JPMA Code of Practice

(Established on January 16, 2013)

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Japan Pharmaceutical Manufacturers Association (JPMA)

[Preamble]

The Japan Pharmaceutical Manufacturers Association (JPMA) was established in 1968 as an organization of R&D-based pharmaceutical companies. The member companies of JPMA consider it their mission to contribute to improvements in the health and welfare of people in Japan and throughout the world through the development of safer, innovative, and highly useful pharmaceuticals. To support appropriate medical care that is ethical and patient-oriented, JPMA calls upon member companies to build mutual relationships of trust with researchers, healthcare professionals, and patient organizations through appropriate industry-academia collaborations.

1. History of JPMA's Efforts

To avoid inappropriate inducements of prescription in promotional activities for prescription drugs, JPMA drew up its "Code of Practices for Promotion of Ethical Drugs" in 1976. In 1981, against the backdrop of heightening social concerns over the proper use of drugs, the International Federation of Pharmaceutical Manufacturers & Associations (IFPMA) perceived the establishment and implementation of a code governing promotional activities to be an important international requirement, and it established the "IFPMA Code of Pharmaceutical Marketing Practice," a code of standards for pharmaceutical companies in countries throughout the world. Then, in 1988, the World Health Organization (WHO) established its "Ethical Criteria for Medicinal Drug Promotion" (hereinafter referred to as the "WHO Ethical Criteria") to support and encourage the improvement of medical care through the rational use of drugs. IFPMA responded to this by extensively revising the IFPMA Code of Pharmaceutical Marketing Practice the same year, and it made compliance with this code a requirement for IFPMA membership. JPMA, while striving for consistency with this code as a member of IFPMA, established the "JPMA Promotion Code for Prescription Drugs" in 1993 based on a consensus among its member companies. This promotion code is grounded in the spirit of the Federation of Pharmaceutical Manufacturers' Associations of Japan (FPMAJ) "Code of Ethical Practice for Pharmaceutical Companies," and it establishes the proper nature of prescription drug promotion and the standards of conduct with which pharmaceutical companies in Japan are required to comply. This code has subsequently been revised a number of times to reflect changes in the law, etc.

Moreover, in order to ensure a high degree of ethicality throughout all corporate activities of pharmaceutical companies, the "JPMA Charter of Corporate Behavior" was drawn up in November 1997 as a set of self-regulations for member companies. In April 2001, the "JPMA Compliance Program Guidelines" were issued to promote more thorough legal compliance on the part of member companies. They were then revised in March 2011 to reflect the changing times. Thereafter, based on the revision of the "Charter of Corporate Behavior" by Keidanren (Japan Business Federation) in October 2017, the "JPMA Charter of Corporate Behavior" and the "JPMA Compliance Program Guidelines" were revised in October 2018. Moreover, the "JPMA Compliance Program Guidelines" were revised in March 2023 based on the promotion of work-style reform and revision of the laws affecting corporate activities, such as the Act on the Protection of Personal Information and the Whistleblower Protection Act.

In March 2012, IFPMA announced its "IFPMA Code of Practice" (hereinafter referred to as the "IFPMA Code") that covered not only marketing activities but also exchanges with healthcare professionals, medical institutions, and patient organizations, as well as the promotion of pharmaceuticals. This replaced the existing "IFPMA Code of Pharmaceutical Marketing Practices." In line with the tenor of this revision of the IFPMA Code, JPMA established its "JPMA Code of Practice" (hereinafter referred to as the "JPMA Code" or the "Code") in January 2013 to expand upon the existing Promotion Code for Prescription Drugs while governing the exchange between all executives and employees of the member companies and researchers, healthcare professionals, and patient organizations. This JPMA Code has been enforced since April of the same year and was revised in May 2017, and the revision took effect in October 2017. Moreover, following the revision of the IFPMA Code in June 2018, the JPMA Code was revised in November 2018 and has been enforced since January 2019.

In addition, to ensure that pharmaceutical companies fulfill their responsibilities regarding information disclosure and accountability for payments to healthcare professionals and medical institutions from the standpoint of conflicts of interest, etc., JPMA established the "Transparency Guideline for the Relation between Corporate Activities and Medical Institutions" (hereinafter referred to as the "Medical Institutions Transparency Guidelines") in January 2011 and has continued to revise it as needed. In accordance with their own guiding principles based on the Medical Institutions Transparency Guidelines, the member companies have been publicly disclosing such information since fiscal year 2013 with the consent of healthcare professionals, medical institutions, etc. Similarly, with respect to relationships with patient organizations, the "Transparency Guideline for the Relationship between Corporate Activities and Patient Organizations" (hereinafter referred to as the "Patient Organization Transparency Guidelines") were established in March 2012, and such information has been publicly disclosed since fiscal year 2014.7

In addition, in September 2018, the Ministry of Health, Labour and Welfare notified its "Guidelines for Provision of Sales Information on Prescription Drugs" (hereinafter referred to as the "Guidelines for Provision of Sales Information"), which aim to improve environmental health by regulating advertising and activities similar to advertising in the provision of sales information on prescription drugs. Their partial application started in April 2019 and complete application began in October of the same year. As a response to the notification on the Guidelines for Provision of Sales Information, JPMA revised the JPMA Code in September 2019 and enforced in October 2019.

To ensure consistency with the abovementioned IFPMA Code and the Guidelines for Provision of Sales Information, we have decided to revise the JPMA Code by reviewing the definition of "promotion" stipulated therein and improving the descriptions to eliminate the duplication of provisions in the JPMA Code.

2. Ethics of Pharmaceutical Companies

In general, competition among corporations has a natural tendency to heat up to an immoderate extent, and we cannot deny that this kind of conduct existed in drug promotion in the past. For this reason, numerous laws, ordinances and industry self-regulations have been established today, beginning with the "Act on Securing Quality, Efficacy and Safety of Products Including Pharmaceuticals and Medical Devices" (hereinafter referred to as the "Pharmaceuticals and Medical Devices Act") and the "Re-revision of the Standard for Adequate Advertisement of Pharmaceutical Products" (PSEHB Notification No. 0929-4, dated September 29, 2017; hereinafter referred to as the "Standard for Adequate Advertisement of Pharmaceutical Products"), the Guidelines for Provision of Sales Information, the "Fair Competition Code Concerning Restriction on Premium Offers in Ethical Pharmaceutical Drugs Marketing Industry" (hereinafter referred to as the "Fair Competition Code"), "Guideline for Preparation of Product Overview for Prescription Drug" (hereinafter referred to as the "Guideline for Product Overview Preparation"), and "Guidelines for the Certification of MRs." As is generally known, drugs have the following characteristics.

(1) We cannot know the nature of a drug by its appearance.
(2) Drugs have both effects and side effects, the occurrence of which differs from patient to patient.
(3) Thus, drugs that are not accompanied by correct drug information cannot truly function as medicine.
(4) Patients who require treatment are the only consumers.

It is because drugs have these characteristics that the numerous laws, ordinances and industry self-regulations mentioned above are necessary.

At the same time, the environment surrounding pharmaceutical companies is becoming more diverse and complicated, and events that cannot be fully addressed by the philosophies and methods of the past are occurring one after another. In addition, society is calling on pharmaceutical companies to bring greater fairness and transparency to their relationships with healthcare professionals. Under these conditions, disregard for the special nature of drugs could inflict significant damage on patients and the society, paving the way for health hazards or unnecessary use of drugs. It is clear that this would have dire consequences for the companies themselves, which would suffer a self-inflicted loss of credibility, extending to their products, the entire pharmaceutical industry, and the society at large. Needless to say, companies have nothing to gain – but much to

lose – from such activities. Therefore, rather than seeing these laws, ordinances and industry self-regulations as "things with which we have to comply," member companies need to perceive them as "reflections of the society's expectations for pharmaceutical companies" and adopt a broader perspective to understand and own these regulations in the context of their social background and the purpose for which they are established.

It is easy to understand that corporate activities based on this sense of ethics establish a priceless foundation in the form of "public trust" towards drugs and pharmaceutical companies. This becomes even more evident if you examine pharmaceutical companies from the vantage point of an individual patient or a member of society. As a member of a community (be it a family, workplace, or region), everyone has a role that he or she is naturally expected to play. Society works on the assumption that each member performs a certain anticipated role. Any society will crumble if this premise does not hold.

The same applies to companies. When we look at this from the standpoint of drugs, it is clear that members of the society assume that high-quality drugs are being used properly when they receive healthcare, irrespective of whether or not there are laws, ordinances and industry self-regulations in place. This is why it is particularly important for the pharmaceutical industry to perceive "corporate social responsibility" (CSR) as an important mission.

The character "rin" used as the first component of the Japanese word "rinri" (meaning "ethics") signifies our mutual expectations with regard to human and social relationships. This means that member companies are called upon to not only comply with laws, ordinances and industry self-regulations but also adopt the stance of proactively responding to the society's demands and expectations.

3. Basic Principles

Advances in medical and pharmaceutical science and improvements in public health depend on information-sharing interactions between the entire medical community, which comprises researchers, healthcare professionals, patients, wholesalers, and JPMA member companies. Integrity is essential to these interactions, and there must be confidence that decisions are made ethically and in the best interests of patients.

JPMA sets forth the basic principles of corporate behavior in the JPMA Code to ensure appropriate interactions between the member companies and external stakeholders (hereinafter referred to as "stakeholders").

The JPMA Code helps member companies accomplish their mission of making great contributions to public health in Japan and throughout the world while complying with a code of conduct based on high ethical standards. The Code's standards of behavior apply to all interactions between member companies and stakeholders.

JPMA's member companies bear the responsibility to perform their corporate activities with high ethicality and transparency. They are called upon to foster awareness of the JPMA Code throughout society, beginning with researchers, healthcare professionals, patients, and wholesalers, and to promote activities based on the Code. Each member company needs to establish its own "in-house code" that reflects the spirit of the JPMA Code but lends more concreteness and specificity to the requirements through the addition of elements of its own management philosophy and other unique provisions.

Moreover, the criterion for judgment of the member companies' own conduct must always be whether that conduct conforms to the spirit of the JPMA Code, regardless of whether the conduct in question is concretely described in 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.

Composition of the JPMA Code

The composition of the JPMA Code is as follows.

- Preamble, 1. History of JPMA's Efforts, 2. Ethics of Pharmaceutical Companies, 3. Basic Principles
- I-1. Code of Practice
- I-2. Promotion Code for Prescription Drugs
- II-1. Commentary on the Code of Practice
- II-2. Commentary on the Promotion Code for Prescription Drugs
- III. Definitions and Commentary on Terms

I-1. Code of Practice

In keeping with the provisions of the "3. Basic Principles" of the Preamble of the JPMA Code and in view of the fact that member companies engage in their corporate activities as members of the life sciences industry, which operates under the public medical insurance system, the member companies shall conform to not only the Pharmaceuticals and Medical Devices Act, related laws and regulations, the "Standard for Adequate Advertisement of Pharmaceutical Products," and the "Guidelines for Provision of Sales Information," but also the industry self-regulations set forth in the "Fair Competition Code," the "Code of Practice for Pharmaceutical Industry," the "JPMA Charter of Corporate Behavior," the "JPMA Compliance Program Guidelines," etc., as well as maintain high ethical standards in all their conduct.

1. Scope and Definition of Promotion

1.1 Scope

The JPMA Code applies not only to the promotion of prescription drugs but to all interactions among member companies and researchers, healthcare professionals, medical institutions, patient organizations, and wholesalers, etc. Based on the JPMA Code, member companies shall establish their own in-house codes governing all executives and employees, and while complying with the JPMA Code and their in-house code, they shall also respect the IFPMA Code, the code of the organization with which JPMA has signed up as a member. Moreover, the criterion for judgment of the member companies' own conduct must always be whether or not the 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.

1.2 Definition of Promotion

The word "promotion" as it is used here means "to engage with healthcare professionals in the provision, collection, and communication of pharmaceutical product information for promoting the proper use and broader adoption of prescription drugs based on those interactions." This includes all activities implemented by member companies that may influence the prescribing decisions of healthcare professionals.

2. Responsibility of Top Management

The top management of the member companies shall execute the following.

(1) With the awareness that acting in accordance with the "Basic Principles" is their own role, top-level managers shall set an example by implementing the provisions of the JPMA Code and making them known to all as they strive to maintain and improve the internal organization. Top-level managers shall perceive the conduct of all executives and employees to be their own responsibility.

(2) When circumstances arise that run counter to the spirit of the JPMA Code, top-level managers shall take responsibility for resolving the problems, investigate and identify the cause, and take measures to prevent recurrence.

(3) Even in departments that are in charge of matters other than pharmaceutical products, top management shall observe the spirit of the JPMA Code in conducting corporate activities.

(4) Subsidiaries that manufacture and sell drugs in Japan shall also be required to comply with the JPMA Code.

(5) Member companies shall demonstrate their compliance with the JPMA Code to parent companies, affiliates, and subsidiaries that manufacture and market pharmaceuticals, whether in Japan or overseas, and seek their understanding of the Code.

3. Fundamentals of Interaction

3.1 Fundamentals of Interaction

Advances in medical and pharmaceutical sciences and improvements in public health depend on information-sharing interactions among the entire medical community, which comprises researchers, healthcare professionals, patients, wholesalers, and JPMA member companies, and integrity is essential for these exchanges. The society relies upon pharmaceutical companies to make decisions ethically and in the best interests of patients when engaging in such interactions, and member companies must always conduct themselves in such a manner that the government, healthcare professionals, and patients trust them to engage in ethical activities at all times.

3.2 Transparency of Interactions

Pharmaceutical companies are called upon to maintain a high sense of ethics as life sciences companies, and JPMA member companies shall be accountable for interactions with researchers and healthcare professionals and ensure that collaboration with patient organizations is conducted ethically and in good faith. Member companies shall maintain transparency in their corporate activities and properly discharge their accountability to the society in accordance with their own guiding principles based on the Medical Institutions Transparency Guidelines, Guidelines on Collaboration with Patient Organizations (hereinafter, "Patient Organization Collaboration Guidelines"), and the Patient Organization Transparency Guidelines.

