JPMA Code of Practice

(Established January 16, 2013  Enforced April 1, 2013)
Japan Pharmaceutical Manufacturers Association (JPMA)

[Preamble]
The member companies of Japan Pharmaceutical Manufacturers Association (JPMA) consider it their mission to contribute to improving the health of people not only in Japan but also throughout the world through the development of innovative, highly useful, and safer medicines. To this end, these member companies have been called upon to make efforts to build mutual relationships of trust with researchers, healthcare professionals, and patient organizations under an appropriate alliance of industry and academia so that medical care can be offered ethically and optimally from the patient’s standpoint.

To avoid inappropriate prescription inducements in promotional activities for ethical drugs, JPMA drew up its “Code of Practices for Promotion of Ethical Drugs” in 1976. Then, in March 1993, JPMA established the more developed “JPMA Promotion Code for Prescription Drugs,” which meets the International Federation of Pharmaceutical Manufacturers & Association’s (IFPMA) “IFPMA Code of Pharmaceutical Marketing Practices” and has since been revised several times to accommodate revisions in laws, etc.

Moreover, in order to ensure a high degree of ethicality throughout all corporate activities, not limited to promotional activities, “JPMA Code of Conduct” was drawn up in November 1997 as a set of industry self-regulations adopted by the member companies. In April 2001, “JPMA Compliance Program Guideline” was issued to promote more thorough compliance on the part of member companies and were then revised in March 2011 to reflect the changing times.

In addition, to fulfill its responsibilities regarding public disclosure and accountability for payments from pharmaceutical companies to healthcare professionals, medical institutions, etc., including the issue of conflicts of interest, JPMA established the “Transparency Guideline for the Relation between Corporate Activities and Medical Institutions” (hereinafter referred to as the “Transparency Guideline”) in January 2011. In accordance with their own guiding principles based on this Transparency Guideline, member companies will begin public disclosure of such information in fiscal year 2013 with the consent of healthcare professionals, medical institutions, etc. Similarly, with respect to relationships with patient organizations, “Guideline for Transparency of Relationship between Corporate Activities and Patient Organizations” (hereinafter referred to as “Patient Group Transparency Guideline”) was established in March 2012 with the intention of beginning public disclosure of information in fiscal 2014.

As a member of JPMA, each company has thus made efforts over the years to ensure a higher degree of ethicality and transparency and to increase the reliability of the pharmaceutical industry.
as a whole. In March 2012, IFPMA announced its “IFPMA Code of Practice” (hereinafter referred to as the “IFPMA Code”) as a code covering not only marketing activities but also interactions with healthcare professionals, medical institutions, and patient organizations, as well as the promotion of medicines, to replace the existing “IFPMA Marketing Code.” In line with the intention of this revision of the IFPMA Code, JPMA established its “JPMA Code of Practice” (hereinafter referred to as the “JPMA Code”) in January 2013 to expand upon the existing “JPMA Promotion Code for Prescription Drugs” while governing interactions between all of the executives and employees of the member companies and researchers, healthcare professionals, and patient organizations, etc., and this new code is to be enforced starting in April of this year.

JPMA’s member companies must prove themselves worthy of the trust of society by ensuring a high degree of ethicality and transparency in their activities at all times and by fulfilling their accountability for their interactions with researchers, healthcare professionals, patient organizations, etc. Accordingly, it is necessary for each of the member companies to establish its own “company code of practice” based on the JPMA Code that may substantiate the JPMA Code in more concrete terms and address items that are particular to its own situation, and make such an individual code its standard of business conduct. Moreover, the criterion for judgment of the member companies’ own conduct must always be whether or not that conduct conforms to the spirit of the JPMA Code, regardless of whether or not the conduct in question is concretely described in the JPMA Code.
Part 1
Code of Practice

Chapter 1. Fundamental Responsibilities as a Pharmaceutical Company
The member companies of JPMA have the fundamental responsibilities to conform to the following principles in view of the fact that their corporate activities are conducted under the public medical insurance system as a member of the life sciences industry.

(Principles)
• The standard of judgment will be to put the highest priority on contributing to the health and lives of patients in corporate activities.
• In corporate activities, the member companies shall conform not only to the Pharmaceutical Affairs Law and related laws and regulations but also to the industry self-regulations set forth in the "Code of Practice for Pharmaceutical Industry," “JPMA Code of Conduct,” and “JPMA Compliance Program Guideline,” etc., and maintain high ethical standards in all their conduct.
• In corporate activities, the member companies shall maintain transparency and appropriately fulfill their responsibility to be accountable to the society under corporate policies based on the “Transparency Guideline” and “Patient Group Transparency Guideline.”
• In order to contribute to advances in medical / pharmaceutical sciences and the development of the life sciences as well as promote appropriate industry-academia collaboration, member companies shall make efforts to build relationships of trust with researchers, healthcare professionals, and patient organizations, while at the same time avoid activities that could exert an inappropriate influence upon them.

Chapter 2. Responsibility of Top Management
The top management of the member companies shall execute the following.
• With the awareness that the “Fundamental Responsibilities as a Pharmaceutical Company” that are described in the preceding chapter are their own role, top management shall perceive the conduct of all executives and employees as their own responsibility after setting an example by taking the initiative to implement the provisions of the JPMA Code, and shall make these provisions known to all concerned while improving internal systems.
• When circumstances have arisen that run counter to the spirit of the JPMA Code, top management shall make efforts to resolve the problems as their own responsibility, as well as investigate and identify the cause and take measures to prevent recurrence.
• Even in departments that are in charge of products or matters other than ethical drugs, top management shall observe the spirit of the JPMA Code in conducting corporate activities.
• The JPMA Code shall be observed by domestic subsidiaries as well (companies where there is a 50% share in stock holdings or equity).
• The member companies shall demonstrate their compliance with the JPMA Code to parent companies, affiliates, and subsidiaries that manufacture and market pharmaceutical products, whether in Japan or overseas, and seek their understanding of the Code.

Chapter 3. General Rules Governing Corporate Activities
The members companies shall establish and conform to individual company codes that cover not only promotional activities targeting healthcare professionals and medical institutions, but all other corporate activities as well, and are applicable to all executives and employees. In particular, the provisions of the Fair Competition Code of the Ethical Drug Manufacturing Industry (Hereinafter referred to as the “Fair Competition Code”) and the IFPMA Code shall be observed in the handling of offers of money, goods, food and drink, or the like. Moreover, even in cases where the specific situation is not described in the JPMA Code, judgments shall be based on the tenor of the JPMA Code. However, at times of major natural disaster or other emergency, it shall be necessary to adopt a flexible stance that gives highest priority to respect for human life.

1. Study and Research Activities
Activities involved in non-clinical studies, clinical researches / epidemiological researches, clinical studies (clinical trials and post-marketing studies), and other studies / researches must at all phases have highly ethical and appropriate scientific objectives that conform to the standards established by the national government, as well as to ethical guidelines. Moreover, research and development expenses and scientific research funding derived from the conduct of such studies / researches shall be subject to public disclosure of information under the “Transparency Guideline,” and member companies shall bear appropriate accountability in this regard. As regards ensuring transparency in information on clinical studies, member companies shall disclose information on clinical studies in conformity with the “Joint Position on the Disclosure of Clinical Trial Information via Clinical Trial Registries and Databases” (2009) and the “Joint Position on the Publication of Clinical Trial Results in the Scientific Literature” (2010), which were jointly issued by JPMA, IFPMA, EFPIA (European Federation of Pharmaceutical Industries and Associations), and PhRMA (Pharmaceutical Research and Manufacturers of America). Additionally, in order to minimize harm from adverse reactions to pharmaceutical products, member companies shall make efforts to develop safer, more effective drugs while at the same time promoting improvements in the research and development system so as to exercise appropriate self-control from the standpoint of animal welfare for the laboratory animals necessary to drug development.
2. Information Dissemination Activities

The provisions of Part 2 shall apply to activities involved in the provision of information to healthcare professionals, medical institutions, etc., for the purpose of promotion. Moreover, advertisement of ethical drugs to ordinary consumers shall be limited by the Pharmaceutical Affairs Law and the Standard for Adequate Advertisement of Pharmaceutical Products. Accordingly, even when it comes to information dissemination activities that are not for the purpose of promotion, the member companies shall take steps to avoid this information transfer from turning into an inappropriate promotional activity for the corporation’s own commercial purposes. For instance, even in the case of information transmission through press releases, disease education activities targeting ordinary citizens and patients, and provision of information to investors, it shall be necessary to take measures such as closely inspecting the content from the planning stages so that there is no suspicion of this information transmission constituting advertisement of ethical drugs to ordinary consumers or advertising that recommends unapproved drugs or off-label uses.

Moreover, as regards the utilization of digital communications using so-called social media, etc., the member companies shall bear all responsibility for the content while checking for JPMA Code compliance with related subsidiaries, parent companies, affiliates, planning companies, agencies, employees, etc., when engaging in these activities. At this time, special attention should be given to the following points.

(1) Compliance with the Pharmaceutical Affairs Law, advertising regulations of the Standard for Adequate Advertisement of Pharmaceutical Products, and the provisions of Part 2.

(2) When planning or supporting social media, etc., the member company concerned shall take responsibility for confirming the appropriateness of the content of postings, including the content of contributions made by third parties, and shall take appropriate measures as its own responsibility in the event that there has been a posting of inappropriate information on unapproved use, slander and/or defame of other companies’ products, etc., or of information on adverse events.

(3) Only information that has passed scrutiny by the appropriate department within the member company shall be released by member companies.

(4) When a member company is acting as a sponsor, it shall clearly indicate the name of the company.

3. Collaboration with Patient Organizations

In all types of collaboration with patient organizations, the member companies shall maintain a high degree of ethicality and respect the independence of the patient group. Moreover, they shall strive to promote sufficient mutual understanding of the objectives and content of the collaboration with the patient organizations. To this end, the member companies who are
collaborating with patient organizations shall establish guidelines for their own companies on the basis of the “Guideline on Collaboration with Patient Organizations.”

With regard to financial support, etc., provided to patient organizations by a member company, the member company shall ensure transparency by making clear the fact that it is involved, securing written consent for the objectives and content of the support, and retaining records so as to foster widespread understanding of the fact that the activities contribute to the activities and development of the patient group. To this end, the member company that is providing financial or other support to the patient group shall establish its own guideline based on the “Patient Group Transparency Guideline.”

4. Relationship with Wholesalers
The relationship between pharmaceutical company and wholesaler must be a fair business relationship that complies with the Antimonopoly Act and other related laws and regulations and the industry’s self-regulations. Moreover, since this relationship is expected to ensure a greater degree of ethicality and transparency than similar relationships in other industries in consideration for the fact that its transactions take place under the public medical insurance system, the member companies shall establish and comply with their own standards in cases where money, goods, food and drink, or the like is offered to wholesalers, as well as in cases where these offers are accepted.

5. Activities outside Japan
Even in activities that take place overseas, the member companies shall respect the JPMA Code while at the same time complying with whatever pharmaceutical organization codes are in existence within the relevant country, or to the IFPMA Code in the absence of such codes.

Chapter 4. Promotional Activities Targeting Healthcare Professionals, Medical Institutions, etc.
In promotional activities targeting healthcare professionals, medical institutions, etc., member companies shall comply with the provisions of “Part 2 JPMA Promotion Code for Prescription Drugs.” Moreover, the provisions of Part 2 shall apply even to the activities described in the preceding chapter in cases where they are considered promotional activities. Moreover, the provisions of Part 2 shall apply to promotional activities that are directed toward healthcare professionals, medical institutions, etc., through wholesalers.
Part 2
JPMA Promotion Code for Prescription Drugs

【Preamble】
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”). Another obligation of the pharmaceutical industry is 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. Since the activities of the pharmaceutical industry are deeply involved in human life, the industry needs to not only maintain a high morality but also ensure transparency of its activities and live up to the trust of society.

