code shall be performed by the Promotion Code Committee established within JPMA (the Code Committee hereinafter).

(3) The Code Committee shall consist of members recommended from the JPMA Committees that have relations with promotional activities, a member recommended by the JPMA President's Company, external academic experts, and the chairperson of the Working Committee that is established as an assisting organization of the Code Committee. The Code Committee members shall be commissioned by the president of JPMA.

(4) In response to inquiries and complaints relevant to the code, or suspected code violation cases, the Code Committee shall carry out necessary procedures according to the separately established "Procedures for Inquiries and Complaints Related to the JPMA Promotion Code". When the JPMA Promotion Code is judged to have been breached, the Code Committee shall take actions against the relevant Member Company to address the violation, according to a separately established "Rules of Actions against the Breach of the JPMA Promotion Code".

(5) Necessary provisions related to the organization and operation of the Code Committee, other than those stipulated in the JPMA Promotion Code, shall be separately established.

**Supplementary Provision**

The JPMA Promotion Code revision was adopted by the General Assembly of JPMA at the meeting held on March 19, 2008. The revised JPMA Promotion Code shall come into force as of May 23, 2008.