4. Interactions with Healthcare Professionals

In interactions with healthcare professionals, member companies shall give the highest priority to being of benefit to patients and contributing to the health and welfare of patients. With the goal of contributing to the development of medical and pharmaceutical science and the improvement of public health, member companies' interactions shall focus on the provision of drug information, academic exchange on medical and pharmaceutical science, and support for research. When promoting industry-academia collaboration to further the development of medical and pharmaceutical science, member companies shall make efforts to build relationships of trust with researchers, healthcare professionals, and patient organizations while at the same time avoiding activities that could exert an inappropriate influence upon prescribing decisions.

5. Prohibition on Preapproval Information Provision and Recommendation of Off-Label Uses

Member companies shall not engage in promotion until approval for the drug is received in Japan. They shall also refrain from endorsing off-label uses.

6. Information Dissemination Activities

As life sciences companies, JPMA member companies shall provide scientific and objective information on drugs as needed. When providing information, they shall strive to make the content and mode of expression easy for users to understand, while complying with the laws, ordinances, and self-regulations.

Advertisement of prescription drugs to the general public other than healthcare-related personnel is prohibited by the Pharmaceuticals and Medical Devices Act and the Standard for Adequate Advertisement of Pharmaceutical Products. This applies to information disseminated through press releases, disease education activities targeting the general public and patients, and provision of information to investors. This scrutiny is necessary so that there will be no suspicion that such type of information dissemination constitutes the advertisement of prescription drugs or recommendations of unapproved drugs or off-label uses. Rules governing the dissemination of information to healthcare professionals are set forth in I-2. Promotion Code for Prescription Drugs

6.1 Promotional Materials (Including Digital Media)

Member companies shall prepare promotional materials (including digital media; hereinafter referred to as "promotional materials") in accordance with the related laws and self-regulations such as the Guideline for Product Overview Preparation.

6.2 Social Media

Member companies shall bear all responsibility for content when utilizing digital communication via social media, etc. Accordingly, compliance with the in-house code must first be confirmed with related subsidiaries, parent companies, affiliates, planning companies, agencies, employees, etc.

7. Holding of Seminars and Meetings

Member companies can hold seminars for the purpose of providing information on medical and pharmaceutical science, as well as disease education information, etc. Moreover, member companies can hold meetings, etc., of healthcare professionals and others to obtain useful expert knowledge for their activities. When holding a seminar, meeting, etc., of healthcare professionals and others, member companies shall comply with the related laws and ordinances, the Fair Competition Code, and I-2 Promotion Code for Prescription Drugs.

8. Fee for Services

Member companies may engage researchers, healthcare professionals, medical institutions, patient organizations, etc., for service arrangements such as research, clinical studies, post-marketing surveys, consultant and advisories, participation in the planning of meetings, chairing or lecturing at seminars, and training instructor duties, where such participation involves fees such as compensation. However, when making such arrangements for these services, member companies must enter into a written agreement that fulfills all of the following criteria.

(1) A written agreement must be made to specify the purpose of the service to be provided and the basis for payment of those services.
(2) A legitimate need for the services must be clearly identified in advance.
(3) The service providers must be directly related to the identified need and must have the expertise necessary to provide the service.
(4) The number of people to be contracted must be reasonable to meet the specified need.
(5) The hiring must not be an inducement to prescribe, purchase, or recommend any specific drug.
(6) The compensation for the services is reasonable, reflects the fair value of the services provided, and is commensurate with the fair market value.

In addition, when making service arrangements, internal rules, etc., of the service provider shall be respected; the related laws and ordinances and the Fair Competition Code shall be complied with; and the compensation, expenses, etc., associated with the service arrangements shall be disclosed appropriately in accordance with the company's guidelines based on the Medical Institutions Transparency Guidelines and the Patient Organization Transparency Guidelines.

9. Provision of Gifts, Cash, or Cash Equivalents

Member companies shall not directly or indirectly provide researchers, healthcare professionals, medical institutions, patient organizations, wholesalers, and stakeholders with the following gifts, cash, or cash equivalents.

(1) Gifts, cash, or cash equivalents that could exert inappropriate influence upon decision-making (including those that may affect the proper use of drugs)
(2) Gifts that undermine the dignity of pharmaceutical products
(3) Gifts, cash, or cash equivalents that are unlikely to meet with social understanding and acceptance

10. Implementation of Study and Research Activities, as well as Post-Marketing Safety Management Operations and Post-Marketing Surveillance

10.1 Studies and Research Activities

At every phase, studies and research activities involved in epidemiological research, non-clinical studies, clinical research/clinical studies (clinical trials and post-marketing studies), etc., must have highly ethical and appropriate scientific objectives that conform to the laws and ethical guidelines. Moreover, information on R&D expenditures and public research subsidies shall be subject to disclosure under the “Medical Institutions Transparency Guidelines,” and member companies shall bear appropriate accountability in accordance with the Guidelines.

To ensure transparency of information on clinical studies, member companies shall publicly disclose clinical study information in conformity with the “Joint Position on the Disclosure of Clinical Trial Information via Clinical Trial Registries and Databases” (revised in 2018) and “Joint Position on the Publication of Clinical Trial Results in the Scientific Literature” (revised in 2017), which were jointly issued by JPMA, IFPMA, European Federation of Pharmaceutical Industries and Associations (EFPIA), and Pharmaceutical Research and Manufacturers of America (PhRMA).

Additionally, to minimize harm from adverse reactions to pharmaceuticals, member companies shall make efforts to develop safer, more effective drugs while promoting appropriate voluntary self-controls on the use of laboratory animals in drug development from the standpoint of animal welfare so that the R&D will be further improved.

10.2 Post-Marketing Safety Management Operations and Post-Marketing Surveillance

Member companies need to have a proper understanding of the objectives behind the establishment of proper methods of use for post-launch drugs. Post-marketing safety management operations and post-marketing surveillance must be based on scientific evidence and conducted in compliance with laws, ordinances, and self-regulations. These activities should never be used as tools of sales promotion.

11. Collaboration with Patient Organizations

In all types of collaboration with patient organizations, member companies shall maintain a strong sense of ethics, act with integrity, and respect the independence of the patient organizations. Moreover, they shall strive to promote sufficient mutual understanding of the objectives and content of the collaboration with the patient organizations. Therefore, member companies that are collaborating with patient organizations shall establish guiding principles for their own companies by referring to the "Patient Organization Collaboration Guidelines" and implement them faithfully.

A member company providing financial or other support to a patient organization shall make its involvement known to the public to foster a broad understanding of the fact that this support contributes to the activities and development of the patient organization while securing high ethical standards. For that purpose, the member company shall establish its own guiding principles based on the "Patient Organization Transparency Guidelines" and make the information public.

The member company shall ensure transparency of the activity items, funding, etc., in collaboration with patient organizations, by securing a written agreement or consent for the objectives and content of the support before collaboration, as well as by retaining records.

12. Relationship with Wholesalers

The relationship between pharmaceutical companies and wholesalers must be a fair business relationship that complies with the Act on Prohibition of Private Monopolization and Maintenance of Fair Trade (hereinafter referred to as the "Antimonopoly Law") and other laws, ordinances, and self-regulations. Moreover, since this relationship is expected to ensure a greater degree of ethicality and transparency than similar relationships in other industries because its transactions take place under the public medical insurance system, the member companies shall establish and conform to their own standards in cases where cash, goods, food and drink, or the like is offered to wholesalers or accepted from them.

13. Internal Procedures and Education

Member companies shall establish and maintain appropriate internal procedures in order to comply with the related laws and ordinances and the JPMA Code, and all executives and employees must be required to undergo education appropriate to their role.

14. Inquiries, Complaints, and Actions

When there has been an inquiry or complaint about the JPMA Code, or when a code violation is suspected, the Code Compliance Committee shall respond according to the separately established "Procedures for Inquiries and Complaints Related to the Code." When the JPMA Code is judged to have been breached, the Code Compliance Committee shall take action against the offending member company, requiring it to make voluntary improvements in accordance with the separately established "Rules for Handling Breaches of the JPMA Code of Practice."

15. Activities Outside Japan

15.1 Standards Applied to Activities Outside Japan

Even in activities that take place overseas, member companies shall respect the JPMA Code while conforming with the related laws and ordinances of the relevant country, in addition to whatever pharmaceutical organization codes exist within the relevant country, or to the IFPMA Code in the absence of such codes.

15.2 Provision of Information on Drugs Overseas

Member companies shall, when providing medical information to overseas healthcare professionals, provide globally consistent information, whether directly or indirectly through local agents, etc. On this occasion, in addition to the laws and ordinances of the relevant country, if there is a code of a pharmaceutical industry in the relevant country, such code shall be followed; if there is no such code, the IFPMA Code shall be followed.

15.3 Handling of Japanese Healthcare Professionals Overseas and Foreign Healthcare Professionals in Japan

Member companies shall also comply with the JPMA Code when handling Japanese healthcare professionals participating in seminars or scientific meetings overseas. When member companies invite healthcare professionals from overseas to seminars, etc., held in Japan, they shall comply with the laws and ordinances of the relevant country, in addition to the code of the pharmaceutical industry in the relevant country—or, if no such local code exists, to the IFPMA Code.

15.4 Overseas Subsidiary Companies, Licensees and Agencies

When an overseas subsidiary of a member company conducts activities in the relevant country, the member company shall ensure that the overseas subsidiary adheres to the laws and ordinances of the relevant country, in addition to any pharmaceutical organization codes existing within the relevant country, or to the IFPMA Code in the absence of such codes. When a member company has an overseas licensee or agency conduct activities in the relevant country based on a licensing or agency agreement, the member company shall ensure that the overseas licensee or agency adheres to the laws and ordinances of the relevant country, in addition to any pharmaceutical organization codes existing within the relevant country, or to the IFPMA Code in the absence of such codes.

16. Committee in Charge of the Guidelines for Provision of Sales Information

The Code Compliance Committee, as the JPMA committee in charge of the Guidelines for Provision of Sales Information, will cooperate with the related committees to assist member companies in complying with the guidelines.

17. Revision, Abolition and Management of Code

17.1 The decision of the General Assembly of JPMA shall be necessary for revision and abolition of the main body of the JPMA Code.

17.2 The management of the JPMA Code shall be performed by the Code Compliance Committee established within JPMA. However, important matters shall be reported to the President of JPMA.

17.3 Apart from those stipulated in the JPMA Code, items necessary for the organization and steering of the Code Compliance Committee shall be prescribed separately.

I-2. Promotion Code for Prescription Drugs

The “JPMA Promotion Code for Prescription Drugs” (hereinafter referred to as the “Promotion Code”) stipulates the responsibilities and fundamentals of promotional activities by all pharmaceutical companies when conducting promotional activities for prescription drugs, and it mandates that all executives and employees of member companies of the JPMA conduct their drug promotional activities in strict compliance therewith. The word “promotion” means “to engage with healthcare professionals in the provision, collection, and communication of pharmaceutical product information for promoting the proper use and adoption of prescription drugs based on those interactions.” Member companies must always judge whether their activities are in accordance with the spirit of the Promotion Code, regardless of whether or not the Promotion Code contains concrete stipulations or descriptions that are relevant to the activities. Any and all violations of or deviations from the respective laws and ordinances and acts that infringe upon the Standard for Adequate Advertisement of Pharmaceutical Products, the Guidelines for Provision of Sales Information, and the industry's self-regulations for 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.

1. Responsibilities of Member Companies in Promotional Activities

Member companies shall assume the responsibility for their promotional activities. In thorough recognition of this principle, member companies shall be required to establish an in-house system to conduct appropriate promotional activities and ensure that all executives and employees comply with it without exception.

Although the Promotion Code obviously applies to promotional activities, it similarly applies to other activities that are regarded as promotion, irrespective of the name or any position of the organization that performs those activities.

(1) Continuously provide executives and employees with the necessary training and education to support the proper use and adoption of drugs.
(2) Ensure that the evaluation/remuneration system for executives and employees and others is not an inducement to unethical acts.
(3) Establish the internal systems necessary to comply with laws, ordinances, and self-regulations.

2. Fundamentals of Promotional Activities

In promotional activities conducted by their executives and employees, member companies must be fully aware of both their social mission as persons who play a role in healthcare and their positions as executives and employees who provide drug information as representatives of their companies. They are called upon to perform the following duties in a sincere and honest manner:

(1) Member companies shall not engage in promotion until approval for the drug is received in Japan. They shall also not endorse off-label uses.
(2) Not only have the knowledge of the content of the digitized package inserts and risk management plans (hereinafter referred to as “RMP”), etc., for drugs sold by their companies, but also strive to acquire familiarity with the medical and pharmaceutical science on which that information is based, as well as cultivate the ability to present such information correctly.
(3) Conduct promotional activities according to the rules and methods established by their companies.
(4) Provide information on indications, dosage and administration, etc., in a fair and balanced manner in terms of efficacy and safety within the range approved as a drug and in a proper manner based on the most up-to-date scientific data.
(5) Collect and disseminate drug information as accurately and promptly as possible.
(6) Member companies shall not slander and/or defame competitors or competitors’ drugs.
(7) Maintain discipline when visiting a medical institution and abide by the rules of the institution.
(8) Strictly abide by laws and ordinances and self-regulations and behave sensibly.

3. Production and Use of Promotional Materials, Etc.

In recognition of the fact that brochures, advertisements in medical journals, websites targeting healthcare professionals, audiovisual materials such as slides and videos, 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 Pharmaceuticals and

Medical Devices Act, administrative notifications, and relevant self-regulations such as the Guideline for Product Overview Preparation. The statements contained therein shall be correct, fair, objective, and based on scientific data.

Member companies shall appoint a person responsible for the management of prescription drug brochures, etc., and establish an in-house oversight system so that only promotional materials that have passed through a review are used.

4. Holding of Seminars and Meetings

Seminars held by member companies for providing medical/pharmaceutical information, disease awareness information, etc., to healthcare professionals shall be held on their own responsibility, and they shall provide specialized academic and scientific information. Appropriate locales and venues for holding seminars and study meetings shall be selected depending on the purpose, and in principle they shall be within Japan. If food and drinks are offered in association with a seminar, they shall not be extravagant and not damage the dignity of pharmaceutical companies. Payments in cash or cash equivalents that are made in connection with holding a seminar shall be limited to travel expenses (transportation expenses, accommodation expenses, etc.) and compensation such as honoraria for the lecturer, and the compensation shall be within the range appropriate and reasonable to the value of service. Individuals accompanying the lecturer shall not receive travel expenses or participate in the social-gathering event.