“JPMA Promotion Code for Prescription Drugs” (hereinafter referred to as “this 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 to conduct their drug promotional activities in strict compliance therewith. Member Companies need to always judge whether their actions are in compliance with the purposes of the JPMA Promotion Code, regardless of whether there are specific descriptions for the relevant actions or not. 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.

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 promotional activities.

I. Promotion Code
1. Responsibility of Member Companies in Promotional Activities
Member Companies shall assume responsibility for all promotional activities conducted by the companies and their medical representatives (hereinafter called MRs). 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 of which the Member Company owns more than 50% of the shares) in Japan adhere to the JPMA Promotion Code.
Member Companies shall also require their 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 MRs, and to continue to maintain education and training programs for them so that drugs are used properly and that drugs are to be used when necessary.
2. To ensure that the evaluation/remuneration system of MRs should not be such as to induce unethical acts.
3. To provide information such as indications, dosage and administration, which should not deviate from the approved items for the drugs, based on up-to-date scientific data, in the most appropriate manner.
4. To collect and disseminate drug information as accurately and promptly as possible.
5. To establish internal 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 in Promotional Activities
The top management of member companies shall undertake the following tasks with awareness and responsibility as the top management, to meet the societal expectations for companies 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 and to establish in-house systems, taking the lead in setting good examples to others.
2. To take responsibility in solving their own problems, and to endeavor to clarify the causes and prevent recurrences, when situations arise that contravene the spirit of the JPMA Promotion Code.

3. MRs' Activity Standards
MRs shall fully recognize their social mission as persons sharing responsibilities in healthcare services while 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 and / 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 MRs.

4. Production and Use of Promotional Materials and Advertisements

Member Companies shall fully realize that brochures, advertisements in medical journals, website targeting healthcare professionals, audiovisual materials such as slides and moving images, and other promotional materials are important media for the dissemination of drug information. Member companies 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.

(2) No false, exaggerated, or misleading labels, layout and expression shall be used regarding efficacy and safety. Claims relating to or focusing on 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 generic names.

(5) Competitors or competitors' drugs shall not be slandered and / 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 photographs, 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 items described in such an advertisement shall include the name (brand name), therapeutic category (product title), regulatory classification, non-proprietary name, and status of NHI drug price listing. The contact and address for more detailed information shall be given.

(9) Member Companies shall appoint a management representative, etc. for promotional materials and advertisements and establish an in-house oversight system so that only reviewed promotional materials and advertisements are used.
5. Implementation of post-marketing safety management 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 management 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 sales promotional tools.

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 appropriate venues 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 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 healthcare professionals, medical institutions, etc. 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 health professionals, medical institutions, etc., for the purpose of potentially influencing the appropriate use of drugs.
10. Relation to the Fair Competition Code in Ethical Pharmaceutical Drugs Marketing Industry
Member companies must actively and strictly follow the Fair Competition Code in Ethical Pharmaceutical Drugs Marketing Industry based on high ethical awareness.

11. Promotional activities outside Japan
Member Companies must comply with the code of the pharmaceutical industry in the country where it is located, or with the IFPMA Code if there is no such code.
(1) Provision of information on drugs overseas
Member Companies shall provide to overseas healthcare professionals, either directly or indirectly through local agents, information on drugs globally that is consistent and in accordance with relevant pharmaceutical affairs laws, regulations, and pharmaceutical industry 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 code of the pharmaceutical industry in the relevant nation, 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 comply with the code of the pharmaceutical industry in the relevant nation or the IFPMA Code.
(4) Activities overseas for Japanese healthcare professionals
When Member Companies undertake activities aimed at Japanese healthcare professionals overseas by holding seminars or scientific meetings at academic conferences 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 scientific meetings in Japan, they shall comply with the promotion code of the pharmaceutical industry in the relevant nation, or, if no such local code exists, to the IFPMA Code.

II. Administration of the Promotion Code
(1) The management of the Promotion Code shall be performed by the JPMA Code Committee established within JPMA.
(2) In response to inquiries and complaints relevant to the promotion code, or suspected code violation cases, the JPMA Code Committee shall carry out necessary procedures according
to the separately established "Procedures for Inquiries and Complaints Related to the Promotion Code". When the 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 Promotion Code".
Commentary on the JPMA Promotion Code for Prescription Drugs

[Meaning of corporate ethics of pharmaceutical companies]
Various legal regulations and self-regulations apply to the promotional activities for today’s prescription drugs and it is strongly requested that we comply with them. Among the most important are the Pharmaceutical Affairs Law, Education and Training Guidelines for MRs, the Fair Competition Code, and Guidelines for Specifying Product Information Summaries for Prescription Drugs, to name only a few.

Why then have so many regulations been applied to the drug industry? Are these regulations in fact necessary to the industry?

As generally known, drugs have the following characteristics.
(1) The nature of drugs is completely unknown from their appearance.
(2) Drugs have both effects and side effects and the occurrence differs from patient to patient.
(3) Thus drugs that are not accompanied by correct drug information cannot function as drugs.
(4) Patients who require treatment are the only consumers and consumption cannot be created by sales promotion.

When we consider these characteristics of drugs, there should obviously be restraints to be observed voluntarily by pharmaceutical manufacturers performing promotional activities.

Generally speaking, however, competition is liable to become so heated that restraints are left behind. We cannot deny that such behavior has been practiced by pharmaceutical manufacturers in the past. If a pharmaceutical company ignores the nature of drugs, it may cause significant damage to patients and society, in the form of adverse reactions or unnecessary use of drugs. As a result, it is clear that significant damage to society's trust in drugs and to the whole pharmaceutical industry will be self-inflicted, bringing miserable consequences both to the company and to society. Needless to say, companies gain nothing from such activities but loss.

The above-mentioned regulations are convincingly judged from the nature of drugs. It is therefore essential that we view these regulations not as "restrictions" but, more positively, as "reflections of the expectations that society has towards pharmaceutical companies", and that we embrace them as our own. It is easy to understand that corporate activities based on such ethical views, establish priceless intangible assets in the form of “public trust” towards drugs and pharmaceutical companies. These facts will be even easier to understand, if you place yourself in the position of an individual patient or a member of society and examine pharmaceutical companies.
As a member of a society (be it a family, a workplace or a community), everyone has a role that he or she is naturally expected to perform. Society works on the assumption that each member performs their certain anticipated role. Any society will crumble if this precondition is damaged.

This rule also directly applies to companies. With respect to drugs, members of society receive healthcare on the assumption that high-quality drugs are being used properly, irrespective of whether laws and regulations exist or not. It is also important for the pharmaceutical industry to perceive “Corporate Social Responsibility (CSR)”, which has recently been requested by society, as an important mission.

The character "倫:rin" used as the first component of the Japanese word "倫理:rinri" (meaning “ethics”) signifies our mutual expectations with regard to human and social relationships. Thus the word "倫理:rinri" signifies the root condition for the existence of society. And in our daily lives, this is mostly deemed as common sense. For instance, we say "promises must be kept" because that is one of the root conditions underpinning society. There is a strict social rule that breaking a promise results in loss of trust.

[Corporate Ethics of Pharmaceutical Companies in the IFPMA Code]
The IFPMA Code extends beyond promotional activities to embody social expectations regarding the proper nature of corporate activities on the part of pharmaceutical companies in exchange with stakeholders, including the philosophy and behavioral standards that should be brought to bear upon promotional activities.

Regarding the kind of promotional activities that society expects of pharmaceutical companies and the exchange with stakeholders, the IFPMA Code has set the “IFPMA Guiding Principles on Ethical Conduct and Promotion” as the basic principles and has provided eight basic standards.

1. The healthcare and well-being of patients are the first priority for pharmaceutical companies.
2. Pharmaceutical companies will conform to high standards of quality, safety and efficacy as determined by regulatory authorities.
3. Pharmaceutical companies’ interactions with stakeholders must at all times be ethical, appropriate and professional. Nothing should be offered or provided by a company in a manner or on conditions that would have an inappropriate influence.
4. Pharmaceutical companies are responsible for providing accurate, balanced, and scientifically valid data on products.
5. Promotion must be ethical, accurate, balanced and must not be misleading. Information in promotional materials must support proper assessment of the risks and benefits of the
6. Pharmaceutical companies will respect the privacy and personal information of patients.

7. All clinical trials and scientific research sponsored or supported by companies will be conducted with the intent to develop knowledge that will benefit patients and advance science and medicine. Pharmaceutical companies are committed to the transparency of industry sponsored clinical trials in patients.

8. Pharmaceutical companies should adhere to both the spirit and the letter of applicable industry codes. To achieve this, pharmaceutical companies will ensure that all relevant personnel are appropriately trained.

The IFPMA Code also mentions the following about “ethical promotion” and “interactions between pharmaceutical companies and health professionals”.

**Ethical promotion**

“The ethical promotion of prescription medicines is vital to the pharmaceutical industry’s mission of helping patients by discovering, developing, and marketing new medicines. Ethical promotion helps to ensure that healthcare professionals have access to information they need, that patients have access to the medicines they need and that medicines are prescribed and used in a manner that provides the maximum healthcare benefit to patients.”

**Interactions between pharmaceutical companies and healthcare professionals**

**Basis of Interaction**: Member companies’ relationships with healthcare professionals are intended to benefit patients and to enhance the practice of medicine. The interactions should be focused on informing healthcare professionals about products, providing academic and educational information and supporting medical research and education.

**Transparency of Promotion**: Material relating to pharmaceutical products and their uses, whether promotional in nature or not, which is sponsored by a company should clearly indicate by whom it has been sponsored. Promotion should not be camouflaged.

The JPMA Promotion Code is also based on these principles of the IFPMA Code.
I. JPMA Promotion Code

1. Responsibility of Member Companies in Promotional Activities

Member Companies shall assume responsibility for all promotional activities conducted by the companies and their MRs. 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 of which the Member Company owns more than 50% of the shares) in Japan adhere to the JPMA Promotion Code. Member Companies shall also require their 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.

(Commentary)

MRs act according to their company policies. Therefore, it will be difficult for the MRs to conduct activities if the company does not establish an internal system that ensures proper promotional activities without any deviation from the acceptable scope of activities specified in the JPMA Promotion Code.

The reason why member companies shall assume responsibilities for the activities of MRs is exactly because member companies are required to establish such internal systems. Member companies are encouraged to establish their own company codes for the same reason.

Member companies are not only required to take all responsibilities for their own promotional activities but also to make their subsidiaries comply with the JPMA Promotion Code and to request parent companies and affiliates to comply with the Code. In particular, as shown in the document issued by the Chairman of the Promotion Code Committee dated March 10, 2010 in the case of jointly carrying out promotional activities with subsidiaries, parent companies or affiliates, it is important to start such activities only after both companies involved confirm that they adhere to the JPMA Promotion Code.

Responsibilities of the member companies for their overseas subsidiaries, licensees or distributors are set forth in Paragraph 11.

(1) To appoint qualified employees as MRs, and to continue to maintain education and training programs for them so that drugs are used properly and that drugs are to be used when necessary.
Pharmaceutical companies are required to ensure continuous provision, collection, and dissemination of all requisite information on quality, efficacy and safety, related to the use of drugs to health professionals.

It is the MRs that bear this responsibility. The significance of these duties is realized through their daily operations, further high expectations are also placed on them by others. For this reason, in 1979, the “Education and Training Guidelines for Medical Representatives” was established and is still effective as detailed in the “Comprehensive Report Relating to the Research regarding the Status of Medical Representatives of Pharmaceutical Manufacturers (hereinafter referred to as the “Comprehensive Report”) prepared by the Health Science Council Research Project for fiscal year 1990-91 (hereinafter referred to as “the Summary Report”).

This paragraph describes that only appropriate persons are assigned to serve as MRs and continuous education & training for MRs are necessary to ensure continuous improvement of the quality of MRs.

It is to be noted that, as an effective means for ensuring further improvement of the quality of MRs, an “MR Certification System” has been introduced.

Improvement in the quality of MRs cannot be realized solely through the introduction of training programs provided by companies or the “MR Certification System”. It can be realized only when MRs are always conscious of the significance of their roles and the company has appropriate management policies and an appropriate marketing attitude.

(2) To ensure that the evaluation/remuneration system of MRs should not be such as to induce unethical acts of MRs.

(Commentary)
Pharmaceutical companies also have the responsibility to establish fair performance evaluation and remuneration systems for MRs to promote proper promotional activities.

The attitude and actions of MRs engaged in promotional activities in the frontline are the key for the company to carry out proper promotional activities. The performance evaluation/remuneration system of MRs is likely to have substantial effects on the attitude and actions of MRs.

Therefore, not only performance but also the attitude and behavior to comply with statutory and
regulatory requirements and self-regulations such as the JPMA Code should be reflected in personnel appraisal of MRs. Member companies must avoid adopting an evaluation/remuneration system that may induce MRs to commit any excessive sales promotional activities or any actions that may have a negative effect on the proper use of drugs.

(3) To provide information such as indications, dosage and administration, which should not deviate from the approved items for the drugs, based on up-to-date scientific data, in the most appropriate manner.

(Commentary)
Drugs may be recognized as drugs only after manufacturing and marketing approval is granted, and drug information must be supplied within the scope of the approval while complying with the related laws and regulations such as the Pharmaceutical Affairs Law.

Therefore, member companies must refrain from starting promotional activities until the marketing approval or approval for the extended indication is granted.

However, this cannot deprive medical/pharmaceutical experts, as well as the general public, of the right to know about scientific/medical advancements. For instance, this provision does not restrict:

(1) The adequate and appropriate exchange of scientific information about a drug as exemplified by the presentation of research findings in a meeting of any academic society or scientific journal. However, luncheon seminars, etc. sponsored by pharmaceutical companies are not included in these cases.

(2) The display of scientific exhibition materials about an unapproved drug in accordance with separate guidelines in a meeting of the international academic society. Although described as unapproved drugs, they must have been approved at least in one country. In case they have not been approved by any country, such an exhibition cannot be permitted. In addition, such an exhibition may be permitted as an exceptional case, but associated scientific literature and related literature cannot be distributed.

(3) The supply of already reviewed scientific literature, such as a reprint of a research paper upon the request of a doctor. However, member companies must refrain from making active approaches to induce a doctor, etc. to request such scientific literature, etc.; or

(4) The disclosure of medical information to stockholders in accordance with laws and regulations.

Even when providing such information, member companies must provide information by paying sufficient attention not to get involved in inappropriate promotional activities for the profit of pharmaceutical companies. Also, even when disclosing information (trend) on a product under
development to shareholders, member companies must pay sufficient attention so that it is not used for promotional activities that will not be perceived as information for investors.

It is occasionally pointed out that information is given “by emphasizing only the advantages of the product while skipping an explanation about the weaknesses” in the “Summary Report”. It is also pointed out that “baseless and ambiguous explanations are occasionally presented” and that “healthcare professionals are occasionally encouraged to use products without being provided with adequate information”.

These problems occur because MRs want to promote the use of their products, but member companies have to bear the responsibilities to make reliable data available and establish the guidelines for the supply of data to have MRs refrain from committing such activities. Improper information supply damages the trust of not only the MR but also of the company.

Therefore, it is necessary for drug information to be supplied based on scientific evidence and up-to-date data, in an appropriate manner.

Efficacy and safety of drugs are to be further verified through post-marketing safety management operations and post-marketing surveillance. This data should always be updated.

Scientific data supporting promotional presentation or usage must be provided to healthcare professionals upon their request.

(4) To collect and disseminate drug information as accurately and promptly.

(Commentary)
The collection of drug information and communication of the collected results is extremely important since pharmaceutical companies have legal and ethical responsibilities to establish the proper use of drugs. It is essential for pharmaceutical companies to establish the Safety Control Management Department, assign the Safety Control Manager, establish the SOP for post-marketing safety management operations, and carry out post-marketing safety management operations properly and rapidly as specified in the “Ministerial Ordinance on Good Vigilance Practice (GVP Ordinance)”. Although it is the responsibility of MRs to collect drug information, appropriate direction by the Safety Management Implementation Manager is important for MRs to “properly and rapidly” implement the activities.

It is also essential to assign the Post-marketing Surveillance Manager, establish the SOP for Post Marketing Surveillance Operations and correctly perform post-marketing surveillances and
studies in accordance with the “Ministerial Ordinance on Good Post-marketing Surveillance Practice (GPSP Ordinance)”. These are all important responsibilities of pharmaceutical companies.

Pharmaceutical companies also have the responsibility to ensure complete and immediate supply of important information about ADRs, precautions for use or warnings to healthcare professionals.

(5) To establish internal systems necessary to comply with all relevant laws and regulations and the industry's self-regulations.

(Commentary)
It is necessary to establish an internal system to ensure compliance with related laws and regulations and self-regulations for carrying out proper promotional activities.

In 2000, multiple member companies faced criminal penalties for the improper promotion of prescription drugs. Responding to this scandal, JPMA presented the Compliance Program/Guideline in 2001. In 2011, the JPMA revised this Compliance Program/Guideline reflecting the subsequent legal changes and trends of compliance in society, and called for member companies to establish their compliance system. The JPMA Promotion Code Committee requested member companies to establish positions responsible for the management of the JPMA Promotion Code and for practical operations for the JPMA Promotion Code to promote definition of the responsibility system and a system to ensure compliance with the JPMA Promotion Code.

Establishing internal systems does not necessarily mean establishing an organization. The internal system may be established through periodical review by related departments, declaration of compliance policies by the top management, preparation of the practical manual, establishment of the training system and internal auditing of the status of compliance, may also mean establishing an internal system.

Ongoing review and maintenance of an internal system is also necessary. It is desirable to review and maintain an internal system referring to the “Guidance for the Maintenance of the Internal System for the Compliance with the JPMA Promotion Code” issued by the president of the JPMA Promotion Code Committee on January 24, 2001.

The relevant laws and regulations that need to be considered in the above activity include, among others, the Pharmaceutical Affairs Law, the “Ministerial Ordinance on Good Vigilance Practice
(GVP Ordinance)”, the “Ministerial Ordinance on Good Post-marketing Surveillance Practice (GPSP Ordinance)”, the Act on Prohibition of Private Monopolization and Maintenance of Fair Trade, the Act against Unjustifiable Premiums and Misleading Representations and the Act on the Personal Data Information.

In addition to these laws and regulations, it is specified in the National Public Service Ethics Act and the National Public Service Ethics Code that national public officers are prohibited to commit activities that may cause public suspicion or distrust from the citizens in regard to the fairness of execution of their duties when interacting with whose who have interests with their duties. Therefore, pharmaceutical companies must maintain stronger morality when approaching public officers who may have an interest in pharmaceutical companies.

Member companies also must comply with self-regulations such as the Fair Competition Code, the “Guideline for the Preparation of Advertisements Placed for Prescription Drugs in Scientific Journals (Papers)”, the “Guidelines for Specifying Product Information Summaries for Prescription Drugs” and the “Education and Training Guidelines for Medical Representatives”.

2. Responsibility of the Top Management of Member Companies in Promotional Activities

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

(Commentary)

The JPMA enacted the “Charter for the Activities of Pharmaceutical Companies” in November 1997 to increase awareness of corporate ethics of pharmaceutical companies and establish public trust in the pharmaceutical industry, “activities as the top management” are clearly described.

The top management of member companies should play a leading role and carry out “activities as the top management” as specified in the “JPMA Charter for the Activities of Pharmaceutical Companies” also in the promotion of prescription drugs.

“Responsibilities of the top management in promotional activities” are included in the JPMA Promotion Code based on the understanding that the attitude of the top management is extremely important for the compliance with this Code. It was suggested in the questionnaire survey performed for member companies after the 2000 scandal that “understanding by the top management is the most important for the thorough enforcement of the JPMA Promotion Code” and that “the attitude of the top management to prevent recurrence is the most important to
prevent scandals”.

“Responsibilities of the top management” are included in the JPMA Promotion Code also for the expression of the strong intention that MRs and staff of related departments should comply with the JPMA Promotion Code in solidarity under the supervision of the top management.

(1) To realize that achieving the spirit of the JPMA Promotion Code is their duty, and to thoroughly inform related persons and to establish in-house systems, taking the lead in setting good examples to others.

(Commentary)
Prescription drugs are life-related products and the expenses are borne by public insurance.

Patients, as the consumers of prescription drugs, have no choice but to trust healthcare professionals, and completely entrust to them their life and health, which are of the upmost importance. Therefore, to meet the trust of patients, healthcare professionals are required to constantly improve their medical knowledge and skill, and supply the best available healthcare to patients.

Meanwhile, pharmaceutical companies have the responsibility to accurately and promptly provide, collect and disseminate proper drug information in an appropriate manner to ensure that healthcare professionals can provide the best available drug therapy for patients, and should strictly refrain from committing actions that may have a negative effect on the proper use of drugs. Society expects the cost spent by pharmaceutical companies to be appropriate and efficient, since expenses for prescription drugs are borne by public insurance.

Based on these understandings, the JPMA Promotion Code was enacted to show the way and the action standard for the "responsibilities that members companies must obviously discharge", and of the "standards with which they must voluntarily comply to", applied to the promotion of prescription drugs.

It is necessary for the top management of member companies to be fully aware of the importance of their roles in the implementation of the principles of the JPMA Promotion Code and play leading roles in disseminating the JPMA Promotion Code and establishing internal systems.
(2) To take responsibility in solving their own problems, and to endeavor to clarify the causes and prevent recurrences, when situations arise that contravene the spirit of the JPMA Promotion Code.

(Commentary)
This provision is included based on the understanding that the responsibility of the top management is not limited to the communication and establishment of an internal system for the implementation of the principles of the JPMA Promotion Code, but also to clarify that their attitudes are important when situations arise that contravene the principles of the JPMA Promotion Code.

Looking at example cases of scandals related to corporate ethics in other industries, we have often seen poor handling by the top management ending up in increased public criticism.

In the case of encountering a situation that contravenes the principles of the JPMA Promotion Code, the top management should take the initiative to resolve the problem, investigate the cause and prevent recurrence as their own responsibility. This is the only way to maintain public trust in pharmaceutical companies.

3. MRs' Activity Standards
MRs shall fully recognize their social mission as persons sharing responsibilities in healthcare while conducting promotional activities on behalf of their respective companies. They shall perform the following duties in a sincere and honest manner.

(Commentary)
In the “Summary Report”, MRs are positioned as the “persons sharing responsibilities in healthcare”. In both the “Summary Report” and the results of the questionnaire survey conducted by the Japan RAD-AR Council (currently renamed “Council for Proper Use of Drugs”), MRs are the most commonly acknowledged source of drug information for healthcare professionals. The importance of MRs’ roles has always been recognized in the results of various questionnaires conducted after that. MRs are strongly expected to play roles as the “persons sharing responsibilities in healthcare”.

In March 1997, the JPMA Training Committee established the “Roles MRs Should Play”. In the document, there is a notation, “MRs are expected to provide, collect, and disseminate information useful to the patients and the medical fields from an ethical point of view to ensure proper use of drugs as the “partner in pharmaceutical treatment”. The “Roles of MRs” compiled
by Medical Representative Education Center (currently renamed MR Certification Center) in March 2005 also says that “activities of MRs must all be based on the thinking (leading to ethical behavior) that focuses on ‘benefits for patients’ in addition to the above purpose.

MRs must also be well aware that the attitude and behavior of MRs have substantial effects on the image external parties such as healthcare professionals have of pharmaceutical companies.

Furthermore, MRs must also be conscious of the word “faithfully” in the statement “faithfully carry out”. “Faith” means sincerity and cordiality. MRs should implement the seven action standards for MRs described in the subparagraphs given the full awareness of their mission and position. They must implement these action standards with sincerity and cordiality, whether seen by others or not.

(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.

(Commentary)
Package inserts specify the basic information for health professionals in using pharmaceuticals, and the matters to be specified are determined by the Pharmaceutical Affairs Law. MRs are obligated to acquire knowledge of package inserts for their own company’s products. If knowledge of package inserts is deepened to include the underlying medical and pharmaceutical knowledge, that knowledge becomes more realistic.