When providing premiums, etc., member companies shall comply with the Fair Competition Code.

In planning seminars for providing disease awareness information to ordinary consumers who are not healthcare-related personnel, special consideration shall be given to the Pharmaceuticals and Medical Devices Act and the Standard for Adequate Advertisement of Pharmaceutical Products.

Member companies shall not use meetings as a vehicle for promotion, for example, when holding an advisory conference that invites healthcare professionals and others or a meeting for clinical trials, etc., to obtain useful expert knowledge for their activities such as advisory at the time of formulating strategies for products.

5. Supply and Management of Samples

Samples are a means of providing drug information. There are two types of samples: “product samples,” which healthcare professionals can use to confirm the external characteristics of prescription drugs, and “trial-use samples,” which physicians can use to confirm and evaluate the quality, efficacy, safety, and other pharmaceutical particulars of a drug before using it in clinical practice.

Whichever type of sample is provided, it must be accompanied by the relevant prescription drug information, and only the minimum necessary amount should be provided.

In particular, since “trial-use samples” are used in actual clinical practice, a strict system of management shall be constructed and appropriately implemented.

6. Relationship to the Fair Competition Code

Member companies shall more proactively and rigorously comply with the Fair Competition Code.

Member companies shall conduct themselves according to high ethical standards without limiting themselves to mere compliance with the Fair Competition Code.

II-1. Commentary on the Code of Practice

1. Scope and Definition of Promotion

1.1 Scope

The JPMA Code applies not only to the promotion of prescription drugs but to all interactions among member companies and researchers, healthcare professionals, medical institutions, patient organizations, and wholesalers, etc. Based on the JPMA Code, member companies shall establish their own in-house codes governing all executives and employees, and while complying with the JPMA Code and their in-house code, they shall also respect the IFPMA Code, the code of the organization with which JPMA has signed up as a member. Moreover, the criterion for judgment of the member companies' own conduct must always be whether or not the 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.

(Commentary)

At member companies, employees and executives, other than those of sales divisions and marketing divisions, also have interactions with healthcare professionals. For example, employees in divisions that conduct clinical trials and clinical studies explain protocols to healthcare professionals at study sites and confirm progress, etc. Moreover, when member companies conduct joint research with academic institutions such as universities, employees of the research division interact with researchers, healthcare professionals, and others. In March 2012, IFPMA announced its IFPMA Code covering not only marketing activities but also interactions with healthcare professionals, medical institutions, and patient organizations. The new IFPMA Code superseded the existing "IFPMA Code of Pharmaceutical Marketing Practices." JPMA responded by newly establishing the JPMA Code as a further development of the Promotion Code for Prescription Drugs, which had been applied to promotional activities that were conducted by MRs, the sales and marketing divisions and were directed toward healthcare professionals and medical institutions. With a broader scope encompassing researchers and wholesalers, the JPMA Code is a code of behavior that governs all interactions between member company personnel and researchers, healthcare professionals, medical institutions, patient organizations, and wholesalers, etc.

In 1993, when the Promotion Code for Prescription Drugs was enforced, information provided to healthcare professionals by pharmaceutical companies was normally in the form of paper media, and seminar participants generally met together in one place. The content of the original code's provisions was premised on these usual practices. However, with the development of information technology, it has become common to provide information via the Internet or through video content, and web delivery of seminars has made it possible for healthcare professionals to participate while remaining in their own offices. Thus, forms of promotions that were not expected at the time of establishment of the JPMA Code will be implemented more widely in the future.

In such instances, member companies should not engage in activities that run counter to the spirit of the JPMA Code even if they are not specifically mentioned. As stated in the Preamble, pharmaceutical companies are called upon to not merely comply with laws, ordinances, and self-regulations but also adopt the stance of proactively responding to the society's demands and expectations. It is important to judge behaviors from the standpoint of whether they might distort proper use of prescription drugs.

1.2 Definition of Promotion

The word "promotion" as it is used here means "to engage with healthcare professionals in the provision, collection, and communication of pharmaceutical product information for promoting the proper use and broader adoption of prescription drugs based on those interactions." This includes all activities implemented by member companies that may influence the prescribing decisions of healthcare professionals.

(Commentary)

In the WHO Ethical Criteria, "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." The IFPMA Code defines "promotion" as "any activity undertaken, organized, or sponsored by a member company that 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," and it describes the ethical nature of promotion and its standards.

On the other hand, the Guidelines for Provision of Sales Information indicate that the "provision of sales information" means "active or passive provision of information on prescription drugs by marketing authorization holders, etc., in the expectation

of promoting sales by improving the name recognition of a specific prescription drug or awareness of its efficacy and safety, and it includes disease awareness education related to the indications of prescription drugs (including those intended for the general public)."(Note) Moreover, the guidelines seek to ensure proper use of prescription drugs by regulating advertising and activities similar to advertising in the provision of sales information.

Based on this philosophy, "promotion" in the context of the JPMA Code has been defined as follows: "to engage with healthcare professionals in the provision, collection, and communication of pharmaceutical product information for promoting the proper use and broader adoption of prescription drugs based on those interactions, including all activities implemented by member companies that may influence the prescription decisions of healthcare professionals."

Activities with the expectation of promoting sales (advertising and activities similar to advertising) constitute "promotion" under the JPMA Code, but even if they are "activities not with the expectation of promoting sales," there is a possibility that they may influence the prescription decisions of healthcare professionals. Such activities are included in "promotion," and the Promotion Code is applied in such cases. In other words, even if the activities are conducted as exchange of scientific information, "not with the expectation of promoting sales," or as legal obligations, if there is a "possibility that they may influence the prescription decisions of healthcare professionals," their appropriateness will be judged under the application of the Promotion Code; therefore, member companies must conduct the activities with attention to the fact that determination of whether the activities are "promotion" will not be based solely on the intention of the pharmaceutical company. Moreover, it should be noted that whether or not it is "promotion" is determined based on the contents of the activities and not the position or affiliated department of the person who conducts the "promotion."

In addition, without proper drug information, the products cannot function as "medicine." Prescription of medicines is only possible when the right medical information is provided. In other words, appropriate prescription tailored to the patient's condition can be provided only if healthcare professionals acquire a correct understanding of the products through the provision of accurate drug information. Activities that unfairly promote the use of a company's products, such as supply of inappropriate information to mislead healthcare professionals, will impede this appropriate, patient-matched prescription and cannot be considered as proper promotion.

In "promotion," information on adverse reactions is accurately presented so that healthcare professionals using the drugs will use the drug properly with an understanding of the associated ADRs. Ultimately, this prudent approach to the drug reinforces trust in drugs and pharmaceutical companies. In the JPMA Code, definition of the word promotion includes "collection" of drug information as well, because the collection of ADR information occurs within a series of activities that include the analysis and evaluation of results and culminate in communication.

Note: Disease awareness is subject to the Guidelines for Provision of Sales Information, since drug treatment may be especially recommended under the guise of disease awareness (Q&A on the Guidelines for Sales Information Provision Activities for Prescription Drugs [Administrative Notice of the Compliance and Narcotics Division of the Ministry of Health, Labour and Welfare's Pharmaceutical Safety and Environmental Health Bureau, dated February 20, 2019]: Q5 and A5).

2. Responsibility of Top Management

The top management of the member companies shall execute the following.

(1) With the awareness that acting in accordance with the "Basic Principles" is their own role, top-level managers shall set an example by implementing the provisions of the JPMA Code and making them known to all as they strive to maintain and improve the internal organization. Top-level managers shall perceive the conduct of all executives and employees to be their own responsibility.

(2) When circumstances arise that run counter to the spirit of the JPMA Code, top-level managers shall take responsibility for resolving the problems, investigate and identify the cause, and take measures to prevent recurrence.

(3) Even in departments that are in charge of matters other than pharmaceutical products, top management shall observe the spirit of the JPMA Code in conducting corporate activities.

(4) Subsidiaries that manufacture and sell drugs in Japan shall also be required to comply with the JPMA Code.

(5) Member companies shall demonstrate their compliance with the JPMA Code to parent companies, affiliates, and subsidiaries that manufacture and market pharmaceuticals, whether in Japan or overseas, and seek their understanding of the Code.

(Commentary)

In the "Charter for the Activities of Pharmaceutical Companies," revised in October 2018, the responsibilities of top management are clearly specified as follows under "13. Role of Top Management and a Thorough Enforcement of this

Charter":

・ Top management perceive the implementation of the spirit of the Charter to be their own role, and while setting an example, they ensure thorough compliance with the Charter in their own company and other members of the corporate group, and encourage business partners to comply with it as well. Moreover, they harken to voices within and outside of the company at all times and respond by constructing an effective system of governance.

・ When something counter to the spirit of the charter occurs, causing loss of social credibility, the top management themselves shall take the initiative to investigate the cause and prevent recurrence in an effort to solve the problem, and they shall take the responsibility to recover the trust of the society.

Inclusion of the "Responsibilities of Top Management" in the JPMA Code is based on the understanding that the attitude of top management is extremely important for compliance with this Code.

Moreover, member companies are called upon to foster a corporate culture and maintain an internal system in which all executives and employees work as one with the parent company, affiliates, and subsidiaries, etc., under the leadership of top management, and everyone involved is made fully aware of the necessity of respecting and complying with the internal code of conduct. The most important elements of constructing such a system are the top management themselves declaring the policy of compliance; showing their commitment to it; and assigning clear responsibilities to managers, including executives. This will lead to earnest efforts on the part of employees. The internal system mentioned here includes, for example, declaration of compliance policies by the top management, preparation of the practical manual, establishment of the training system, internal auditing of the status of compliance, and establishment of a whistle-blowing system. In addition, when conducting promotional activities jointly with affiliates, etc., ensure that they comply with the JPMA Code based on the notification issued by the president of the JPMA Promotion Code Committee (March 10, 2010, JPMA Notification No. 137) and implement the activities after mutual confirmation of the JPMA Code.

Furthermore, the Guidelines for Provision of Sales Information stipulate the "Responsibilities of Top Management" as follows: "The top management of a marketing authorization holder or other entity bears responsibility for all of the company employees' business activities related to the provision of sales information, and the top management shall ensure that sales information is provided in an appropriate manner by exercising leadership in the creation and maintenance of the necessary internal systems while also evaluating and educating the persons in charge of providing sales information, preparing and managing standard operating procedures and business records, and handling instances of the inappropriate provision of sales information."

In recent years, support for operations by third parties to which operations have been outsourced (CRO, CMO, supply chain companies, etc.) has played a major role in the promotion of the pharmaceutical business. Executives and employees, including the top management, need to be fully aware that they still bear the final responsibility for the operations carried out by the third party to whom the operations have been outsourced. IFPMA has prepared the "IFPMA Note for Guidance on Ethical Third-Party Intermediary Relationships" as a guidance for working with third parties to whom pharmaceutical companies have outsourced operations.

3. Fundamentals of Interaction

3.1 Fundamentals of Interaction

Advances in medical and pharmaceutical sciences and improvements in public health depend on information-sharing interactions among the entire medical community, which comprises researchers, healthcare professionals, patients, wholesalers, and JPMA member companies, and integrity is essential for these exchanges. The society relies upon pharmaceutical companies to make decisions ethically and in the best interests of patients when engaging in such interactions, and member companies must always conduct themselves in such a manner that the government, healthcare professionals, and patients trust them to engage in ethical activities at all times.

3.2 Transparency of Interactions

Pharmaceutical companies are called upon to maintain a high sense of ethics as life sciences companies, and JPMA member companies shall be accountable for interactions with researchers and healthcare professionals and ensure that collaboration with patient organizations is conducted ethically and in good faith. Member companies shall maintain transparency in their corporate activities and properly discharge their accountability to the society in accordance with their own guiding principles based on the Medical Institutions Transparency Guidelines, Guidelines on Collaboration with Patient Organizations (hereinafter, "Patient Organization Collaboration Guidelines"), and the Patient Organization Transparency Guidelines.

(Commentary)

3.1 Fundamentals of Interaction

The word integrity as it is used in this context refers to “good faith and a condition in which a firm sense of ethics can be maintained”. As life sciences companies, pharmaceutical companies are called upon to have the highest sense of ethics. It goes without saying that unless drugs are used properly, the effects they exhibit can even be dangerous. The precondition for the proper use of drugs is the patient’s trust in persons in charge of healthcare, beginning with doctors and other healthcare professionals, but also including researchers and pharmaceutical companies. As a fundamental part, there must be confidence in the society that decisions are always made ethically and in the best interests of patients.

Patients’ interests are the objective that is common to the pharmaceutical industry and the medical community. In 2014, the “Consensus Framework for Ethical Collaboration between Patients’ Organizations, Healthcare Professionals, and the Pharmaceutical Industry” was established by the consensus of five global organizations: International Alliance of Patients’ Organizations, World Medical Association, International Pharmaceutical Federation, International Council of Nurses, and IFPMA. This document declares that cooperation among all stakeholders is essential to reliably deliver optimal care to patients throughout the world, and that further promotion of this cooperation requires that each stakeholder engage in highly ethical and transparent interactions. Furthermore, in Japan in 2018, the “Japanese Consensus Framework for Ethical Collaboration” was agreed upon and signed by the Ministry of Health, Labour and Welfare; Japan Patients Association; Japan Federation of Cancer Patient Groups; Japan Medical Association; Japan Pharmaceutical Association; Japanese Nursing Association; The Federation of Pharmaceutical Manufacturers' Associations of Japan; and The Japan Federation of Medical Devices Associations.

3.2 Transparency of Interactions

Under the mission of creating new value through the provision of innovative drugs and services and contributing to global healthcare and people's well-being, member companies engage in medical and pharmaceutical research, the practical application of their findings, and the promotion of appropriate use of prescription drugs. These efforts rely heavily on collaboration between industry and academia.