Simply acquiring knowledge, however, does not fully discharge the duty of MRs. They must be able to provide it correctly to healthcare professionals. The Comprehensive Report mentions accuracy based on scientific backing and absence of bias in efficacy and safety, as aspects of "correctness".

(2) To conduct promotional activities according to the rules and methods established by their companies.

(Commentary)
In the past, MRs used to prepare original data and use them for promotion, although such a practice is rarely seen these days. Such practice is problematic since it is not known if the data provided in this manner is objective and comprehensive. It also happens that data prepared for internal use only, which are inappropriate as promotional materials, are externally used for promotion. Data prepared for internal use must be limited internally.
Although originality and ingenuity of MRs is encouraged, MRs must follow the procedures for proposing those ideas with originality and ingenuity to the company and implementing them under the responsibility and authorization of the company.

(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.

(Commentary)
This subparagraph describes the activities of MRs corresponding to (3) of “responsibilities of member companies”. No matter how much the companies prepare the latest evidence-based data, it will become meaningless unless the MRs use it properly.

When providing the information, MRs must not promote unapproved drugs or unapproved indications not included in the document prepared by the company and must impartially provide not only efficacy-related information but also safety-related information including the information on ADRs.

This is because the supply of information by MRs is to help healthcare professionals provide the best available drug therapy to patients, whereas the supply of information about unapproved drugs which have not been evaluated publically or unapproved indications or partial supply of information may impair the decision of the optimum prescription.

(4) To collect and disseminate drug information as accurately and promptly as possible.

(Commentary)
Delay of MRs’ collection of unfavorable information or time-consuming collection of information for reasons of sticking to the promotion of use of drugs, may impair the proper use of drugs and an irredeemable situation may arise.

Efficacy-/safety-related information at the time of approval of a drug have been obtained under certain restrictive conditions, and it would not necessarily be the same as the efficacy or ADRs/infections seen under varying post-marketing conditions or extensive use. For this reason, continued post-marketing surveillance/monitoring is necessary. At the same time, it is also necessary for reviewed/analyzed information to be disseminated to healthcare professionals in an appropriate manner to contribute to proper use of drugs.
Based on an adequate understanding of the characteristics of drugs, MRs need to collect safety control information and properly and smoothly implement safety assurance measures based on the results as directed by the Safety Control Implementation Manager according to the SOP for post-marketing safety management operations.

Also post-marketing surveillances and studies must be performed correctly as directed by the Post-marketing Surveillance Manager according to the SOP for PMS Operations. These are also important duties of MRs.

Note) “Under certain restrictive conditions” refers to the following cases.
(1) The data is obtained from a limited number of subjects.
(2) The data is obtained from the patient populations with restrictions of concomitant medications, complications or age.
(3) The treatment period was not long.
(4) The specialist for the target disease served as the investigator.

(5) Not to slander and / or defame competitors or competitors' drugs.

(Commentary)
The reasons that this subject is being taken up are that since MRs handle prescription drugs, which are life-related products, they must conduct themselves as conscientious members of society, and must provide, collect and disseminate appropriate information.

Slandering and / or defaming other companies and products for the promotion of use of the company’s product will damage the dignity of drugs and pharmaceutical companies, and no decent member of society is expected to commit such an action.

A large volume of accurate information on competitors and competitors' drugs is owned by the company concerned. Thus it is that company that can provide, collect and disseminate accurate information, and it is their duty to perform these activities in a responsible manner.

The supply of information about other companies or products distributed by other companies by an MR who has partial information about the companies or products may mislead healthcare professionals and impair the provision of the best available drug therapy. Supply of negative information about other companies or their products as exemplified by the behavior of supplying a copy of a newspaper article describing the ADR to such products is deemed to be slander and / or defamation. In the past, there have been cases where companies have carried information
unqualified for promotional printed materials under the pretext of “internal-use-only”,
mentioning it as “confidential”, and providing comparative data effective to emphasize the
superiority of the company product compared to the competing product to healthcare
professionals. Such provision of information using “internal-use-only” data can be deemed as
slander and/or defamation of products distributed by other companies.

(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 MRs.

(Commentary)
Both subparagraphs require MRs to conduct themselves in a decent manner. As already stressed,
the attitude and behavior of MRs have substantial effects on the trust in the company and on the
drug. JPMA established the “Council for the Improvement of MRs Activities in Hospitals” to
assess and ensure the improvement of problematic areas regarding MRs activities in large
hospitals, and summarized a report.

This report includes the following comment: “Pharmaceutical companies comprise an industry
that is highly social and public in nature and that contributes to healthcare. Based on an
understanding of this, MRs are required to comply with laws and regulations, maintain a level of
dignity that a member of society is expected to have, and to have high ethical awareness and
decency. Establishing a mutual and trustful relationship with healthcare professionals is
essential to bring about a smooth exchange of information about the proper use of the products.”

MRs, who handle drugs as life-related products, must understand related laws and regulations and
self-imposed industry rules and act in compliance with them.

Also, the full understanding shall be shared that national public officers, other public officers and
“deemed public officers” are subject to the code of ethics restricting the supply and receipt of
gifts and cash and cash equivalents.

Apart from public officers, original codes of ethics may be established for specific organizations
and MRs shall act based on the understanding of the codes.

MRs should be always conscious that the hospitals and clinics are places of medical care and
medical research, and MRs should refrain from activities and behaviors that may be unpleasant to
hospital staff or patients. MRs shall act politely as visitors.
4. Production and Use of Promotional Materials and Advertisements

Member Companies shall fully realize that brochures, advertisements in medical journals, websites targeting healthcare professionals, audiovisual materials such as slides and moving images, and other promotional materials are important media in dissemination of drug information. Member companies 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.

(Commentary)

As to regulatory requirements for advertisements, acceptable range and way of placement of drug advertisements are provided in Article 66 to 68 of the Pharmaceutical Affairs Law and the “Standards for Proper Drug Advertisements”. In accordance with the requirements, self-regulations such as the “Guidelines for Preparation of Advertisements of Ethical Drugs Inserted in Scientific Journals (Papers)” and the “Guidelines for Specifying Product Information Summaries for Prescription Drugs” are established by the pharmaceutical industry to ensure proper preparation of the Product Information Summaries and advertisements.

As repeatedly emphasized, drug information is indispensable to the use of drugs. Product Information Summaries and advertisements are important tools for supplying drug information, but must be prepared properly so that the contents, expression, and usage of such materials is not misinterpreted by healthcare professionals. Other promotional materials include poster displays or exhibition panels at academic conference venues and electronic media (e.g. DVD, CD-ROM, internet content, email).

Medical/pharmaceutical articles supplied upon request of healthcare professionals do not fall under this subparagraph; however, when a company voluntarily distributes such materials to healthcare professionals, they are treated as promotional materials provided in this subparagraph.

Cited data including figures and tables in the promotional materials and advertisements should correctly convey the true meaning of original articles, be carefully written to avoid distortion, exaggeration, unfair emphasis or deletion that may cause a misunderstanding, and always come with notes of the sources. When using the results of the questionnaire survey (especially those concerning the safety and efficacy conducted after the marketing approval), the Guidelines for Specifying Product Information Summaries for Prescription Drugs must be complied.

Furthermore, it is essential that the contents and expression in the Product Information
Summaries and advertisements inserted in scientific journals (papers) be proper in accordance with the “review board report” of the Review Committee for Product Information Summaries.

Promotional materials such as advertising in direct mail or specialized journals (paper) must not be such as to misrepresent the inherent content. As an example of promotional materials that misrepresent this inherent content, we may mention advertisements that are displayed as if they were part of an article in a medical journal, and it is therefore necessary that a clear distinction be drawn between advertising and articles or editorial content. Specifically, as shown in the message from the Chairman of the JPMA Promotion Code Committee dated August 15, 2002 and “Points to note when preparing advertising in the guise of articles or editorial content” since advertising in the guise of articles or editorial content is part of the advertisement of a pharmaceutical company, such advertising that slanders and/or defames a competitor's product, by recommending non-approved indications or dosage and administration, or emphasizing adverse reactions only, must be strictly avoided.

Also for “product promotional materials” prepared/distributed by wholesalers, the company needs to give cooperation/guidance to ensure the properness of the material.

The Internet has from the first been a means by which all people can freely access information, but when a pharmaceutical manufacturer uses its website to provide health professionals with product-related information, it is required, under the relationship with Standards for Proper Advertising of Drugs, to restrict access by persons who are not healthcare professionals. However when it fulfills the conditions set forth below, the website concerned, so long as it does not infringe the laws of Japan (meaning does not appeal to patients or the general public), is recognized as appropriate provision of information even if it does not use any particular method of establishing passwords.

(1) If the name of the pharmaceutical company is provided and it is noted that the information is targeted at healthcare professionals and the access is allowed only if the person who intends to access the website confirms that the information is targeted at healthcare professionals;
(2) If the information is appropriate for healthcare professionals;
(3) If the company website targeting healthcare professionals is linked with any external website, the content and the website are appropriate for healthcare professionals and the owner (author) of the linked website is apparently recognized.

Also in “6. Electronic materials, including Audiovisuals” in the IFPMA Code, similar website-related requirements are included.

For the preparation of the content supplied to healthcare professionals on the website, the JPMA
Promotion Code and self-regulations shall be fulfilled as in the precautions shown in the document issued by the president of the JPMA Promotion Code Committee on March 6, 2001 applied to other printed materials.

The following is an excerpt of the related part.
Product Information Summaries or advertisements about prescription drugs must not be supplied to the general public other than healthcare professionals (Standards for Proper Drug Advertisements). Therefore, adequate caution must be exercised to prevent exposure of calendars and posters containing product names to the general public when distributing the materials.

(1) Statements regarding indications, dosage and administration, and any other statements, shall not deviate from the approved items.

(Commentary)
Drugs are only permitted to be referred to as "drugs" within the scope for which they are approved, so there should from the first be no possibility of descriptions that deviate from this.

Actually, however, there are examples where expressions are exaggerated or unfavorable information is provided in small letters in a poorly balanced manner, even if the way a drug is described does not deviate from the definition. This is how misconceptions can be formed.

The basic nature of this subparagraph, therefore, is to regulate deviating expressions, and items (2) and to follow specify concrete means of expression, and representative examples of matters to bear in mind.

It is further required that important items conforming to the approval, such as warnings and precautions, including contraindications, (target of administration, dosage, adverse reactions, interactions, etc.), be in agreement with the content specified in product information summaries, and it is important that they be specified in accordance with the Guidelines for Specifying Product Information Summaries for Prescription Drugs.

With the November 1998 revision of the IFPMA Code, based on the separately established Guidelines Concerning the Display of Academic Materials for Unapproved Drugs, it is stated that in displaying scientific materials at international scientific meetings, reference may also be made to unapproved drugs. However, although such drugs are described as being unapproved, some country must have approved them, and in case they have not been approved by any country, such an exhibition cannot be permitted. Moreover such an exhibition may be permitted as an exceptional case,
and the scientific literature concerned and related literature cannot be distributed. Note that this does not apply to providing, in response to a request by a physician, etc. reprints of papers reporting research results or academic papers that have already been highly evaluated.

(2) No false, exaggerated or misleading expression shall be used regarding efficacy and safety. Claims relating to or focusing on 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.

(Commentary)
This is one of the matters to bear in mind specified in subparagraph (1). Emphasis by means of expression that guarantees efficacy or safety, or is superlative or equivalent thereto, is not appropriate. Specifically it is necessary to pay the most careful attention to phraseology for safety, and it is not permissible to use ambiguous phrases like "highly safe", "few adverse reactions" "no deleterious effects" or “as safe as placebo” as characteristics or catch phrases that emphasize safety.

Note that when so stated, it is necessary, based on precise and objective data, to use concrete expressions such as "the incidence of adverse reactions is 12.3%" together with a summary of the data that backs this up.

It is also necessary, when citing results of animal studies, to specify what animal species is used, and when citing the results of in vitro tests, to make this clear. Based on such results it is impermissible to use expressions that would guarantee efficacy or safety when used by humans.

(3) Fair statements shall be made by presenting both efficacy data and safety data, including adverse reactions.

(Commentary)
This item is also a matter to bear in mind. Attention must be paid that statements on efficacy information and safety information including adverse reactions maintain balance in terms of the product information summary as a whole or the advertisement as a whole. For example even in advertisements where space is limited, it is necessary to assure the fairness of the information by displaying warnings and precautions, including contraindications, fairly and in type as conspicuous and easy to read as efficacy and the like.

(4) Comparisons with other drugs shall be based on scientific data and, in principle, shall be made using generic names.
For health professionals, comparing new drugs with drugs that have been previously used and finding out where and in what way they differ is extremely important in deciding which drug to use. Thus it is imperative that they be introduced based on accurate data with scientific backing, in compliance with the Guidelines for Specifying Product Information Summaries for Prescription Drugs, while avoiding ambiguous expressions that could lead to misunderstandings.

When making a comparison with another drug, the drug that is being compared against shall, in principle, be referred to using its generic name.

However when making a comparison with one's own company product, or when the agreement of the company supplying the drug that is being compared against has been obtained, it may happen that the brand name is used. For this reason we have said "in principle".

Further, when in citing from the literature, the data of a competitor is used, the agreement of the company concerned must be obtained.

In using the results of clinical trials performed for comparison with drugs supplied by a competitor, careful attention must be paid to the contractual conditions between the companies concerned under the terms of the JPMA's "discussions regarding the supply and acceptance of drugs for comparison (comparators)".

5) Competitors or competitors' drugs shall not be slandered and/or defamed.

Member Companies must take great care in preparing the product information summaries based on the guidelines for statements in product information summaries in order to avoid being perceived as slander and/or defamation to competitors or competitors’ drugs.

Conducting comparisons based on objective data has been referred to in the previous subparagraph. However, as is shown by the supplement 2 (clinical comparative studies) of guidelines for statements in product information summaries, it is not permissible to include everything just because it is a fact even in product information summaries and other printed matter for promotional use.

Including comparative data that emphasizes the advantages of one's own company's product, and is thus biased against a competitor's product, is deemed as slander and/or defamation.

There is a possibility that provision of improper information including the falsified price-related
information or misleading price comparison in promotional materials or promotional activities may be deemed as slander and / or defamation.

Careful attention is being paid to the introduction of clinical results, but areas in which attention tends to be insufficient include "background of development" and "non-clinical studies".

In "background of development", the purpose of development may in some cases be stated as developing a drug that represents an improvement over an existing drug. In such a case, excessive emphasis on the disadvantages of the existing drug could be taken as slander and / or defamation, and if included, the expression must be carefully crafted.

And when, in "non-clinical studies", particularly in pharmacological studies, data on medicinal titer or affinity with receptors is introduced, sufficient care must be taken so that it does not emphasize inferior points of competitors' drugs.

(6) Extraordinary data shall not be presented by using an expression that may give an impression that the data represent a universal fact.

(Commentary)
This subparagraph describes one aspect of the idea that drug information must be scientific, objective and fair. Presenting data that happen to be favorable to one's own company product by using expression that represents the data as a universal fact must be avoided. Since case reports may lead to the presentation of extraordinary data, it is not permitted to prepare case reports or collection of case reports in principle. As for the type of cases that may be introduced, such as the introduction of cases to call for attention to adverse reactions or cases with special diseases (e.g. which are treated by only orphan drugs), a description may be found in the Supplement 1 of Guidelines for preparing product information brochure for prescription drugs.

(7) Misleading or indecent photographs, illustrations, etc., that are not suitable to the socially respected role of drugs shall not be used.

(Commentary)
Materials such as photographs or illustrations, which appeal to the sense of sight, can mislead or have a suggestive effect on the viewer. Photographs or illustrations must not be used in a way that interferes with the correct understanding of drug information.

Drugs also have an image in society as drugs. Keeping and / or heightening that image is the responsibility of persons involved in the pharmaceutical industry. When photographs or illustrations
are used, emphasis must not be merely on attracting attention; there must be nothing that damages its image as a drug. "Plays on words" that have unclear meanings are not desirable.

As used here "etc." refers to figures and tables, catch phrases, phrases and abbreviations.

A product advertisement that contains a portrait of healthcare professionals may give an erroneous impression that opinion leaders, etc. recommend or guarantee the product. Thus, such an advertisement is not suitable as a product advertisement of a drug and should not be used.

(8) When an advertisement is aimed mainly to promote only the name of a drug, the items described in such an advertisement shall include the name (brand name), therapeutic category (product title), regulatory classification, non-proprietary name, and status of NHI drug price listing. The contact and address for more detailed information shall be given.

(Commentary)

In Western countries there are printed materials known as "reminders", which have the purpose of calling the product name to mind, but in Japan this type of materials must always be accompanied by drug information. As an exceptional case, there may be brand name advertisements printed in scientific journals. In these cases, sufficient information may not be carried due to considerations of space, therefore, in order to keep the information well-balanced, items that can be described are set forth, and the contact address for more detailed information must be given.

Therefore it has been decided not to cite information on safety (precautions, including warnings and contraindications) together with information on efficacy (catch copy, indications, and dosage and administration, etc).

As used here "product title" means an expression of characteristics in terms of formulations and/or efficacy of products, and refers to the therapeutic category given in the package insert. For example, drug for type 2 diabetes, slow-released XX and the like. Thus it is not, in principle, permissible to cite as the product title anything other than the therapeutic category in the package insert. Since information on efficacy is not to be given, the product title must be given together with the product name. It is not permissible to use it in the manner of catch copy on efficacy, separated from the product name.

Ball-point pens and other such items bearing the product name may be considered to be objects not mainly intended as advertising, and decisions should be made based on “8. Gifts”.
(9) Member Companies shall appoint a management representative, etc. for promotional materials and advertisements and establish an in-house oversight system so that only reviewed promotional materials and advertisements are used.

(Commentary)
With respect to product information brochure for prescription drugs and advertisements in scientific journals (paper), an in-house oversight system has been established, centered on the person responsible for oversight product information brochure for prescription drugs (Note). In addition to that, an oversight system must also be established to assure that other promotional materials are created and used properly. This is because once these materials are released outside a company, they will be deemed as the ones issued by the company.

The materials for in-house training which are not assumed to be used in outside promotional activities also need to be created and used properly

(Note) A designated company employee (so-called “Promotional Materials Officer”), with sufficient knowledge and appropriate academic qualifications shall be responsible for the management of product information brochure. A senior manager could be PMO, if specialists in medical information who can provide appropriate advice to creators would be available.

5. Implementation of post-marketing safety management 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 management 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 sales promotional tools.

(Commentary)
Appropriate implementation of post-marketing safety control management is an important requirement to obtain permissions as a marketing approval holder. Post-marketing safety management operations include safety assurance activities and early post-marketing phase vigilance (EPPV), etc. Safety assurance activities are defined in the GVP Ordinance as follows; “collection and review of safety management information, and necessary measures based on the review results.”

Post-marketing surveillance is defined in the GPSP Ordinance as follows; “PMS indicates drug use results surveys (including specific use results surveys) or post-marketing clinical studies
which are conducted by a company to collect, obtain, verify or validate information on the quality, efficacy and safety of medicines.”

As mentioned above, post-marketing safety management operations and post-marketing surveillance, etc. bear importance related to the nature of drugs, and therefore, pharmaceutical companies have the social responsibility to constantly seek for a more effective and safer usage based on the post-marketing condition of the use of drugs (e.g. conditions of patient compliance, interaction with other drugs, treatment period, etc.) and the change of conditions (e.g. advancement of medical technology, change of assessment criteria, new pathologies and pathological images, change in pathogenic microorganisms, etc.).

Needless to say, implementation of post-marketing safety management operations and post-marketing surveillance, etc. must be evidence based. If the data are ever to be used as a disguise for sales promotion, this action would inflict damage on the inherent nature of drugs and would invite considerable loss of trust in drugs and pharmaceutical companies.

Compliance with related laws and regulations such as the GVP Ordinance and the GPSP Ordinance, etc. and the Fair Competition Code is absolutely necessary, so that post-marketing safety control management and post-marketing surveillance, etc. are not doubted or mistaken as a disguise for sales promotion.

**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.

(Commentary)
Pharmaceutical samples may be either clinical samples for trial use, or product samples for reference. The Fair Competition Code defines; "clinical samples are intended so that physicians can confirm and evaluate the quality, efficacy, safety and pharmaceutical characteristics of the drug concerned prior to clinical use, while product samples are intended so that healthcare professionals can confirm the characteristics of their appearance such as dose form, color, taste and smell before using the prescription drug concerned", and it allows them to be provided free of charge. In other words, drug samples can be provided only within these limits.
Even if it is not possible to claim reimbursement from health insurance, drug samples are not entirely free of inducing transactions.

Provision of pharmaceutical samples must always accompany information on the relevant drug, and to achieve the original purpose of pharmaceutical samples, only the minimum necessary quantity should be provided, even when it meets the specifications of the Fair Competition Code. The person responsible for the management of pharmaceutical samples must constantly monitor the provision of samples, and also must pay as close attention as possible to its operation and management.

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 appropriate venues 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 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.

(Commentary)

Seminars and study meetings related to their own products that pharmaceutical manufacturers conduct for healthcare professionals are for the purposes of providing the latest scientific and academic information uniformly and efficiently to large numbers of healthcare professionals, and for carrying out the exchange of information on the same site. Seminars and study meetings are also an important tool to supply information similar to the information supplied by MRs. Whether hosting or co-hosting, it is the responsibility of member companies to fully discuss the details of presentations, for example, by checking them with lecturers beforehand, comply with the JPMA Promotion Code and hold seminars and study meetings. Care must be taken so that such meetings are not deemed to recommend the use of unapproved drugs or slander and / or defame competitors or competitors' drugs.

Events such as social gatherings held in conjunction with seminars or study meetings must be on a modest scale, so that they do not obscure the original objective of the seminar or study meeting.
or appear to society as unnatural.

When pharmaceutical companies are involved in seminars or study meetings organized by healthcare professionals in any form, member companies must be restrained so as not to invite any misunderstandings.

Seminars and study meetings are defined in “7. Interactions with Healthcare Professionals” of the IFPMA Code. The main contents are as shown below.

• Scientific and Educational Objectives: The purpose and focus of all symposia, congresses and other promotional, scientific or professional meetings (an “Event”) for healthcare professionals organized or sponsored by a company should be to provide scientific or educational information and/or inform healthcare professionals about products.

• Appropriate Venue: All Events must be held in an appropriate venue that is conducive to the scientific or educational objectives and the purpose of the Event or meeting. Companies must avoid using renowned or extravagant venues.

• Events Involving Foreign Travel: No company may organize or sponsor an Event for healthcare professionals that takes place outside of their home country unless it is appropriate and justified to do so from a logistical or security point of view. International scientific congresses and symposia that expect participants from many countries are therefore justified and permitted.

• Sponsorship: Sponsorship to healthcare professionals is limited to the payment of travel, meals, accommodation and registration fees.
  • No payments are made to compensate healthcare professionals for time spent in attending the Event.
  • Any sponsorship provided to individual healthcare professionals must not be conditional upon an obligation to prescribe, recommend or promote any pharmaceutical product.

• Guests: Companies shall not pay any costs at all associated with individuals accompanying invited healthcare professionals.

• Limits: Simple refreshments and / or meals incidental to the main purpose of the Event and should be provided only in the following cases:
  • exclusively to participants of the Event; and
  • if they are moderate and reasonable as judged by local standards.

• Entertainment: No entertainment or other leisure or social activities is to be provided or paid for by member companies.

Member associations are encouraged in the IFPMA Code to provide written guidance on the meaning of the terms “renowned”, “extravagant” and “restrained” and “reasonable” as used in the code. In the JPMA Code, the definitions are provided in “Definitions and Commentary on Terms”. 