In all of these activities, collaboration between industry and academia is indispensable. However, the more extensive this collaboration, the more situations there are in which medical institutions and healthcare professionals are deeply involved in specific companies and products, and there are concerns that they may have some sort of influence on the judgment of medical institutions and healthcare professionals. There is a higher requirement of transparency of activities in the pharmaceutical industry than in other industries because of the impact life sciences companies have on the lives and health of patients and ordinary citizens, as well as the position of the industry in Japan under the Japanese national health insurance system. The Medical Institutions Transparency Guidelines was established to ensure the kind of transparency that fosters a broad understanding of the fact that member companies conduct their activities under the highest ethical standards, and that the pharmaceutical industry contributes to the development of life sciences, beginning with medical and pharmaceutical sciences.

Moreover, member companies are called upon to understand and respond to the needs and worries of patients and their families and supporters in all situations involving drugs and patients, from the discovery of new drugs to the promotion of proper use and post-marketing safety measures. There are also a growing number of opportunities for member companies to work together with the patient organizations that represent the voices of the patients and their families. These include activities where funding is provided to patient organizations either directly or indirectly. Like the medical community, the government also attaches increasing importance to the “voice of patients,” and in a growing number of cases, representatives of patient organizations are participating in committee meetings and discussion meetings of administrative organs. However, as patient organizations become more vocal and influential, there is a concern that the deeper relationships between member companies and patient organizations resulting from more extensive collaboration will influence the judgment of these groups in some way. The Patient Organizations Collaboration Guidelines and Patient Organization Transparency Guideline were established to help the member companies contribute to the activities and development of patient organizations through collaboration with the guarantee of transparency and high ethical standards.

4. Interactions with Healthcare Professionals

In interactions with healthcare professionals, member companies shall give the highest priority to being of benefit to patients and contributing to the health and welfare of patients. With the goal of contributing to the development of medical and pharmaceutical science and the improvement of public health, member companies' interactions shall focus on the provision of drug information, academic exchange on medical and pharmaceutical science, and support for research. When promoting industry-academia collaboration to further the development of medical and pharmaceutical science, member companies shall make efforts to build relationships of trust with researchers, healthcare professionals, and patient organizations while at the same time avoiding activities that could exert an inappropriate influence upon prescribing decisions.

(Commentary)

Matters of the greatest priority for pharmaceutical companies include the health and the development of medical and pharmaceutical sciences, and this coincides with the objectives of healthcare professionals. Close cooperation between pharmaceutical companies and healthcare professionals is indispensable to achieving these objectives. For this cooperation to continuously expand and develop, the most important thing is to gain the trust of the society regarding the fact that both pharmaceutical companies and healthcare professionals make the interests of patients the highest priority in their interactions. However, in the past, there have been doubts about the relationship between the two parties due to interactions that did not put the interests of the patients first, but instead prioritized the interests of corporations or healthcare professionals. Incidents such as these cause the society to lose confidence in the interactions between pharmaceutical companies and healthcare professionals, leading to the introduction of stricter regulations and further limitation of these interactions. This reduces the opportunities to contribute to patients and makes the existence of pharmaceutical companies less meaningful. The pharmaceutical industry is bound by numerous laws, ordinances, and self-regulations with which we naturally need to comply. At the same time, we need to ask ourselves, “What is the society asking of us?” and make that an important standard of judgment. In order to be trusted by society, we need to make giving the highest priority to the interests of patients at all times the basis for our interactions with healthcare professionals while maintaining ethicality and transparency.

Interactions with healthcare professionals also include wholesalers’ promotional activities directed at healthcare professionals and medical institutions.

5. Prohibition on Preapproval Information Provision and Recommendation of Off-Label Uses

Member companies shall not engage in promotion until approval for the drug is received in Japan. They shall also refrain from endorsing off-label uses.

(Commentary)

Article 68 of the Pharmaceuticals and Medical Devices Act prohibits advertising of drug before marketing approval is received. Moreover, Article 66 of the same law prohibits false or exaggerated advertising of products, whether explicit or implicit. Based on these provisions, advertising of indications or dosage and administration that exceeds the scope of approval is prohibited by the “Standard for Adequate Advertisement of Pharmaceutical Products.” Accordingly, it is not permissible to engage in promotion before approval is obtained or to recommend off-label use in ways that differ from the approved indications, dosages, or administrations.

Not only healthcare professionals but also the general public have the right to know about scientific/medical advancements. Specific cases regarding this are explained in commentary (4) of “2. Fundamentals of Promotional Activities” in “II-2. Promotion Code for Prescription Drugs.”

6. Information Dissemination Activities

As life sciences companies, JPMA member companies shall provide scientific and objective information on drugs as needed. When providing information, they shall strive to make the content and mode of expression easy for users to understand, while complying with the laws, ordinances, and self-regulations.

Advertisement of prescription drugs to the general public other than healthcare-related personnel is prohibited by the Pharmaceuticals and Medical Devices Act and the Standard for Adequate Advertisement of Pharmaceutical Products. This applies to information disseminated through press releases, disease education activities targeting the general public and patients, and provision of information to investors. This scrutiny is necessary so that there will be no suspicion that such type of information dissemination constitutes the advertisement of prescription drugs or recommendations of unapproved drugs or off-label uses. Rules governing the dissemination of information to healthcare professionals are set forth in I-2. Promotion Code for Prescription Drugs.

(Commentary)

Pharmaceutical companies are called upon by the society to issue scientific, objective, and accurate information as appropriate to help prevent health injuries caused by drugs and promote the spread of proper use based on the unique nature of drugs: (1) We cannot know the nature of a drug by its appearance. (2) Drugs have both effects and side effects, the occurrence of which differs from patient to patient. (3) Accordingly, drugs cannot function as medicine without accurate drug information. On the other hand, the Standard for Adequate Advertisement of Pharmaceutical Products states that advertising to the general public other than healthcare-related personnel is prohibited for all prescription drugs. In particular, for drugs specified by the MHLW ministerial ordinance among drugs used for cancer and other specific diseases (sarcoma and leukemia), advertising to the general public other than healthcare-related personnel is prohibited by Article 67 of the Pharmaceuticals and Medical Devices Act, as the risk of harm is considered particularly great unless the drugs are used under the guidance of a physician or dentist. For this reason, even if the purpose is a press release, patient education activity, or provision of information to an investor, it is necessary to closely examine the content beforehand so that the content is not perceived as an advertisement of a prescription drug to the general public. Regarding relevance to advertising described here, the Ministry of Health, Labour and Welfare issued a notification stating that content that "fulfills any of the following requirements is judged to correspond to advertising" (PMSB-IGD Notification No. 148, dated September 29, 1998).

- When the intention of inducing customers (stimulating customers' will to purchase) is clear.
- When the brand name of a specific pharmaceutical, etc., has been disclosed.
- When it is a condition that can be recognized by the general public.

6.1 Promotional Materials (Including Digital Media)

Member companies shall prepare promotional materials (including digital media; hereinafter referred to as "promotional materials") in accordance with the related laws and self-regulations such as the Guideline for Product Overview Preparation.

(Commentary)

Drug information is the sine qua non of a prescription drug. Because the product information brochure for prescription drugs (hereinafter referred to as "product information brochure") and advertisements in specialized journals (paper media) are important tools for supplying drug information, they must be prepared properly to ensure the appropriateness of the content, expression, and usage of such materials and avoid misinterpretation by healthcare professionals.
Details of promotional materials are specified in I-2. Promotion Code for Prescription Drugs.

6.2 Social Media

Member companies shall bear all responsibility for content when utilizing digital communication via social media, etc. Accordingly, compliance with the in-house code must first be confirmed with related subsidiaries, parent companies, affiliates, planning companies, agencies, employees, etc.

(Commentary)

When utilizing digital communication via social media, etc., it is necessary to pay particular attention to the following:

(1) It should comply with the Pharmaceuticals and Medical Devices Act and the advertising regulations of the Standard for Adequate Advertisement of Pharmaceutical Products.

(2) When planning or supporting social media, etc., each member company shall take responsibility for confirming the

appropriateness of the content of postings, including the content of contributions made by third parties. In the event that there has been a posting of inappropriate information (e.g., on unapproved drugs, off-label use, or slander of other companies' products) or of information on adverse events, the member company shall take responsibility for taking the appropriate measures.

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

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

IFPMA has developed a Joint Note for Guidance on Social Media and Digital Channels as a guidance for considering activities on social media and digital channels.

7. Holding of Seminars and Meetings

Member companies can hold seminars for the purpose of providing information on medical and pharmaceutical science, as well as disease education information, etc. Moreover, member companies can hold meetings, etc., of healthcare professionals and others to obtain useful expert knowledge for their activities. When holding a seminar, meeting, etc., of healthcare professionals and others, member companies shall comply with the related laws and ordinances, the Fair Competition Code, and I-2 Promotion Code for Prescription Drugs.

(Commentary)

Seminars, etc., include ordinary seminars that are held to provide information on medical and pharmaceutical science to healthcare professionals, and open lectures held to educate the general public about diseases.

Meetings, etc., of healthcare professionals and others also include advisory meetings held to obtain advice when formulating product strategy as well as meetings associated with clinical trials and other studies.

Details of seminars, meetings, etc., of healthcare professionals and others are specified in I-2. Promotion Code for Prescription Drugs.

8. Fee for Services

Member companies may engage researchers, healthcare professionals, medical institutions, patient organizations, etc., for service arrangements such as research, clinical studies, post-marketing surveys, consultant and advisories, participation in the planning of meetings, chairing or lecturing at seminars, and training instructor duties, where such participation involves fees such as compensation. However, when making such arrangements for these services, member companies must enter into a written agreement that fulfills all of the following criteria.

(1) A written agreement must be made to specify the purpose of the service to be provided and the basis for payment of those services.

(2) A legitimate need for the services must be clearly identified in advance.

(3) The service providers must be directly related to the identified need and must have the expertise necessary to provide the service.

(4) The number of people to be contracted must be reasonable to meet the specified need.

(5) The hiring must not be an inducement to prescribe, purchase, or recommend any specific drug.

(6) The compensation for the services is reasonable, reflects the fair value of the services provided, and is commensurate with the fair market value.

In addition, when making service arrangements, internal rules, etc., of the service provider shall be respected; the related laws and ordinances and the Fair Competition Code shall be complied with; and the compensation, expenses, etc., associated with the service arrangements shall be disclosed appropriately in accordance with the company's guidelines based on the Medical Institutions Transparency Guidelines and the Patient Organization Transparency Guidelines.

(Commentary)

When making arrangements, it is necessary to observe the service provider's rules and also exercise care to see that the National Public Service Ethics Code is not violated. Particularly when making service arrangements related to drugs, which are life-related products, the financial relationship with companies related to the contents of the lecture will be disclosed at the beginning of the lecture presentation (Notification by the President of the JPMA [JPMA Notification No. 237, dated April 18, 2013]) in accordance with any guidelines on the management of conflicts of interest that have been established by the service

provider's institutions, scientific society, or other organization, and such a relationship shall not be for the purpose of exerting an influence on the service provider.

Provision of the following is limited by the Fair Competition Code: "cash, gifts, travel, entertainment, etc., provided as a means of inducing selection or purchase of prescription drugs to doctors, dentists, other medical professionals belonging to medical institutions, etc." However, there are no limitations imposed on cash paid as remuneration for requested work, such as for lecturing or writing, as a fee, etc., unless the fees are remarkably high given the nature of the services.

When making arrangements, please comply with the Fair Competition Code so that a transaction nominally performed as a service arrangement will not constitute the provision of gifts, cash, or cash equivalents as a means of improper inducement.

IFPMA has prepared the "IFPMA Note for Guidance on Fees for Services" to provide additional interpretation and guidance for the relevant provisions (Article 7.4 Fees for Services) of the IFPMA Code.

The compensation and expenses associated with service arrangements shall be appropriately made public in accordance with the company's own guiding principles based on the "Medical Institutions Transparency Guidelines." Regarding the standards for calculating such compensation, it is required to further ensure transparency by setting certain calculation standards, etc., from the viewpoint of securing the reliability of clinical studies for the public (Notification by the Chairperson of the Code Compliance Committee [JPMA Notification No. 233, dated October 6, 2020]). Moreover, engagements with patient organizations shall be performed appropriately in accordance with the company's own guiding principles based on the "Patient Organization Collaboration Guidelines", and funding and other payments shall be made public in accordance with the company's own guiding principles based on the "Patient Organization Transparency Guidelines".

9. Provision of Gifts, Cash, or Cash Equivalents

Member companies shall not directly or indirectly provide researchers, healthcare professionals, medical institutions, patient organizations, wholesalers, and stakeholders with the following gifts, cash, or cash equivalents.

(1) Gifts, cash, or cash equivalents that could exert inappropriate influence upon decision-making (including those that may affect the proper use of drugs)

(2) Gifts that undermine the dignity of pharmaceutical products

(3) Gifts, cash, or cash equivalents that are unlikely to meet with social understanding and acceptance

(Commentary)

Advances in medical and pharmaceutical science and improvements in public health depend on information-sharing interactions among the entire medical community, which comprises researchers, healthcare professionals, medical institutions, patients, wholesalers, and JPMA member companies. Integrity is essential in these interactions, and there must always be confidence that decisions are made ethically and in the best interests of patients.

The Fair Competition Code limits unfair provisions of any premiums in order to prevent unfair soliciting of customers and ensure voluntary and rational selection of products by general consumers and fair competition among business operators. Thus, the code states that pharmaceutical manufacturers must not offer to medical institutions, etc., any premiums (gifts, cash or cash equivalents offered to the opposite party in their commercial transactions to solicit customers) as a means of unfairly soliciting commercial transactions involving prescription drugs.

The Code of Practice, on the other hand, includes an item that approaches the "provision of gifts, cash, or cash equivalents" from the standpoint of what kind of giving of gifts, cash, or cash equivalents is appropriate for pharmaceutical companies, irrespective of whether the provision of gifts is restricted by the Fair Competition Code. In other words, the provision of gifts, cash, or cash equivalents, must be considered from the perspectives of whether it may affect the proper use of drugs; may be perceived by the society to interfere with the neutrality of prescriptions; and may damage the socially respected role of drugs, which are life-related products. Especially, even justified receipt and payment of cash and cash equivalents by pharmaceutical companies and medical institutions tend to cause doubt or mistrust among the society or patients. Such doubt or mistrust has negative effects on the trusting relationship between healthcare professionals and patients and may damage 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.