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The Fair Competition Code also defines the points to be adhered to concerning seminars and study meetings. Thus with respect to holding seminars and study meetings, it is necessary that pharmaceutical companies definitely comply with the Fair Competition Code, and that even when an act may not be deemed a violation of the Code, they must examine its suitability with an even more rigorous attitude in accordance with their ethical insight.

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

(Commentary)
The Fair Competition Code limits unfair offerings of any premiums in order to prevent unfair soliciting of customers and ensure voluntary and rational selection of products by general consumers and fair and orderly competition among business operators. Thus, the Code states that pharmaceutical manufacturers must not offer to medical institutions, etc. any premiums (gifts or monetary benefits offered to the opposite party in their commercial transactions as a means of attracting buyers) as a means to unfairly solicit transactions of prescription drugs. In other words, it does not entirely restrict the offering of gifts, monetary benefits, etc., but rather restricts the offering of gifts, monetary benefits in forms of premiums, as a means to induce unfair transactions.

On the other hand, the JPMA Promotion Code includes the item on gifts (offering of gifts) to deal with the offering of gifts from the standpoint of what is appropriate for pharmaceutical companies to offer, irrespective of whether or not the offering of gifts is restricted by the Fair Competition Code. In other words, the offering of gifts must be considered from the standpoints such as whether it may affect proper use of drugs, whether it may be perceived by society to interfere with neutrality of prescriptions and whether it may ruin the socially respected role of drugs, which are life-related products. Nevertheless, complying with the Fair Competition Code when offering gifts classified as premiums is an overriding assumption, and any member company who violates this Code will violate the JPMA Promotion Code.

The IFPMA Code says that “the interactions between companies and healthcare professionals should be intended to benefit patients and to enhance the practice of medicine”. In “7.5.1 Prohibition of Cash and Personal Gifts”, the IFPMA Code defines that “Payment in cash equivalents (such as gift certificates) must not be provided or offered to healthcare professionals. Gifts for the personal benefit of healthcare professionals (such as sporting or entertainment tickets, electronics items, etc.) must not be provided or offered”. Among them, the IFPMA Code also
defines the following as exceptions in the Q&A.

“In some countries, if allowed under local law and in accordance with local practice, an inexpensive customary gift not related to the practice of medicine may be given on an exceptional basis to a healthcare professional in acknowledgment of significant national, cultural or religious events. However, even in these circumstances such gifts may not be provided on occasions when it could be perceived as interfering with the independence of a healthcare professional’s decision to prescribe, recommend or purchase medicines”.

On the other hand, though it is not as frequent as before, there are gifts in the business society of our country that are associated with summer/winter gifts or congratulatory or condolence gifts to be provided as a national, cultural and religious custom, despite the fact that such gifts benefit healthcare professionals personally. However, if pharmaceutical companies provide such gifts to healthcare professionals, medical institutions, etc., depending on the kind of items, cost, frequency, etc. of such gifts, it may be perceived by society that such gifts will interfere with the neutrality of healthcare professionals’ judgment. It is also considered difficult to gain the understanding of society if pharmaceutical companies conducting their businesses in the public health insurance system and NHI drug price system provide such gifts that do not lead to benefits of patients or improvement of medical care.

Therefore, member companies need to define clear standards for such gifts in their companies and strictly observe them according to the principles of this JPMA Code and IFPMA Code.

On the other hand, the IFPMA Code defines the offering of goods in “7.5.2 Promotional Aids” and “7.5.3 Items of Medical Utility”.

Promotional Aids: Promotional aids of minimal value and quantity may be provided or offered to healthcare professionals if relevant to the practice of the healthcare professional.

Items of Medical Utility: In accordance with local laws and regulations, items of medical utility may be offered or provided if such items are of modest value, do not offset routine business practices and are beneficial to enhancing the provision of medical services and patient care.

It is specified in the IFPMA Code that member associations shall provide guidance using local currency, on the precise value for “minimal” and “modest value”. In the JPMA Code, the definitions are provided in “Definitions and Commentary on the Terms”.

Specific requirements for the offering of above mentioned promotional aids and items of medical utility are also specified in the Fair Competition Code. It is most obvious that pharmaceutical companies must comply with the Fair Competition Code when offering gifts. However, they must
also examine its suitability with an even more rigorous attitude based on ethical awareness as a pharmaceutical company, even when they are not deemed a violation of the Fair Competition Code.

Meanwhile, caution must be exercised for the regulation that national public officers and other public officers and “deemed public officers” are subject to the code of ethics restricting supply and receipt of gifts. Apart from public officers, original codes of ethics may be established within specific institutions or organizations, and therefore thorough confirmation is necessary.

Whether classified as premiums or not, gifts are frequently used as an advertising media, by printing the name of the company or product, and in such cases it is necessary that the name is displayed based on the relevant laws, regulations and self-regulations. In other words, member companies must be careful so that they are clearly distinguished from the materials for prescription drugs information, and are not mistaken as advertisements towards the general public outside of the healthcare field.

This issue is mentioned in the document issued by the Chairman of the JPMA Marketing Committee on April 1, 1994 as “it is not desirable that the names of prescription drugs are placed conspicuously in view of the general public, and product names should not be printed on nametags or bags carried by MRs.”

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<th>9. Provision of cash or its equivalents</th>
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<td>Member Companies shall not offer, either directly or indirectly, any cash or its equivalents to healthcare professionals, medical institutions, etc., for the purpose of potentially influencing the appropriate use of drugs.</td>
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(Commentary)
The purpose of this subparagraph is the same as that of “Offering of gifts”.

Even justified receipt and payment of cash and cash equivalents by pharmaceutical companies and medical institutions tend to cause doubt or mistrust among society or patients. Such doubt or mistrust has negative effects on the trustful relationship between healthcare professionals and patients and may damage the trust in pharmaceutical companies. Since the trust of patients in healthcare professionals and pharmaceutical companies is the precondition of the proper use of drugs, greatest attention must be paid in offering cash and cash equivalents to prevent such offers from causing mistrust.

With respect to the offering of cash and cash equivalents to individual healthcare professionals, it
is specified in the IFPMA Code that “Payments in cash or cash equivalents (such as gift certificates) must not be offered to healthcare professionals.”

This requirement is based on the principle that “3. The interactions between pharmaceutical companies and stakeholders must be always ethical, appropriate and professional. Companies must not offer or provide anything in a manner or on conditions that would have an inappropriate influence on a healthcare professional’s prescribing practices” in “Guiding Principles” of the IFPMA Code.

In Japan, congratulatory or condolence payments are generally offered to individual healthcare professionals. The JPMA Promotion Code defines that a reasonable condolence payment given for a national, cultural or religious reason is not deemed as an offer of cash or cash equivalent that may affect the healthcare professional’s prescribing practices or the proper use of drugs. On the other hand, member companies shall refrain from giving congratulatory payments, as the interpretation or range of congratulatory events are difficult to be specified, and that congratulatory payments are likely to cause public misunderstandings. The range and amount of reasonable condolence payment is defined in the “Definitions and Commentary on the Terms”.

The WHO Ethical Criteria for Medicinal Drug Promotion forbids healthcare professionals from accepting such offers of goods or monetary benefits, stating that "healthcare professions shall not request or be provided with promotional items in material or monetary form that would influence the prescribing of the healthcare professionals”

Pharmaceutical companies may pay remunerations for receiving consulting services from healthcare professionals. But consignment of consulting services must never be used as a disguise to justify the payment of cash and cash equivalents to healthcare professionals. When receiving consultation, the following requirements must be fulfilled.

(1) Purpose and legitimate need for the services has been clearly identified in advance of requesting the services and entering into arrangements with the prospective consultants.
(2) The criteria for selecting consultants are directly related to the identified purpose and the persons responsible for selecting the consultants have the expertise necessary to evaluate whether the particular healthcare professionals meet those criteria.
(3) The number of healthcare professionals retained is not greater than the number reasonably necessary to achieve the identified purpose.
(4) A payment for services must be appropriate and comparable to the services provided.
(5) A written contract which specifies the nature of the services to be provided and the basis for payment of those services.
(6) The retaining company maintains records concerning the services provided by consultants.
and makes appropriate use of them.

(7) The hiring of the healthcare professional to provide a relevant service is not an inducement to prescribe a particular product.

Meanwhile, caution must be exercised for the regulation that national public officers and other public officers and “deemed public officers” are subject to office routine regulations and the code of ethics restricting any offers of consultant service or supply and any receipt of cash and cash equivalents.

Apart from public officers, original office routine regulations or codes of ethics may be established within specific institution or organizations to restrict any offers of consultant service or payments and receipt of cash and cash equivalents and therefore thorough confirmation is necessary.

10. Relation to the Fair Competition Code in Ethical Pharmaceutical Drugs Marketing Industry

Member companies must actively and strictly follow the Fair Competition Code in Ethical Pharmaceutical Drugs Marketing Industry based on high ethical awareness.

(Commentary)
The Fair Competition Code is the pharmaceutical industry’s self-imposed rule to prevent unfair soliciting of customers by limiting the provision of unfair gifts in the ethical pharmaceutical drugs marketing industry and ensure voluntary and rational selection of drugs by general consumers and fair and orderly competition among business operators based on the Act against Unjustifiable Premiums and Misleading Representations under the authorization of the Minister of Consumer Affairs Agency and the Fair Trade Commission. Therefore although the Fair Competition Code is established voluntarily by the industry, it is legally substantiated.

Meanwhile, the JPMA Promotion Code, consists of voluntary rules of the pharmaceutical industry that have the purpose of indicating the status of promotional activities and standards of conduct required of the industry, responding to the expectations of society. Obviously the promotional activities required of pharmaceutical enterprises include compliance with the Fair Competition Code.

The reason for addressing the relationship between the Fair Competition Code and the JPMA Promotion Code is that Member Companies must not limit themselves to a position of simply complying with the Fair Competition Code, but must conduct themselves so that, even though there is an act that does not infringe the Fair Competition Code or an act that is not clearly outlined, they will be moved to re-evaluate its suitability with an even more stringent attitude in accordance with their
Drugs are life-related products of which true value is invisible, and for this reason, improvement and maintenance of public trust in drugs can be nurtured only through pharmaceutical companies’ daily endeavors. Trust nurtured for the period of many years may be destroyed instantly by a thoughtless action. It is essential that Member Companies conduct their promotional activities bearing constantly in mind that society's trust in drugs is the foundation of the pharmaceutical industry's existence.

11. Promotional activities outside Japan

Member Companies must comply with the code if there is a code of the pharmaceutical industry in the relevant nation or with the IFPMA Code if there is no such code.

(1) Provision of information on drugs 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 codes applicable in such countries.

(Commentary)

Overseas promotional activities must be consistent with the laws and regulations and codes enforced in the relevant nation.

Member companies should provide internationally consistent information, wherever possible within the range of the regulations and promotion codes enforced in the relevant nation, with respect to the indications, dosage and administration, contraindication, warning, precautions and ADRs. In particular, information concerning the safety of drugs should be appropriate and consistent.

This is also applicable not only when directly provided by member companies but also when provided indirectly by distributors.

It is also specified in the IFPMA Code that “healthcare professionals in developing countries should have access to similar data to those being communicated in developed countries, while respecting that promotional activities must be consistent with local labels and approved contents of drugs”.

Safety-related significant information such as the information on serious and previously unknown
ADRs must be reported to the regulatory authorities of the relevant nation on a priority basis.

(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 code of the pharmaceutical industry in the relevant nation, 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 comply with the code of the pharmaceutical industry in the relevant nation or the IFPMA Code.

(Commentary)
Member companies need to have their overseas subsidiaries (whose majority shares are owned by the companies), licensees and distributors comply with the code established by the pharmaceutical industry of the relevant nation during their promotional activities.

If there is no relevant code in the nation, member companies shall request them to comply with the IFPMA Code.

It is desirable to include request for compliance in the license agreement or the agency agreement or make a written agreement in advance.

This subparagraph does not, by means of the JPMA Code, regulate the conduct of the licensee or agent; rather it regulates the conduct of the Member Companies themselves, and clarifies the supervisory responsibility of Member Companies over their subsidiaries.

(4) Activities overseas for Japanese healthcare professionals
When Member Companies undertake activities aimed at Japanese healthcare professionals overseas by holding seminars or scientific meetings or at academic conferences overseas, they shall comply with the JPMA Promotion Code.

(Commentary)
Member companies must also comply with the JPMA Promotion Code when offering gifts, cash or cash equivalents or food and drinks to Japanese healthcare professionals in foreign countries.
As shown in the document issued by the president of the JPMA Promotion Code Committee on February 18, 2003, pharmaceutical companies are required to act modestly towards Japanese healthcare professionals in academic conferences held in foreign countries based on ethical awareness.

(5) Activities in Japan for healthcare professionals from overseas
When Member Companies invite healthcare professionals from overseas to seminars or scientific meetings in Japan, they shall comply with the code of the pharmaceutical industry in the relevant nation, or, if no such local code exists, to the IFPMA Code.

(Commentary)
When inviting foreign healthcare professionals to domestic seminars or scientific meetings and offering gifts, cash or cash equivalents or food and drinks, member companies must comply with related laws and regulations and the codes of the nation.

Offers of unjustifiable interest to foreign public officers is prohibited in the Unfair Competition Prevention Law, and this shall also be borne in mind in regards to interactions with foreign public officers.
Part 3
Definitions and Commentary on Terms

These “Definitions and Commentary on Terms” have been established to ensure a clearer understanding of the scope and provisions of the JPMA Code of Practice. These “Definitions and Commentary on Terms” are part of the JPMA Code of Practice.

**Healthcare professionals**

In general, those engaged in medical care are called “healthcare professionals” or “healthcare service providers”.

The Medical Service Law uses the term “Healthcare professionals”, and the Fair Competition Code uses the term “healthcare service providers”. The IFPMA Code uses the term “Healthcare professionals” as well.

In the JPMA Code, the term “healthcare professionals” is used as in the Pharmaceutical Affairs Law and the Medical Services Law.

In the Medical Service Law, “healthcare professionals” refer to “doctors, dentists, pharmacists, nurses and other persons engaged in medical service.”

In the JPMA Code, “healthcare professionals” refer to “physicians, dentists, pharmacists, nurses, public health nurses, midwife, dental hygienists, dental technicians, medical radiology technicians, physical therapists, occupational therapists, clinical laboratory technicians, hygienic technologists, orthoptists, clinical engineers, prosthetists, emergency life-saving technicians, registered dietitians, welfare caretakers, care managers among other professionals”.

In the IFPMA Code, “healthcare professional means any member of the medical, dental, pharmacy or nursing professions or any other person who in the course of his or her professional activities may prescribe, recommend, purchase, supply, or administer a pharmaceutical product” and it is used in essentially the same sense as in the JPMA Code.

**Healthcare service providers**

In the Operating Standards of the Fair Competition Code healthcare service providers are collectively defined as “doctors, dentists, pharmacists, public health nurses, nurses and other persons engaged in medical service.”

**Advertisement of ethical drugs**

PMSB/IGD Notification No. 148, “Re the applicability of the Pharmaceutical Affairs Law to advertising of pharmaceuticals, etc.,” was issued by the Inspection and Guidance Division of the Pharmaceutical and Medical Safety Bureau on September 29, 1998, and with regard to what constitutes advertising of pharmaceuticals, etc., any activity which meets one of the following
criteria is judged to correspond to advertising under the Pharmaceutical Affairs Law.

- When the intention of inducing customers (whetting customers’ will to purchase) is clear.
- When the brand name of a specific pharmaceutical, etc., has been made clear.
- When it is a condition that can be recognized by ordinary people.

Accordingly, member companies must engage in information dissemination activities only after carefully examining these activities in light of whether the aforementioned criteria are met and whether these information dissemination activities on their part correspond to matters that are limited by the Pharmaceutical Affairs Law and the Standard for Adequate Advertisement of Pharmaceutical Products.

**Healthcare-related personnel**

In the Pharmaceutical Affairs Law and the Standards for Proper Drug Advertisements, the term “healthcare-related personnel” is a broader term than healthcare professionals. In the JPMA Code, healthcare-related personnel are interpreted as “including employees of wholesalers and medical/pharmaceutical students as well as healthcare professionals such as doctors, dentists, pharmacists and nurses”.

**Drug information**

Information exchanged between MRs and healthcare professionals is classified into general information and drug information.

General information refers to the information concerning the common sense of a member of society/employee of a company.

Drug information refers to the information concerning a medical/pharmaceutical area.

Medicinal compounds are allowed to be treated as drugs within the range of approval, and it is unlikely that explanations about indications, effects, dosage regimen deviate from the range of approval, etc.

Healthcare professionals may inquire about the information beyond the range of approval as exemplified by the data obtained for obtaining the approval of new indications. In this case, this type of information may be provided upon the request of healthcare professionals, although it cannot be used for promotion. It is also not permitted to encourage healthcare professionals to request such information from MRs.

It shall always be borne in mind that drug information must be evidence-based, impartial and objective to prevent the misleading of healthcare professionals.

**Proper use of drugs**

“Proper use of drugs” is defined as follows in the final report issued by the advisory board for the Director-general of Pharmaceutical Affairs Bureau, MHW, “Council for Desirable Way of Drugs toward the 21st Century” (May 1993): “Proper use of drugs refers to a cycle of determination of
the optimal pharmaceutical preparation, dosage form and dosage regimen for the condition of the patient based on correct diagnosis, dispensing the pharmaceutical preparation based on the decision, patient’s sufficient understanding of the pharmaceutical preparation, correct use, evaluation of the effects and ADRs and feedback about the prescription. Appropriate provision of drug information to healthcare professionals and patients and sufficient understanding is essential to ensure proper use. It is possible to achieve the purpose of a drug only when necessary information is supplied.”

Drugs can be harmful rather than effective under improper use and proper use is naturally indispensable for drugs. Since it is the healthcare professionals who use drugs, pharmaceutical companies must follow a series of basic procedures in a reliable manner for providing correct drug information to healthcare professionals, collect information on ADRs immediately and disseminate the results of assessment/analysis without delay to healthcare professionals to contribute to the proper use of drugs. Misleading healthcare professionals by providing biased information or unfair promotion of company products through activities violating the Fair Competition Code will surely result in improper use of drugs.

**Standard for Adequate Advertisement of Pharmaceutical Products**

PAB Notification No. 1339, “Re the Standard for Adequate Advertisement of Pharmaceutical Products,” was issued on October 9, 1980 by the Pharmaceutical Affairs Bureau. This Notification was issued in addition to the Pharmaceutical Affairs Law to provide guidance and control over the advertising of pharmaceuticals to prevent health damage from drugs by avoiding false or exaggerated claims and to ensure the appropriateness of the content. Accordingly, member companies are expected not only to comply with the Pharmaceutical Affairs Law but also to evince a thorough understanding of the content and tenor of this Notification when engaging in information dissemination activities.

**Ethical Criteria for Medicinal Drug Promotion provided by WHO**

Ethical Criteria for Medicinal Drug Promotion was adopted unanimously by 167 member nations in the WHO general assembly in 1988.

The main objective of ethical criteria for medicinal drug promotion is to “support and encourage the improvement of healthcare through the rational use of medicinal drugs”. Ethical criteria for drug promotion must “lay the foundation for proper behavior concerning the promotion of medicinal drugs” and “assist in judging if promotional practices related to medicinal drugs are in keeping with acceptable ethical standards.”

These criteria apply to both prescription and non-prescription medicinal drugs (over-the-counter drugs), and it is encouraged that they be adopted by governments, healthcare professionals, patients, consumer organization, educational organizations and the general public.
**Patient Organizations**

“Patient Organizations” refer to patient associations or patient support groups that are composed mainly of patients, their families, and supporters. They represent the voice of the patients with the goal of mutual support for patients and their families and improvement of the care environment; and in principle have the roles and objectives defined by their articles of incorporation and regulations.

**Collaboration with patient organizations**

Includes a broad range of activities extending from exchange with and support for patient organizations to activities aiming to resolve shared problems.

**Lecture meetings**

In the IFPMA Code, “events refer to all symposia, academic meetings and other promotional, scientific or professional meetings for healthcare professionals organized or sponsored by a company”. Lecture meetings in the Promotion Code correspond to these events. It is specified in the IFPMA Code that “companies must avoid using renowned or extravagant venues” for these events.

In the Promotion Code, “renowned venue” is interpreted as a “place well known by the general public for sightseeing or recreation rather than as a meeting site, when they first hear the name of the venue”, and “extravagant venue” is interpreted as a “place considered as a first impression by the general public to be extravagant for a meeting place”.

It is specified in the IFPMA Code that “refreshments and / or meals incidental to the event can be offered only when they are restrained and reasonable as judged by local standards”. It is also specified in principle that the refreshments and / or meals, as well as travel costs must not exceed the amount of money usually payable by participants.

In the Promotion Code, “restrained and reasonable” is interpreted as “the amount of money usually payable by healthcare professionals and considered as a first impression by the general public not to be extremely high”.

**Company code**

Pharmaceutical companies engaged in research & development, production, and supply of drugs as life-related products are required to have high ethical awareness. Pharmaceutical companies are required to have an attitude of self-rule based on their own ethics. The company code is the embodiment of self-rule. The company code may cover the principles of the JPMA Code, original management policies of the member company, original items and specific rules of the JPMA Code, but what is important is that the company code embodies “principles for the company’s exchange with healthcare providers and other stakeholders”.
**Post-marketing studies**

“Post-marketing studies” refer to those studies within the category of post-marketing surveillance, etc., that are conducted using the dosage, administration, and indications approved for the drug in question under Article 14 or Article 19, Section 2 of the Pharmaceutical Affairs Law, for the purpose of verifying the assumptions, etc., obtained by the marketing approval holder as a result of clinical trials or results of clinical experience investigations, or for the purpose of collecting information on quality, efficacy, and safety that cannot be obtained through routine clinical practice (definition given in Article 2, Section 4 of “Good Post-Marketing Study Practice (GPSP Ordinance)” (MHLW Ordinance No. 171, dated December 20, 2004).

**Social media**

“Social media” refer to media that are formed by bidirectional communication in which users, including individuals, transmit information, mainly over the Internet. Social media have the characteristic of enabling individuals to easily disseminate information to large, unspecified numbers of people, and they also have the characteristic of rapid dissemination of that information. For this reason, it is possible that, even if the information transmitted is false or otherwise of inappropriate content, it will be broadly disseminated without its accuracy being questioned. Accordingly, when social media are utilized for information dissemination activities, it is necessary to subject these activities to careful scrutiny, reviewing them in the light of the Pharmaceutical Affairs Law, Standard for Adequate Advertisement of Pharmaceutical Products, and “JPMA Promotion Code for Prescription Drugs,” to ensure that no untoward consequences are invited.

**Clinical trials**

“Clinical trials” refer to clinical studies that are conducted in connection with the manufacturing and marketing of pharmaceuticals or medical devices to obtain approval for them under the Pharmaceutical Affairs Law. In other words, they are studies whose purpose is to collect materials on the results of clinical studies that will be included among the materials that must be appended to applications submitted to the Minister of Health, Labour and Welfare to obtain approval to manufacture and market pharmaceuticals under Article 14, Section 3 of the Pharmaceutical Affairs Law (citation from Article 2, Section 16 of Pharmaceutical Affairs Law).

**Condolence payment**

In the JPMA Promotion Code, condolence payment is interpreted as condolence money for funerals. The acceptable amount of condolence money for funerals unlikely to affect the prescribing practice of healthcare professionals is usually considered to be about 10,000 yen.
Transparency
[Transparency of relationship with medical institutions, etc.]
The industry-academia collaboration activities between pharmaceutical companies and medical institutions, etc. are essential for the development of medicine and pharmacy, spread of proper use of drugs, etc. However, when such collaboration activities become more active, there will be more cases where medical institutions, healthcare professionals, etc. get deeply involved in specific companies and products, raising concerns that pharmaceutical companies may have some sort of influence on the judgment of medical institutions, healthcare professionals, etc. Since pharmaceutical companies are a life-related industry conducting its activities under the public health insurance system, based on the concept that transparency of its activities is more important in the pharmaceutical industry than in any other industries, the “Guidelines for Transparency for Relationship between Pharmaceutical Companies and Medical Institutions, etc.” were approved at the General Assembly of the JPMA in January 2011. As a result, member companies also formulated their own guidelines to improve transparency. It will be more important for member companies to comply with the related laws and regulations including the JPMA Code and conduct corporate activities that are ethical in the eyes of the general public.