Nevertheless, offers of gifts, cash, or cash equivalents classified as premiums must comply with the Fair Competition Code as a major principle, and any member company that violates this code will violate the JPMA Code.

The IFPMA Code notes that "interactions between companies and healthcare professionals should be intended to benefit patients and to enhance the practice of medicine." In "7.5.1.1 Prohibition of Gifts," the IFPMA Code stipulates the following: "Gifts for healthcare professionals' personal benefit (e.g., sporting or entertainment tickets, electronics items, and social courtesy gifts; either directly or through clinics and institutions) are prohibited." Providing or offering cash, cash equivalents

or personal services is also prohibited. For these purposes, personal services are any type of service unrelated to the healthcare professional's profession and that confer a personal benefit to the healthcare professional." This requirement is based on the principle to "Act responsibly, ethically, and professionally. Do not offer, promise, provide, or accept anything of value in order to inappropriately influence a decision or gain an unfair advantage." stated in the "Integrity" section of "Our Ethos" of the IFPMA Code.

The IFPMA Code stipulates in "7.5.1.2 Promotional Aids" that "A promotional aid is a non-monetary item given for a promotional purpose (which does not include promotional materials as defined in Articles 5 and 6). Providing or offering them to healthcare professionals in relation to the promotion of prescription-only medicines is prohibited." However, in Q&A 14, the IFPMA Code states with respect to promotional aids of prescription-only medicines that "pens and notepads can be provided to healthcare professionals in the context of company-organized events for the purpose of taking notes during the meeting. They must not bear the name of any medicine but may bear the name of the company providing them. In addition, they must be of minimal value and only the necessary quantity is distributed. Examples of banned promotional aids include sticky notes, mouse pads, calendars, etc."

With respect to items of medical utility that can be provided for patient care, the IFPMA Code categorizes the items as "7.5.2 Items of Medical Utility to Enhance the Provision of Medical Services and Patient Care" and "7.5.3 Informational or Educational Items that Enhance Patient Care" and specifies them respectively as follows:

"7.5.2 Items of Medical Utility to Enhance the Provision of Medical Services and Patient Care"

Items of medical utility may be offered or provided by member companies 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.

They should not be offered on more than an occasional basis, even if each individual item is appropriate.

Items of medical utility can include the company name, but must not be product branded, unless the product's name is essential for the correct use of the item by the patient.

"7.5.3 Informational or Educational Items that Enhance Patient Care"

Informational or educational items provided to healthcare professionals for their education or for the education of patients on disease and its treatments may be offered by member companies provided that the items are primarily for educational purposes and do not have independent value.

These informational and educational items can include the company name, but must not be product branded, unless the product's name is essential for the correct use of the item by the patient.

The value of books and subscriptions must be reasonable. Other informational or educational items must be of modest value.

When determining a "minimal value" and "modest value" as described above, the Fair Competition Code should also be consulted, which stipulates specific requirements for offering the items. It is most obvious that pharmaceutical companies must comply with the Fair Competition Code when offering gifts. However, they must also examine the gifts' suitability with an extremely rigorous attitude based on their ethical values as a pharmaceutical company, even when the gifts are not deemed to be in violation of the Fair Competition Code.

Meanwhile, consideration must be given to the stipulation that national public officials, other public officials, and those regarded as such are subject to the code of ethics restricting supply and receipt of gifts. Specific institutions or organizations may have their own codes of ethics governing personnel other than public officials as for supply and receipt of gifts, and it is necessary to confirm this thoroughly in advance.

Moreover, with regard to the printing of names on gift items, member companies must be careful so that they are clearly distinguished from the materials for prescription drugs information, and are not mistaken as advertisements directed towards the general public outside of the healthcare field. In this regard, a notification by the chairperson of the Code Compliance Committee (JPMA Notification No. 381, dated July 2, 2015) requires member companies to refrain from printing the names of products on promotional aids.

The WHO Ethical Criteria forbid 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."

10. Studies and Research Activities

At every phase, studies and research activities involved in epidemiological research, non-clinical studies, clinical research/clinical studies (clinical trials and post-marketing studies), etc., must have highly ethical and appropriate scientific objectives that conform to the laws and ethical guidelines. Moreover, information on R&D expenditures and public research subsidies shall be subject to disclosure under the "Medical Institutions Transparency Guidelines," and member companies shall bear appropriate accountability in accordance with the Guidelines.

To ensure transparency of information on clinical studies, member companies shall publicly disclose clinical study information in conformity with the "Joint Position on the Disclosure of Clinical Trial Information via Clinical Trial Registries and Databases" (revised in 2018) and "Joint Position on the Publication of Clinical Trial Results in the Scientific Literature" (revised in 2017), which were jointly issued by JPMA, IFPMA, European Federation of Pharmaceutical Industries and Associations (EFPIA), and Pharmaceutical Research and Manufacturers of America (PhRMA).

Additionally, to minimize harm from adverse reactions to pharmaceuticals, member companies shall make efforts to develop safer, more effective drugs while promoting appropriate voluntary self-controls on the use of laboratory animals in drug development from the standpoint of animal welfare so that the R&D will be further improved.

(Commentary)

Needless to say, in order to keep studies and research fair and impartial, member companies must comply with laws and the various guidelines, and the research institutions that conduct the studies must cooperate in acting in compliance with these. The laws referred to here include the Pharmaceuticals and Medical Devices Act, Personal Information Protection Law, Act on Regulation of Human Cloning Techniques, and related governmental and ministerial ordinances; the ethical guidelines include the "Ethical Guidelines for Medical and Biological Research Involving Human Subjects" (MEXT, MHLW, and METI), "Guidelines on the Handling of Specified Embryos" (MEXT), "Guidelines on the Establishment of Human ES Cells" (MEXT and MHLW), "Guidelines on the Distribution and Use of Human ES Cells" (MEXT), "Guidelines on Research on Preparing Germ Cells from Human iPS Cells or Human Tissue Stem Cells" (METI and MHLW), "Guidelines on Assisted Reproductive Technology for Preparing Human Fertilized Embryos" (METI and MHLW), etc.

In addition, to increase the transparency of funding provided to medical institutions by member companies, JPMA has established the Medical Institutions Transparency Guidelines, and member companies are conducting information disclosure in accordance with these guidelines. Moreover, JPMA published the "Re-updating of the 'Basic Position on the Ideal Nature of Support for Clinical Research by Pharmaceutical Companies' Pursuant to Enforcement of the Clinical Trials Act" on May 28, 2018, to deliberate on the ideal form of support for clinical research by member companies (Notification by the Chairperson of the Code Compliance Committee [JPMA Notification No. 296, dated May 28, 2018]).

In 2009, four associations—the IFPMA, PhRMA, EFPIA, and JPMA—prepared the "Joint Position on the Disclosure of Clinical Trial Information via Clinical Trial Registries and Databases" (later revised on January 15, 2018) in the form of a joint statement calling for disclosure of all clinical study registration (except for exploratory studies); in Japan, this is disclosed through the Japan Registry of Clinical Trials (jRCT) and each company's website. This database covers and discloses concise study titles, explanations of studies in nontechnical terms, study phases, study types (interventional research, etc.), present status of the studies, study objectives (treatment, diagnosis, prevention, etc.), type of intervention (drugs, vaccine, etc.), symptom and disease, main eligibility criteria (gender, age, etc.), region where the study was conducted, and information on liaison.

In 2010, the IFPMA approved and issued the "Joint Position on the Publication of Clinical Trial Results in the Scientific Literature" (later revised on October 30, 2017). Beginning with JPMA, each association, including PhRMA and EFPIA, and their member companies are required by these guidelines to contribute at least the results of all Phase 3 clinical studies sponsored by the company to peer-reviewed medical journals, as well as other study results deemed to be medically important. Moreover, IFPMA has prepared the "Diversity and Inclusion in Clinical Trials: Bioethical Perspective and Principles" to provide principles that support continuous and sustainable improvement in clinical trial diversity globally.

10.2 Post-Marketing Safety Management Operations and Post-marketing Surveillance

Member companies need to have a proper understanding of the objectives behind the establishment of proper methods of use for post-launch drugs. Post-marketing safety management operations and post-marketing surveillance must be based on scientific evidence and conducted in compliance with laws, ordinances, and self-regulations. These activities should never be used as tools of sales promotion.

(Commentary)

Appropriate implementation of post-marketing safety management operations is an important requirement for acceptance as marketing approval holders. Post-marketing safety management operations include safety assurance activities and early post- marketing phase vigilance (EPPV), etc. Safety assurance activities are defined in the Ministerial Ordinance on Good Vigilance Practice (hereinafter referred to as "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 Good Post-marketing Surveillance Practice Ordinance (hereinafter referred to as "GPSP Ordinance") as follows: "Post-marketing surveillance indicates drug use results surveys (including specific use results surveys) or post-marketing clinical studies that are conducted to collect, obtain, verify, or validate information on the quality, efficacy, and safety of pharmaceutical products."

Thus, post-marketing safety management operations and post-marketing surveillance are important as they relate to the essential nature of drugs, and pharmaceutical companies have the social responsibility to constantly pursue more effective and safer usage in response to the actual use conditions of post-launch drugs (e.g., conditions of patient compliance, interaction with other drugs, and treatment period) and changes in the overall situation (e.g., advances of medical technology, changes in assessment criteria, new pathologies, clinical pictures, and changes in pathogenic microorganisms). In addition, one of the most important mandatory responsibilities of pharmaceutical companies is to ensure thorough safety management, such as reporting of adverse drug reactions within a predetermined period without omission, in accordance with the Pharmaceuticals and Medical Devices Act and GVP Ordinance; further enhancement of the safety management system is required by the notification of the chairperson of the Code Compliance Committee (JPMA Notification No. 46, dated January 21, 2016).

Needless to say, implementation of post-marketing safety management operations and post-marketing surveillance, etc. must be based on scientific evidence and must protect the human rights of patients and seek to maintain their security and improve their welfare. If we use these data as a means of sales promotion, we mar the essential nature of drugs with our own hands and invite considerable loss of trust in drugs and pharmaceutical companies.

Compliance is necessary with not only the Pharmaceuticals and Medical Devices Act, GVP Ordinance, GPSP Ordinance, and administrative notifications but also the Fair Competition Code so that post-marketing safety management operations, post-marketing surveillance, etc., are not doubted or mistaken as a disguise for sales promotion.

11. Collaboration with Patient Organizations

In all types of collaboration with patient organizations, member companies shall maintain a strong sense of ethics, act with integrity, and respect the independence of the patient organizations. Moreover, they shall strive to promote sufficient mutual understanding of the objectives and content of the collaboration with the patient organizations. Therefore, member companies that are collaborating with patient organizations shall establish guiding principles for their own companies by referring to the "Patient Organization Collaboration Guidelines" and implement them faithfully.

A member company providing financial or other support to a patient organization shall make its involvement known to the public to foster a broad understanding of the fact that this support contributes to the activities and development of the patient organization while securing high ethical standards. For that purpose, the member company shall establish its own guiding principles based on the "Patient Organization Transparency Guidelines" and make the information public.

The member company shall ensure transparency of the activity items, funding, etc., in collaboration with patient organizations, by securing a written agreement or consent for the objectives and content of the support before collaboration, as well as by retaining records.

(Commentary)

In order to further improve medical care in Japan, it will be necessary for pharmaceutical companies to contribute to the realization of patient-participatory medical care, in which the parties receiving medical care walk hand in hand with the parties that provide it.

Member companies are increasingly aware of the need to understand and respond to the needs and worries of patients and their families in all situations involving drugs and patients—from the discovery of new drugs to the promotion of proper use and post-marketing safety measures—and actively and continuously cooperate with patient organizations. Both of the medical

community and the government also attach increasing importance to the "voice of patients," and in a growing number of cases, representatives of patient organizations are participating in committee meetings and discussion meetings of administrative authorities.

Thus, as patient organizations become more vocal and influential, opportunities for pharmaceutical companies to work together with patient organizations have increased, and it has become increasingly important to ensure transparency in order to secure the correct understanding of society.

It is important for the public to understand that the financial support JPMA member companies provide to patient organizations comprise sincere activities that contribute to the activities and development of these groups, and they are conducted with the guarantee of the highest ethical standards. To foster this broad understanding by ensuring further transparency, JPMA established the "Patient Organization Transparency Guidelines" on March 14, 2012. These guidelines promote transparency by requiring information on financial support to be disclosed under set criteria. Member companies must establish guiding principles for the relationship with patient organizations for their own companies with reference to the Patient Organization Transparency Guidelines and make them the standards of behavior for their own companies.

Moreover, JPMA established the Patient Organization Collaboration Guidelines on January 16, 2013, as an effort to ensure that member companies maintain a strong sense of ethics, act with integrity in all types of collaborations with patient organizations, respect the independence of patient organizations, and ensure mutual understanding with patient organizations about the purpose and content of collaboration. Member companies who are collaborating with patient organizations must establish guiding principles regarding such collaboration for their own companies with reference to the Patient Organization Collaboration Guidelines and implement them faithfully.

In addition, IFPMA has prepared the "IFPMA Note for Guidance on Patient and Patient Organization Interactions" to provide additional interpretation and guidance regarding the relevant provisions (Article 11, "Interactions with Patient Organizations") of the IFPMA Code.

12. Relationship with Wholesalers

The relationship between pharmaceutical companies and wholesalers must be a fair business relationship that complies with the Act on Prohibition of Private Monopolization and Maintenance of Fair Trade (hereinafter referred to as the "Antimonopoly Law") and other laws, ordinances, and self-regulations. Moreover, since this relationship is expected to ensure a greater degree of ethicality and transparency than similar relationships in other industries because its transactions take place under the public medical insurance system, the member companies shall establish and conform to their own standards in cases where cash, goods, food and drink, or the like is offered to wholesalers or accepted from them.

(Commentary)

The IFPMA Code "covers interactions with healthcare professionals, medical institutions and patient organizations, and the promotion of pharmaceutical products" and it does not extend to wholesalers. However, interactions with wholesalers are covered by the JPMA Code.