[Transparency of clinical trial information]
In the IFPMA Code revised in 2012, transparency of clinical trial information was defined in “9. Clinical Studies and Transparency” based on both the “Joint Position on the Disclosure of Clinical Trial Information via Clinical Trial Registries and Databases (2009)” and “Joint Industry Position on the Publication of Clinical Trial Results in the Scientific Literature (2010)” issued by the IFPMA, European Federation of Pharmaceutical Industries and Associations (EFPIA), Japanese Pharmaceutical Manufacturers Association (JPMA) and Pharmaceutical Research and Manufacturers of America (PhRMA). The IFPMA Code also defines in “9. Clinical Studies and Transparency” that all studies including clinical studies and observation research conducted in human subjects, not limited to post-marketing surveillance, etc., must have a legitimate scientific purpose and must not be disguised as promotion. In addition, transparency, member companies of JPMA need to comply with the above two joint guidelines in their approach to transparency of clinical trials.

【Transparency of relationship with patient organizations】
In 2007, European Federation of Pharmaceutical Industries and Associations adopted the “EFPIA Code of Practice on relationships Between the Pharmaceutical Industry and Patient Organisations.” The revised 2012 version of the IFPMA Code also includes provisions that elucidate the nature of alliances with patient organizations under Section 11, “Interactions with Patient Organizations.” In order to respond to the needs and problems of the patients and their
families with understanding, JPMA member companies in Japan also have increasing opportunities to collaborate with patient organizations. At the same time, as the patient organizations’ powers of expression and influence over administrative authorities, etc., grow, it is increasingly important to ensure transparency through the disclosure of information on financial and other support provided to patient organizations by member companies, and to foster a broad understanding of the fact that those activities contribute to the activities of patient organizations while maintaining high ethical standards.

When working in collaboration with patient organizations, member companies of JPMA need to comply with the “Guidelines on Collaboration with Patient Organizations” established in January 2013 and the “Guidelines on Transparency of the Relationship between Corporate Activities and Patient Organizations,” established in March 2012.

**Non-clinical studies**

“Non-clinical studies” are almost synonymous with “pre-clinical studies,” and they include pharmacokinetic studies (ADME), pharmacological/effectiveness studies, and safety studies (toxicity studies). These are non-clinical studies conducted to elucidate the effects and toxicity of pharmaceuticals, etc. Their results must be in compliance with Article 43 of the Enforcement Regulations of the Pharmaceutical Affairs Law (Criteria for the Reliability of Application Materials). In particular, GLP (Good Laboratory Practice) standards are established for safety studies by the Ministry of Health, Labour and Welfare.

**Gifts**

The IFPMA Code specifies the gifts that can be provided as follows:

1. **Promotional Aids**: Promotional aids or reminder items may be provided or offered to healthcare professionals, provided the gift is of minimal value and minimum amount.

2. **Items of Medical Utility**: Items of medical utility may be offered or provided free of charge provided that such items are of modest value, do not cover the cost of daily business and are beneficial to the provision of medical services and for patient care according to the laws and regulations of each country.

In the JPMA Promotion Code:

1. “Of minimal value” is interpreted as “approximately 3,000 yen, which is the criteria shown for acceptable inexpensive gifts in the Fair Competition Code”.

2. “Of modest value” for items of medical utility is interpreted as “approximately 3,000 to 5,000 yen, which is the value considered modest even by patients and the general public” for gifts not related to company drugs based on the specifications/price criteria shown in the Fair Competition Code.
Promotion

In WHO’s Ethical Criteria for Medicinal Drug Promotion, promotion refers to “all informational and persuasive activities by manufacturers and distributors, the effect of which is to induce the prescription, supply, purchase and/or use of medicinal drugs.”

“To induce use” means “to convince someone to use”. Even if we can encourage the use of medicines, the reality is that we cannot create the demand. This is because the consumers are limited to the patients who need treatment, and sales promotion does not create patients. “To induce use” is acceptable only through supply of proper drug information because, without the supply of proper drug information, medicinal compounds cannot act as “drugs”. In other words, optimal prescription appropriate to the condition of the patient is unlikely to be achieved without the supply of proper drug information and accurate understanding by healthcare professionals. Misleading healthcare professionals by supplying biased information or unfair promotion of company products by offering cash and cash equivalents or gifts will impair optimal prescription and is not deemed as proper promotion.

“Promotion” in WHO’s Ethical Criteria for Medicinal Drug Promotion is based on the nature of drugs.

“Promotion” in the JPMA Promotion Code means the same as above and does not mean “sales promotion” as it has a unique meaning “that promotion derives from the nature of drugs”.

“All information” used in WHO’s Ethical Criteria for Medicinal Drug Promotion naturally includes information on ADRs judged from “rational use of medicinal drugs” in the objectives of the criteria.

In promotion, the supply of ADR-related information and understanding by healthcare professionals will contribute to proper use. Such a trustful use of drugs will eventually reinforce trust in drug and pharmaceutical companies.

Although there is no specific description about the relation between the promotion and collection of ADR-related information in WHO’s Ethical Criteria for Medicinal Drug Promotion, promotion refers to, in the JPMA Promotion Code, “pharmaceutical companies’ provision / collection / dissemination of drug information to healthcare professionals to contribute to proper use and dissemination of drugs” since collection of ADR-related information is a series of activities that will result in communication based on the analysis/evaluation of the results.

In the IFPMA Code, promotion means “any activity undertaken, organized or sponsored by a member company which is directed at healthcare professionals to promote the prescription, recommendation, supply, administration or consumption of its pharmaceutical product(s) through all means for transmitting information, including the Internet.”

Pharmaceutical Affairs Law

The Pharmaceutical Affairs Law was enacted for the purpose of promoting the improvement of health and sanitation by establishing the regulations necessary to ensure the quality, efficacy, and
safety of pharmaceuticals, quasi-drugs, cosmetics, and medical devices while at the same time establishing measures for the regulation of designated drugs as well as measures necessary for the promotion of research and development of pharmaceuticals and medical devices for which there is an especially high level of medical need.

When disseminating information, member companies are expected to comply with the provisions of the Pharmaceutical Affairs Law, particularly those parts of Article 8, “Advertisement of pharmaceuticals, etc.,” that pertain to “exaggerated advertising, etc.,” “limitations on advertising of drugs for designated diseases,” and “bans on advertising of pharmaceuticals, etc., that have not yet been approved.”

Clinical research / epidemiological research
The main objectives of clinical research are to improve methods of preventing, diagnosing, and treating diseases in medical care; to further understand the causes and pathology of diseases; and to improve quality of life for patients. Even the methods of prevention, diagnosis, and treatment that are currently recognized as best in care must ceaselessly be re-verified through clinical research on their efficacy, efficiency, convenience, and quality. Moreover, advances in medical care must ultimately depend upon clinical research.

In clinical research, consideration for the welfare of the study participants must take precedence over scientific or social benefits.

Epidemiological research is scientific research that surveys the frequency and distribution of diseases and other health-related events and elucidates the causal factors behind them. Epidemiological research is indispensable to exploration of the causes of disease, verification of the efficacy of methods of prevention and treatment, and clarification of the relationship between the environment or lifestyle and health, and it plays a major role in the development of medical science and the maintenance and improvement of citizens’ health.

In epidemiological research, there is handling of specific information on the physical and emotional state of the many research subjects, as well as on the environments that surround them, their lifestyle habits, etc. Moreover, epidemiological research has the characteristic of involving many kinds of personnel other than physicians in the research.

Ethical guidelines
In order to ensure that clinical research and epidemiological research (hereinafter referred to as “research”) are conducted in an ethical, scientific manner, the following guidelines were issued: “Ethical guidelines on clinical research” (Notification No. 415 of the Ministry of Health, Labour and Welfare, dated July 31, 2008) and “Ethical guidelines on epidemiological research” (Joint Notification No. 2 of the Ministry of Education and the Ministry of Health, Labour and Welfare, 2002).
IFPMA (International Federation of Pharmaceutical Manufacturers & Associations, Geneva, Switzerland) is a non-profit non-governmental organization established in 1968 representing industry organizations and research-oriented global pharmaceutical companies from about sixty developing and industrialized nations in the world. The JPMA acts as one of the key members of the IFPMA.

The IFPMA Code of Practice sets out standards for the ethical promotion of pharmaceutical products to healthcare professionals to ensure that member companies’ interactions with healthcare professionals are appropriate and perceived as such. The IFPMA requests all member associations and companies, and companies under the member associations, to comply with the IFPMA Code.

The IFPMA Code of Practice
(IFPMA Code of Practice)
The IFPMA Code of Practice (IFPMA Code) was enacted in 1981 and underwent some revisions. The present code was approved in 2012. In the revision in 2012, because not only the healthcare professionals but also the stakeholders such as medical institutions and patient organizations were targeted, the name of the code was changed from “IFPMA Code of Pharmaceutical Marketing Practice” to “IFPMA Code of Practice”. The IFPMA acknowledges the role of Ethical Criteria for Medicinal Drug Promotion provided by the World Health Organization (WHO) and the role of relevant codes of ethics developed by the World Medical Association, International Council of Nurses and the International Federation of Pharmacists. The IFPMA Code sets forth standards for the ethical promotion of pharmaceutical products to healthcare professionals and other stakeholders, and for member companies’ interactions with them.

It is a requirement of IFPMA membership that member companies of IFPMA member associations (e.g. member companies of JPMA) and IFPMA member companies must comply with ethical standards set forth in the IFPMA Code and that IFPMA member associations, subject to local laws and regulations, adopt codes that meet local requirements but are consistent with, and as comprehensive as, the IFPMA Code.

IFPMA member companies must comply directly with applicable national codes of member associations where such codes exist. In all other territories, i.e. where there are no local codes or appropriate laws and regulations, or where a member company is not a member of local/regional association, the IFPMA Code acts as a default code for the activities of member companies and the IFPMA operating procedures apply.

Medical Representatives (MRs)
In Article 2-4 of GVP Ordinance, MRs are defined as “persons who meet healthcare professionals to mainly collect and supply safety control information to contribute to proper use of drugs.”
MRs are defined by the Educational and Training Guidelines of MR Certification Center of Japan, a public interest incorporated foundation, as “persons who meet healthcare professionals representing companies to mainly provide, collect, and disseminate information on the quality/efficacy/safety of drugs for the purpose of promoting proper use and dissemination of drugs”.

MRs are positioned in the same manner in the Promotion Code. Judged from the significance of the roles, the action standards of MRs are specified in the JPMA Promotion Code.

WHO
(World Health Organization)
The WHO (World Health Organization: Geneva, Switzerland) was established in 1946 as one of the UN special agencies in charge of public health representing about 190 nations in the world. WHO acts to provide a high level of health to people in the world and is operated by the general assembly, board of directors and secretariat. Japan has been a member of WHO since 1951.
Part 4
Application and Management

1. The decision of the General Assembly of JPMA shall be necessary for revision or abolition of the JPMA Code.
2. The JPMA Code shall be managed by the Code Committee. However, important matters shall be reported to the Chairperson of JPMA.
3. With the exception of the procedures provided for by Part 2, items necessary to the application of the JPMA Code and the processing of complaints, etc., shall be prescribed separately.
4. Apart from those stipulated in the JPMA Code, items necessary for the organization and steering of the Code Committee shall be prescribed separately.

Supplementary Provisions
1. The JPMA Code shall be enforced effective April 1, 2013.
2. “JPMA Promotion Code for Prescription Drugs” (established on March 24, 1993) shall be abolished.