The reason for this is that the functions of Japanese wholesalers differ from those of wholesalers in the United States and Europe. Broadly speaking, Japanese wholesalers have four types of functions: physical distribution, sales, information, and financial. Unlike wholesalers in the US and EU, Japanese wholesalers have the unique function of "information provision", and they perform duties pertaining to proper use, such as providing information on adverse reactions to medical institutions, etc. In this way, Japanese wholesalers shoulder part of the promotional activities of pharmaceutical companies, and in this they differ greatly from wholesalers in the US and EU. Because these functions of Japanese wholesalers are unique to Japan, the interactions with wholesalers are covered by the JPMA Code.

Although the relationship between pharmaceutical companies and wholesalers is a transaction between fellow private companies, JPMA member companies must establish and abide by their own appropriate standards for interactions with wholesalers in consideration of the wholesalers' functions and the fact that these are transactions conducted under the public medical insurance system.

Moreover, the Guidelines for Provision of Sales Information clearly stipulate the following: "The top management of the marketing authorization holder shall urge contractors, partner companies, and pharmaceutical wholesalers that engage in the provision of sales information to provide sales information appropriately."

13. Internal Procedures and Education

Member companies shall establish and maintain appropriate internal procedures in order to comply with the related laws and ordinances and the JPMA Code, and all executives and employees must be required to undergo education appropriate to their role.

(Commentary)

In order to clarify the management structure for compliance and observance of the JPMA Code, member companies establish a person responsible for compliance management, a person in charge of compliance-related business, a person responsible for code management, and a person in charge of code-related business within the company and register them in the JPMA Code Compliance Committee.

The role of the person responsible for compliance management and the person in charge of compliance-related business is to promote compliance within the company. At the same time, the person responsible for code management and the person in charge of code-related business play the roles of promoting understanding of the JPMA Code within the company, ensuring thorough compliance, promoting establishment of their own company's code, and contact and coordination with other member companies, etc. It is important for the persons responsible for compliance management and code management to maintain close contact and implement internal operations.

To clarify the management structure for compliance with the Guideline for Product Overview Preparation, member companies shall register with JPMA the following designated employees: a "Promotional Materials Officer" (PMO) responsible for the management of product information brochures for prescription drugs and a "Practical Operations Supervisor" (POS) responsible for practical operations regarding product information brochures for prescription drugs.

The PMO bears supervisory responsibility for the general management of the following matters pertaining to promotional materials, etc.

1) Ensuring company-wide knowledge of and thorough compliance with the standards such as "Guideline for Product Overview Preparation", established by the Review Board of Ethical Drug Product Information Brochure (Product Information Review Board)
2) Optimization of content of description in promotional materials, etc., and maintenance of internal review system for these materials
3) Replies and response based on the results of review by the Product Information Review Board and reporting to said board

The POS assists the PMO in performing business operations related to 1) through 3) above.

Please provide appropriate education commensurate with role to all executives and employees for the purpose of promoting understanding of and ensuring thorough compliance with the JPMA Code and internal company code.

The Guidelines for Provision of Sales Information stipulate that top management of the marketing authorization holder "shall periodically implement education for executives and employees so that sales information can be provided appropriately."

Moreover, IFPMA has prepared the "IFPMA Note for Guidance on Ethical Third-Party Intermediary Relationships" as a practical guideline to provide additional target for education and further guidance regarding the relevant provisions (12. Company Procedures and Responsibilities) of the IFPMA Code.

14. Inquiries, Complaints, and Actions

When there has been an inquiry or complaint about the JPMA Code, or when a code violation is suspected, the Code Compliance Committee shall respond according to the separately established "Procedures for Inquiries and Complaints Related to the Code." When the JPMA Code is judged to have been breached, the Code Compliance Committee shall take action against the offending member company, requiring it to make voluntary improvements in accordance with the separately established "Rules for Handling Breaches of the JPMA Code of Practice."

(Commentary)

The "inquiries" referred to here refers to inquiries about the interpretation of uncertain aspects of the JPMA Code as it pertains to the company's corporate activities, and "complaints" refers to complaints regarding suspicion of code violation regarding the corporate activities of other companies.

Before filing a "complaint", member companies must talk it over thoroughly with the other company and make efforts to achieve a swift resolution. Matters pertaining to "inquiries" and "complaints" are specified in the "Procedures for Inquiries and Complaints Related to the Code."

"Action" refers to the Code Compliance Committee calling upon a member company that has violated the JPMA Code to make voluntary improvements. The decisions on violation and actions are stipulated in the "Rules for Handling Breaches of

the JPMA Code of Compliance."

15. Activities Outside Japan

15.1 Standards Applied to Activities Outside Japan

Even in activities that take place overseas, member companies shall respect the JPMA Code while conforming with the related laws and ordinances of the relevant country, in addition to whatever pharmaceutical organization codes exist within the relevant country, or to the IFPMA Code in the absence of such codes.

(Commentary)

When a member company is active outside of Japan, it must comply with the JPMA Code as well as the code of the pharmaceutical organization effective in the country or the IFPMA Code, in addition to the laws and ordinances of the country.

15.2 Provision of Information on Drugs Overseas

Member companies shall, when providing medical information to overseas healthcare professionals, provide globally consistent information, whether directly or indirectly through local agents, etc. On this occasion, in addition to the laws and ordinances of the relevant country, if there is a code of a pharmaceutical industry in the relevant country, such code shall be followed; if there is no such code, the IFPMA Code shall be followed.

(Commentary)

In particular, information provided to overseas healthcare professionals (directly or indirectly through local agents) by member companies must be globally consistent. On this occasion, in addition to the related laws and ordinances of the relevant country, if there is a code of a pharmaceutical industry in the relevant country, such a code shall be followed, and if there is no such code, the IFPMA Code shall be adhered to.

Within a scope that does not deviate from the laws, ordinances, and self-regulations, member companies should provide the information on indications, dosage and administration, contraindications, warnings and other precautions, and ADRs in a uniform and globally consistent manner wherever possible. In particular, information concerning safety should be provided and disseminated appropriately and consistently.

The IFPMA Code also establishes the following standard: "Respecting the requirement that promotion should be consistent with the label and approved uses locally, healthcare professionals in developing countries should have access to similar data to those being communicated in developed countries."

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

15.3 Handling of Japanese Healthcare Professionals Overseas and Foreign Healthcare Professionals in Japan

Member companies shall also comply with the JPMA Code when handling Japanese healthcare professionals participating in seminars or scientific meetings overseas. When member companies invite healthcare professionals from overseas to seminars, etc., held in Japan, they shall comply with the laws and ordinances of the relevant country, in addition to the code of the pharmaceutical industry in the relevant country—or, if no such local code exists, to the IFPMA Code.

(Commentary)

Member companies must also comply with the JPMA Code when engaging in an interaction with; offering gifts, cash, or cash equivalents to; or offering food and drinks to Japanese healthcare professionals at seminars, etc., held in foreign countries.

When member companies invite healthcare professionals from overseas to seminars, etc., held in Japan and offer gifts, cash or cash equivalents or offer food and drinks, they must comply with the laws and ordinances of the relevant country, in addition to the code of the pharmaceutical industry in the relevant country—or, if no such local code exists, to the IFPMA Code. In addition, offers of unjustifiable interest to foreign public officials are prohibited under the Unfair Competition Prevention Law, and special attention must be paid regarding interactions with foreign public officers.

In addition, when handling healthcare professionals at academic conferences, etc., held overseas, member companies are required to act with restraint and in accordance with their ethical awareness as a pharmaceutical company, based on the notification issued by the president of the JPMA Promotion Code Committee (February 18, 2003, JPMA Notification No. 137).

15.4 Overseas Subsidiary Companies, Licensees and Agencies

When an overseas subsidiary of a member company conducts activities in the relevant country, the member company shall ensure that the overseas subsidiary adheres to the laws and ordinances of the relevant country, in addition to any pharmaceutical organization codes existing within the relevant country, or to the IFPMA Code in the absence of such codes. When a member company has an overseas licensee or agency conduct activities in the relevant country based on a licensing or agency agreement, the member company shall ensure that the overseas licensee or agency adheres to the laws and ordinances of the relevant country, in addition to any pharmaceutical organization codes existing within the relevant country, or to the IFPMA Code in the absence of such codes.

(Commentary)

When a corporation such as a subsidiary established by corporate law or other party over which a member company exercises substantial control engages in activities outside Japan, the member company must see that the subsidiary, etc., complies with the laws and ordinances of the relevant country, in addition to whatever pharmaceutical organization codes are in existence within the relevant country, or the IFPMA Code in the absence of such codes. Moreover, when dealing with licensees and agencies outside Japan, member companies need to require them to comply with the laws and ordinances of the relevant country, in addition to whatever pharmaceutical organization codes are in existence within the relevant country, or the IFPMA Code in the absence of such codes; moreover, it is desirable to stipulate that the other party is obligated to comply with these laws, regulations, and codes in the license or agency agreement.

16. Committee in Charge of the Guidelines for Provision of Sales Information

The Code Compliance Committee, as the JPMA committee in charge of the Guidelines for Provision of Sales Information, will cooperate with the related committees to assist member companies in complying with the guidelines.

(Commentary)

The Guidelines for the Provision of Sales Information stipulate that the following are “actions to be taken by the related organizations”: “Related organizations shall take action for marketing authorization holders to prevent problem cases from occurring by providing the necessary guidance and advice to member companies, without waiting for the administration to take action. This shall entail monitoring the status of sales information provision activities on the part of member companies through the construction of a mechanism for grasping the status of compliance (and in the case of sales information provision activities on the part of contractors and partner companies, this entails monitoring the activities through the member company that is the outsourcer or initiator of the partnership).” Accordingly, the JPMA Code Compliance Committee shall gain an understanding of the status of provision of sales information and of supervision and guidance of member companies, as well as assist member companies in complying with the guidelines by conducting training meetings, etc., as the committee in charge of the Guidelines in cooperation with related committees.

17. Revision, Abolition and Management of Code

17.1 The decision of the General Assembly of JPMA shall be necessary for revision and abolition of the main body of the JPMA Code.

17.2 The management of the JPMA Code shall be performed by the Code Compliance Committee established within JPMA. However, important matters shall be reported to the President of JPMA.

17.3 Apart from those stipulated in the JPMA Code, items necessary for the organization and steering of the Code Compliance Committee shall be prescribed separately.

II-2. Commentary on the Promotion Code for Prescription Drugs

1. Responsibilities of Member Companies in Promotional Activities

Member companies shall assume the responsibility for their promotional activities. In thorough recognition of this principle, member companies shall be required to establish an in-house system to conduct appropriate promotional activities and ensure that all executives and employees comply with it without exception.

Although the Promotion Code obviously applies to promotional activities, it similarly applies to other activities that are regarded as promotion, irrespective of the name or any position of the organization that performs those activities.

(Commentary)

The definition of the word "promotion" is "to engage with healthcare professionals in the provision, collection, and communication of drug information and promote the proper use and adoption of prescription drugs on the basis of those interactions." It includes all activities implemented by member companies that may influence the prescription decisions of healthcare professionals. This includes a broad range of activities that may influence the prescription decisions of healthcare professionals; these include not only drug information activities that medical representatives (hereinafter referred to as "MRs") perform to raise awareness and understanding of drugs but also surveys and information collection activities to ensure the quality and safety of drugs as well as support for studies and research useful in promoting their proper use. In other words, the current situation is one where the sales division and MRs are not the only ones performing the task of promotion. Rather, many organizations within a single pharmaceutical company are involved in promotion under the great objective of realizing appropriate prescribing tailored to the condition of the patient. In particular, new approaches are being taken, such as establishment of a new job type called the medical science liaison (hereinafter referred to as "MSL"), whose role is to conduct medical/scientific exchange with healthcare professionals to provide them information. The ideal mode of providing support to the healthcare community is now being utilized, and it has become necessary for various organizations in each member company to respond to these needs.

Irrespective of the name or any position of the division or organization in charge of the activities, it is considered a promotion unit as long as the member company's executives and employees perform activities that meet the definition of "promotion," and the member company needs to be fully aware that it bears all responsibility for these activities. In addition, member companies must establish their own codes adapted to their own activities and organization in order to ensure that the activities are in line with the spirit of the Promotion Code and to clarify transparency and accountability as a company. They must also establish the internal organization for conducting proper promotion, which should include the following requirements.

(1) Continuously provide executives and employees with the necessary training and education to support the proper use and adoption of drugs.

(Commentary)

Pharmaceutical companies are required to ensure continuous provision, collection, and communication of all requisite information on quality, efficacy, and safety related to the use of drugs to healthcare professionals.

This responsibility is mainly borne by the MRs. The importance of this role is consistently recognized through day-to-day activities, and it is one that is accompanied by high expectations from stakeholders. For this reason, in 1979, the "Education and Training Guidelines for Medical Representatives" were established and are still effective, as detailed in the "Comprehensive Report Relating to the Research Regarding the Status of Medical Representatives of Pharmaceutical Manufacturers" prepared by the Health Science Council Research Project for fiscal year 1990–91 (hereinafter referred to as the "Summary Report").

Only appropriate persons should be assigned to serve as MRs, and an "MR Certification System" was introduced in 1997.

However, since the persons who conduct promotional activities are not limited to MRs, continuous education and training are required for all executives and employees.

The Guidelines for Provision of Sales Information clearly describe the "responsibilities of the person in charge of the provision of sales information" as follows: "The person in charge of the sales information provision activities shall make efforts to achieve self-improvement, beginning with acquiring the necessary knowledge and developing a sense of ethics as well as awareness of the social position of his or her own activities."

The promotional activities concerning generic drugs must be thoroughly communicated within the company based on notifications issued by the president of the JPMA Promotion Code Committee (July 13, 2009, JPMA Notification No. 390; December 25, 2009, JPMA Notification No. 721).

(2) Ensure that the evaluation/remuneration system for executives and employees and others is not an inducement to unethical acts.

(Commentary)

Pharmaceutical companies also have the responsibility to establish fair performance evaluation and remuneration systems to promote proper promotional activities.

The performance evaluation/remuneration system is likely to have substantial effects on the attitude and actions of executives and employees.

Therefore, not only performance as a result of promotional activities but also the attitude and behavior of complying with statutory and regulatory requirements and self-regulations such as the JPMA Code should be reflected in the personnel appraisal of executives and employees. Member companies must avoid adopting an evaluation/remuneration system that may induce executives and employees to commit any excessive sales promotional activities or any actions that may have a negative effect on the proper use of drugs. The Guidelines for Provision of Sales Information clearly state that "The top management of the marketing authorization holder or other entity shall check whether its executives and employees have been able to engage in, and also make others engage in, appropriate sales information provision activities and appropriately reflect the results of the activities in the evaluation of the executives and employees."

(3) Establish the internal systems necessary to comply with laws, ordinances, and self-regulations.

(Commentary)

It is necessary to establish an internal system to ensure compliance with related laws and ordinances 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. Subsequently, in 2011, 2018, and 2023, JPMA revised this Compliance Program/Guideline reflecting the legal changes and trends of compliance in the society and called for member companies to establish their compliance system. The JPMA Code Compliance Committee has 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, and 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 are 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 (JPMA Notification No. 112, dated January 24, 2001), the "Basic Ideas on Enhancement of Internal Review System" issued by the president of the JPMA Promotion Code Committee and chairperson of the Product Information Brochure Review Committee for Prescription Drugs (JPMA Notification No. 53, dated January 28, 2015), the notification by the chairpersons of the Code Compliance Committee and Product Information Brochure Review Committee for Prescription Drugs (JPMA Notification No. 223, dated March 22, 2016; JPMA Notification No. 153, dated March 5, 2019), etc.

Related laws and ordinances include the Pharmaceuticals and Medical Devices Act, Clinical Trials Act, GVP Ordinance, GPSP Ordinance, Antimonopoly Law, Act Against Unjustifiable Premiums and Misleading Representations (hereinafter, "Premiums and Representations Act"), and "Act on the Protection of Personal Information" (hereinafter, "Personal Information Protection Law").

As an administrative notification, the Guidelines for Provision of Sales Information call for the establishment of a division for the supervision of sales information provision activities, responsible for reviewing the materials for use in providing sales information and monitoring the appropriateness of the sales information provision activities.

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 officials 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 parties who have interests with their duties. Therefore, pharmaceutical companies must maintain stronger morality when approaching public officials who may have an interest in pharmaceutical companies.

While, needless to say, member companies must comply with the JPMA Code, compliance with other self-regulations, such as the Fair Competition Code, the Guideline for Product Overview Preparation, and general plan for certification of MRs, is

also mandatory.

2. Fundamentals of Promotional Activities

In promotional activities conducted by their executives and employees, member companies must be fully aware of both their social mission as persons who play a role in healthcare and their positions as executives and employees who provide drug information as representatives of their companies. They are called upon to perform the following duties in a sincere and honest manner:

(Commentary)

In the "Summary Report," MRs are positioned as the "persons who play a part in healthcare." Recently, not only MRs but also employees with various job types such as MSLs conduct promotional activities. Similar to MRs, all persons who conduct promotional activities must be fully aware of both their social mission as persons who play a role in healthcare and their positions as executives and employees who provide drug information as representatives of their companies.

Persons who conduct promotional activities must also be well aware that the attitude and behavior of persons who conduct promotional activities have substantial effects on the image that stakeholders such as healthcare professionals have of pharmaceutical companies.

Furthermore, the phrase "carry out with integrity" includes the word "integrity," which must be fully understood. Integrity means being sincere and cordial. Persons who conduct promotional activities should implement the eight action standards as the "fundamentals of promotional activities" for persons who conduct promotional activities, as described in the subparagraphs, given full awareness of their mission and position. They must implement these action standards with integrity. When conducting medical information activities for healthcare professionals, it is desirable to comply with the Guidelines for Provision of Sales Information and the Q&A on the guidelines as well as conduct promotional activities after fully understanding the current system so that there will be no interference with medical care.

(1) Member companies shall not engage in promotion until approval for the drug is received in Japan. They shall also not endorse off-label uses.

(Commentary)

Article 68 of the Pharmaceuticals and Medical Devices Act prohibits advertising of drug before marketing approval is received. Moreover, Article 66 of the same law prohibits false or exaggerated advertising of products, whether explicit or implicit. Based on these provisions, advertising of indications or dosage and administration that exceeds the scope of approval is prohibited by the "Standard for Adequate Advertisement of Pharmaceutical Products." Accordingly, it is not permissible to engage in promotion before approval is obtained or to recommend off-label use in ways that differ from the approved indications, dosages, or administrations. With regard to the prohibition of information provision before approval and the recommendation of off-label use, it is necessary to ensure that inappropriate promotional activities are not performed with reference to the "examples of unapproved indications and dosage and administration" in the notification issued by the chairpersons of the Code Compliance Promotion Committee and Review Board of Ethical Drug Product Information Brochure (JPMA Notification No. 89, dated February 19, 2020). With regard to the prevention of erroneous transmission of the company's drug information before approval, it is necessary to consider requests made by the chairperson of the Code Compliance Committee (JPMA Notification No. 161, dated April 18, 2023).

Even before obtaining approval, things such as the collection of information necessary for a stable supply of products after approval and proper medical information activities (e.g., market surveys and advisory meetings) conducted to obtain demand forecasts necessary for making production plans, etc., and obtain information essential for appropriate medical information provision activities are not to be interfered with. However, it is required that member companies strictly specify and manage the objectives, targets, implementation departments, timing of implementation, contents of implementation, and other necessary matters with sufficient attention to the fact that these activities can easily be disguised as promotion if the objectives and means are not appropriate.

Not only healthcare professionals but also the general public have the right to know about scientific/medical advancements. Specific cases regarding this are explained in commentary (4) of "2. Fundamentals of Promotional Activities" in "II-2. Promotion Code for Prescription Drugs."

(2) Not only have the knowledge of the content of the digitized package inserts and risk management plans (hereinafter referred to as "RMP"), etc., for drugs sold by their companies, but also strive to acquire familiarity with the medical and pharmaceutical science on which that information is based, as well as cultivate the ability to present such information correctly.

(Commentary)

Digitized package inserts and RMPs, etc., specify the basic information for healthcare professionals in using pharmaceuticals, and the matters to be specified are determined by the Pharmaceuticals and Medical Devices Act. It is obligatory to acquire knowledge of digitized package inserts and RMPs, etc., for own company's products in conducting promotional activities.

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

(3) Conduct promotional activities according to the rules and methods established by their companies.

(Commentary)

Individuals must never prepare materials by themselves and use them. Such practice is problematic since it is not known if the information provided in this manner is objective and comprehensive. It should never happen that information prepared for internal use only, which is inappropriate as promotional materials, is used externally for promotion. Information prepared for internal use must be limited to internal use.

Although originality and ingenuity are encouraged, the procedures for proposing those ideas with originality and ingenuity to the company and implementing them under the responsibility and authorization of the company must be followed.

(4) Provide information on indications, dosage and administration, etc., in a fair and balanced manner in terms of efficacy and safety within the range approved as a drug and in a proper manner based on the most up-to-date scientific data.

(Commentary)

Drugs, except those not requiring marketing approval specified by the Minister of Health, Labour and Welfare, 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 Pharmaceuticals and Medical Devices Act, as well as with the Standard for Adequate Advertisement of Pharmaceutical Products, the Guidelines for Provision of Sales Information, and self-regulations.

Therefore, member companies shall not start promotional activities until the approval is granted or from recommending off-label use.

However, this cannot deprive healthcare professionals, 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 that constitute the provision of sales information are not included in these cases.

(2) The display of scientific exhibition materials about an unapproved drug in accordance with the separate "Guidelines on the Display of Scientific Exhibition Materials for Unapproved Drugs" in a meeting of an international academic society. However, even unapproved drugs must have been approved at least in one other country. They cannot be exhibited if they have not been approved in any country. In addition, such an exhibition may be permitted as an exceptional case, and associated scientific literature and related literature cannot be distributed.

(3) Materials and scientific literature provided in response to the request of a healthcare professional, etc. However, member companies must refrain from making active approaches to induce a healthcare professional and others to request such materials and scientific literature, etc.

(4) The disclosure of medical information to shareholders in accordance with laws and ordinances.
Even when providing such information, member companies must pay sufficient attention to avoiding being perceived as engaging in inappropriate promotional activities for the purpose of generating profit for pharmaceutical companies. Compliance with the Guidelines for Provision of Sales Information is particularly

necessary when providing information on unapproved drugs or off-label use. Moreover, if the information disclosed to shareholders concerns a product under development, member companies must not use it for promotional activities that will not be perceived as information for investors.

Moreover, even in Summary Reports, it is often pointed out that drug information "only emphasizes the advantages of the product and does not touch upon the weaknesses". 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 explanation".

Therefore, in providing drug information, it is necessary that what is written in documents prepared by the company should not merely emphasize efficacy but also impartially provide safety-related information, including information on ADRs, and provide information based on scientific evidence.

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.

(5) Collect and disseminate drug information as accurately and promptly as possible.

(Commentary)

The collection of drug information and communication of the collected results are extremely important since pharmaceutical companies have legal and ethical responsibilities to establish the proper use of drugs.

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.

Delay in the collection of unfavorable information, time-consuming collection of information, or similar conduct by persons who perform promotional activities 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- or safety-related information at the time of approval of a drug has been obtained under certain restrictive conditions.(Note) Moreover, since conditions such as the number of cases differ from the information on adverse events/infections seen under varying post-marketing conditions or extensive use, provision of only efficacy and safety information from the time of approval cannot be considered to be adequate for proper 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. Moreover, an RMP must be established for some of the prescription drugs for which applications are submitted in or after April 2013, and consistent risk management from development through post-marketing is practiced. An RMP is a "living document" in which safety specifications (important identified risks, important potential risks, and important missing information) are stated, along with how "information collection (pharmacovigilance activities)" and "provision of information (risk minimization activities)" for this matter will be organized and reviewed as necessary. It is expected that the use and application of RMPs by healthcare professionals will further enhance and strengthen post-marketing safety measures.

Notes) Examples of "under certain restrictive conditions":

(1) The data are obtained from a limited number of subjects.
(2) The data are obtained from patient populations with restrictions of concomitant medications, complications, or age.
(3) The treatment period is not long.
(4) The physician in charge of the investigation is a specialist for the targeted disease.

(6) Member companies shall not slander and/or defame competitors or competitors' drugs.

(Commentary)

This subject is being taken up because persons who handle prescription drugs, which are life-related products, must conduct themselves as conscientious members of the society and must provide, collect, and disseminate appropriate information.

Slandering and/or defaming other companies and products to promote the use of the company's product will damage the dignity of drugs and pharmaceutical companies, and no decent member of the 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.

Supply of information about other companies or products distributed by other companies by a person who has partial information about the companies or products may mislead healthcare professionals and impair provision of the appropriate 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. Moreover, there must never be cases where companies incorporate expressions unsuitable for inclusion in promotional materials in materials for "internal use only," and they must not provide comparative data emphasizing the superiority of the company product compared to the competing product to healthcare professionals under the pretext that it is "confidential." Such provision of information using "internal-use-only" data can be deemed slander and/or defamation of products distributed by other companies.

Besides the information provision described above, comparison with other companies' products based on scientific evidence is not prohibited. However, even comparison with other companies' products according to scientific evidence needs to be accurate and fair based on promotional materials that have passed review in accordance with the management system specified in "3. Preparation and Use of Promotional Materials" in "II-2. Promotion Code for Prescription Drugs." Further, in using the results of clinical trials performed to compare 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)" (revised and implemented on November 1, 2005). Moreover, if healthcare professionals request the provision of information on other companies' products or comparative information between our company's products and competitors' products, this must be handled in compliance with the requirements of the Q&A specified in "13 Principles for Provision of Sales Information (2) (iv) (Prohibition of Slander of Other Company's Products, etc.)" of (4) with regard to the Q&A on the Guidelines for Provision of Sales Information.

(7) Maintain discipline when visiting a medical institution and abide by the rules of the institution.
(8) Strictly abide by laws and ordinances and self-regulations and behave sensibly.

(Commentary)

Both subparagraphs require persons who conduct promotional activities to conduct themselves in a decent manner. The attitude and behavior of persons who conduct promotional activities have substantial effects on trust in the company, the drug, and ultimately the industry.

Persons who conduct promotional activities and thus handle drugs as life-related products must understand the related laws, ordinances, and self-imposed industry rules and act in compliance with them.

Persons who conduct promotional activities should always be conscious that hospitals and clinics are places of medical care and medical research. Moreover, MRs should follow the rules established by the medical institution, etc. (visiting rules, rules for explanatory meetings, etc.), and refrain from activities and behaviors that may be unpleasant to the hospital staff or patients. Persons who engage in promotional activities shall conduct themselves politely as visitors.

3. Production and Use of Promotional Materials, Etc.

In recognition of the fact that brochures, advertisements in medical journals, websites targeting healthcare professionals, audiovisual materials such as slides and videos, 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 Pharmaceuticals and Medical Devices Act, administrative notifications, and relevant self-regulations such as the Guideline for Product Overview Preparation. The statements contained therein shall be correct, fair, objective, and based on scientific data.

Member companies shall appoint a person responsible for the management of prescription drug brochures, etc., and establish an in-house oversight system so that only promotional materials that have passed through a review are used.

(Commentary)

Regulatory requirements for acceptable scope and proper nature of drug advertisements are provided in Articles 66 to 68 of the Pharmaceuticals and Medical Devices Act and the "Standard for Adequate Advertisement of Pharmaceutical Products". Accordingly, the pharmaceutical industry established the Guideline for Product Overview Preparation and other self-regulations to ensure that product information brochures and advertisements are properly prepared.

As repeatedly emphasized, drug information is indispensable to the use of drugs. The product information brochure for prescription drugs (hereinafter referred to as “product information brochure”) and advertisements are important tools for supplying drug information, and they must be prepared properly to ensure the appropriateness of the contents, expression, and usage and avoid misinterpretation by healthcare professionals. Other promotional materials include visual aids, tablet-type digital content, poster displays or exhibition panels at academic conference venues, and electronic media (e.g., DVD, CD-ROM, internet content, and email).

In the Guideline for Product Overview Preparation, basic items to be included in preparation of materials in routine use are established. Member companies are called upon to bear in mind that even materials that are not mentioned in the Guideline for Product Overview Preparation are subject to not only the Pharmaceuticals and Medical Devices Act but also the Standard for Adequate Advertisement of Pharmaceutical Products, the Guidelines for Provision of Sales Information, and the JPMA Code.

Timely provision of information presented at scientific conferences to healthcare professionals upon request is permitted. Data presented at scientific conferences that are not published in articles can only be published in “collected abstracts of scientific conferences” as “other materials” for information provision in accordance with the Guideline for Product Overview Preparation; again, the materials must be prepared with attention to the Pharmaceuticals and Medical Devices Act and other relevant laws, administrative notifications, and self-regulations. The Guideline for Product Overview Preparation must be followed with respect to the method of preparation for collected abstracts of scientific conferences.

Cited data (including figures and tables) in promotional materials, including advertisements, should correctly convey the true meaning of the original articles and must be carefully written to avoid distortion, exaggeration, unfair emphasis, or deletion that may cause a misunderstanding. They must always be accompanied by notes indicating the sources as the basis for the information. Further, when data of a competitor (studies conducted by the competitor, etc.) are used, consent of the concerned company must be obtained. Moreover, when using the results of questionnaires (in particular, post-marketing questionnaires on safety and efficacy), it is necessary to pay attention to the content of “Re-introduction of Results of Questionnaire Surveys on the Efficacy and Safety of One’s Own Company’s Drugs” (JPMA Notification No. 106 by the Chairperson of the Promotion Code Committee, dated February 22, 2010).

Furthermore, it is essential that the contents and expressions in the product information brochures and advertisements inserted in scientific journals (papers) be proper in accordance with the “review board report” of the Review Committee for Product Information Brochures, as well as with the Guideline for Product Overview Preparation.

Promotional materials such as advertising in direct mail or specialized journals (paper media) must not 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. In particular, because editorial advertising is a type of pharmaceutical company advertisement, member companies must strictly refrain from placing editorial advertisements that recommend off-label use or dosage and administration, or slander/defame the products of other companies. Moreover, inclusion of reference information (on secondary effects, etc.) in editorial advertising is prohibited by the Guideline for Product Overview Preparation.

While complying with the Guideline for Product Overview Preparation for materials that provide drug information to wholesalers, member companies need to cooperate with wholesalers and provide guidance so that the “materials for product promotion” that are prepared and distributed by wholesalers are appropriate.

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. Although described as unapproved drugs, they must have been approved at least in one country. If they have not been approved by any country, no such reference can be made. In addition, such an exhibition may be permitted as an exceptional case, and associated scientific literature and related literature cannot be distributed. This does not apply to the scientific literature provided at the request of a doctor, etc.

In recent years, product-related information provision through the Internet has become more popular. The Internet has always been a means by which all people can freely access information, but when a pharmaceutical manufacturer uses its website to provide healthcare professionals with product-related information, it is required to comply with the related laws and ordinances such as the Pharmaceuticals and Medical Devices Act, the Standard for Adequate Advertisement of Pharmaceutical Products, and the Guidelines for Provision of Sales Information, as well as self-regulations.

As with printed matter, it is necessary to comply with the JPMA Code and self-regulations when preparing content to be provided through websites oriented toward healthcare professionals.

To this end, the JPMA established the “Guidelines for Posting of Content on Web Pages” (JPMA Notification No. 497, dated July 15, 2016), based on the “Proposal Regarding Reconsideration of the Proper Form of Advertising for Prescription Drugs” compiled by the “Study Group on Regulatory Compliance by Pharmaceutical Companies”; moreover, it revised the “Guidelines for Posting Content on Websites” in 2022 (JPMA Notification No. 228, dated August 24, 2022) and 2024 (JPMA Notification No. 340, dated July 19, 2024) in view of subsequent changes in the environment, etc. Since the contents of member companies' websites vary widely, the related department that prepares content must make efforts to share the Guidelines for Posting Content on Websites to employees, understand the spirit of these guidelines, and periodically check the content of their own webpages (JPMA Notification No. 340, dated July 19, 2024).

Product information brochures or advertisements about prescription drugs cannot be delivered to the general public other than healthcare-related personnel (the Standard for Adequate Advertisement of Pharmaceutical Products). Therefore, adequate caution must be exercised to prevent exposure of calendars and posters containing product names to the general public other than healthcare-related personnel when distributing the materials. On the other hand, advertising for disease awareness using television or newspapers and tie-up articles (advertisements) are considered useful in raising awareness of diseases that are not well known, protecting the health of citizens, and contributing to public health. However, depending on how these are presented, they could correspond to the kind of advertising that is prohibited by the Pharmaceuticals and Medical Devices Act; therefore, “Points to Pay Attention to in Disease Awareness Advertising and Tie-up Articles (Advertisements)” have been cited in a notification by the chairperson of the Code Compliance Committee (JPMA Notification No. 6, dated January 6, 2015).

With respect to the product information brochure for prescription drugs and advertisements in scientific journals (papers), an in-house oversight system must be established, centered on the Promotional Materials Officer, and only materials that have passed the review must be used. In addition, an oversight system must be established to ensure 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 issued by the company. Accordingly, member companies must construct solid internal systems of review with reference to the notification by the chairperson of the Code Compliance Committee (JPMA Notification No. 223, dated March 22, 2016; JPMA Notification No. 153, dated March 5, 2019). Moreover, the Guidelines for Provision of Sales Information clearly state: “Materials for use in the provision of sales information must be reviewed by the division supervising sales information provision activities before they are used. The division supervising sales information provision activities shall base approval decisions on the advice provided by the Review and Supervisory Committee.”

Materials for in-house training that are not assumed to be used in outside promotional activities also need to be created and used properly (JPMA Notification No. 307, dated June 6, 2007; JPMA Notification No. 276, dated May 22, 2008).

4. Holding of Seminars and Meetings

Seminars held by member companies for providing medical/pharmaceutical information, disease awareness information, etc., to healthcare professionals shall be held on their own responsibility, and they shall provide specialized academic and scientific information. Appropriate locales and venues for holding seminars and study meetings shall be selected depending on the purpose, and in principle they shall be within Japan. If food and drinks are offered in association with a seminar, they shall not be extravagant and not damage the dignity of pharmaceutical companies. Payments in cash or cash equivalents that are made in connection with holding a seminar shall be limited to travel expenses (transportation expenses, accommodation expenses, etc.) and compensation such as honoraria for the lecturer, and the compensation shall be within the range appropriate and reasonable to the value of service. Individuals accompanying the lecturer shall not receive travel expenses or participate in the social-gathering event.

When providing premiums, etc., member companies shall comply with the Fair Competition Code.

In planning seminars for providing disease awareness information to ordinary consumers who are not healthcare-related personnel, special consideration shall be given to the Pharmaceuticals and Medical Devices Act and the Standard for Adequate Advertisement of Pharmaceutical Products.

Member companies shall not use meetings as a vehicle for promotion, for example, when holding an advisory conference that invites healthcare professionals and others or a meeting for clinical trials, etc., to obtain useful expert knowledge for their activities such as advisory at the time of formulating strategies for products.

(Commentary)

Pharmaceutical manufacturers conduct seminars and study meetings related to their own products for healthcare professionals to provide the latest scientific and academic information simultaneously and efficiently to a large number of healthcare professionals and to enable bidirectional exchange with participants.

It is the responsibility of member companies to fully discuss the details of presentations, whether they are hosting or co-hosting them, by, for example, checking them with lecturers beforehand and complying with the JPMA Promotion Code when holding seminars and study meetings.

Care must be taken so that such meetings are not deemed as recommending the use of unapproved drugs or slandering and/or defaming competitors or competitors' drugs (JPMA Notification No. 593, dated October 6, 2010).

In addition, it is necessary for member companies to appropriately handle materials, etc., used for seminars and meetings, etc., so that they do not deviate from the Guidelines for Provision of Sales Information.

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 exhibit restraint so as not to invite the misunderstanding that they are engaged in unfair business inducement.

The Fair Competition Code also defines the points to be adhered to with respect to seminars and study meetings. When holding seminars and study meetings, pharmaceutical companies must not only comply with the Fair Competition Code but also intensify the scrutiny of conduct to ensure it does not violate the letter of the code, assessing its suitability from the standpoint of their corporate sense of ethics.

At the same time, caution is warranted with respect to seminars for the general public other than healthcare professionals, so that the seminars themselves will not constitute advertisements for prescription drugs.

In addition, IFPMA has prepared the “IFPMA Note for Guidance on Sponsorship of Events and Meetings” to provide additional interpretation and further guidance on the relevant provisions (Article 7.1 Events and Meetings) of the IFPMA Code. IFPMA has also prepared the “Joint Guidance on Virtual and Hybrid International Medical Congresses” that applies to all virtual and hybrid international congresses organized by medical associations/societies that involve healthcare professionals from multiple countries, as well as activities organized by companies at these congresses (e.g., exhibition stands and satellite symposia) with the aim to inform other stakeholders, such as medical associations/societies and third-party organizers, about the arrangements companies should ensure in a virtual and hybrid setting.

5. Supply and Management of Samples

Samples are a means of providing drug information. There are two types of samples: “product samples,” which healthcare professionals can use to confirm the external characteristics of prescription drugs, and “trial-use samples,” which physicians can use to confirm and evaluate the quality, efficacy, safety, and other pharmaceutical particulars of a drug before using it in clinical practice.

Whichever type of sample is provided, it must be accompanied by the relevant prescription drug information, and only the minimum necessary amount should be provided.

In particular, since “trial-use samples” are used in actual clinical practice, a strict system of management shall be constructed and appropriately implemented.

(Commentary)

The Fair Competition Code permits the provision of samples, defining the respective types as follows: “Trial-use 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.” Provision is permitted only for the intended purpose, and provision or use for purposes other than the intended purpose is not permitted.

Insurance claims cannot be filed for trial-use samples. However, when they are provided, they must always be accompanied by information on the relevant drug so as not to induce transactions, and only the minimum necessary quantity should be provided, even when it meets the specifications of the Fair Competition Code.

Under the Fair Competition Code, through a system of management, it is necessary to designate one supervisory “person responsible for trial-use sample management” and to establish one “trial-use sample manager” in each office to exercise proper management at each step, that is, trial-use sample planning, storage, distribution, and provision.

6. Relationship to the Fair Competition Code

Member companies shall more proactively and rigorously comply with the Fair Competition Code.

Member companies shall conduct themselves according to high ethical standards without limiting themselves to mere compliance with the Fair Competition Code.

(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, as well as to ensure voluntary and rational selection of drugs by general consumers and fair and orderly competition among business operators based on the Premiums and Representations Act 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 Promotion Code consists of self-regulations of the pharmaceutical industry that stipulate the responsibilities and fundamentals of promotional activities that must be adhered to by pharmaceutical companies that are members of JPMA when conducting promotional activities for prescription drugs; it also mandates that all executives and employees of JPMA member companies conduct their drug promotional activities in strict compliance therewith. Obviously, proper conduct of promotional activities, as required of pharmaceutical enterprises, includes 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; rather, they must conduct themselves in such a manner that even if there is an act that does not infringe the Fair Competition Code or that is not clearly outlined, they will be moved to re-evaluate its suitability with an even more stringent attitude in accordance with their ethical self-examination.

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. It is essential that member companies conduct their promotional activities while constantly bearing in mind that the society's trust in drugs is the foundation of the pharmaceutical industry's existence.

(Reference) History of enactment and revision of the "Promotion Code for Prescription Drugs" enacted on March 24, 1993; enforced on April 1, 1993
Revised on May 18, 1995; effective on June 1, 1995
Revised on January 10, 1996; effective on February 1, 1996
Revised on March 18, 1998; effective on April 1, 1998
Revised on January 11, 2001; effective on April 1, 2001
Revised on January 7, 2004; effective on April 1, 2004
Revised on September 13, 2006; effective on January 1, 2007
Revised on March 19, 2008; effective on May 23, 2008
Revised on May 16, 2012; effective on September 1, 2012

III. 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. These “Definitions and Commentary on Terms” are part of the JPMA 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 IFPMA Code was approved in 2018. In the 2018 revision, the code revised its previous guiding principles for ethical promotion of prescription medicines and presented the ethos applicable to all member companies of IFPMA and those acting on behalf of them.

IFPMA requires that member companies of its member associations (e.g., member companies of JPMA) and companies that belong to IFPMA must directly comply with the ethical standards set forth in the IFPMA Code; moreover, IFPMA member associations, subject to local laws and regulations, must 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.

Healthcare-related personnel

Healthcare-related personnel refers to persons in charge of medical care, such as doctors, dentists, pharmacists, and nurses, as well as wholesalers and students in departments of medicine and pharmaceutical sciences.

In the Pharmaceuticals and Medical Devices Act and the Standard for Adequate Advertisement of Pharmaceutical Products, the term “healthcare-related personnel” seems to be a broader term than healthcare professionals.

Drug information

Drug information refers to information that is exchanged between pharmaceutical companies and healthcare professionals to promote the proper use of drugs. Drug information is scientific, medical, and pharmaceutical information, and it is strongly required to be accurate, fair, objective, and based on scientific evidence. It is also important that the information is kept up-to-date.

Medical Representatives (MRs)

MRs are defined by the Guidelines for the Certification of MRs of the MR Certification Center of Japan, a public interest incorporated foundation, as “persons who represent the company and mainly provide, collect, and disseminate information on the quality/efficacy/safety of drugs through meetings or information exchanges using digital tools with healthcare professionals, to promote proper use of drugs and improve pharmacotherapy.” Moreover, the website of the MR Certification Center of Japan also uses the wording “drug information experts who handle information on the quality, efficacy, safety, etc., of drugs to contribute to proper use of their own company’s drugs and improvement of pharmacotherapy.”

Article 2-4 of the GVP Ordinance provides the following definition: “In this Ministerial Ordinance, ‘medical representatives’ refers to persons who meet healthcare professionals to mainly collect and supply safety control information to contribute to proper use of drugs.”

Drugs and Medical Devices Law

The formal title of this law is “The Law on Securing Quality, Efficacy and Safety of Products Including Pharmaceuticals and Medical Devices”. It is a revised version of the former Pharmaceutical Affairs Law, and it became effective on November 25, 2014.

The Pharmaceuticals and Medical Devices Act was enacted for the purpose of promoting the improvement of health and sanitation by establishing the necessary regulations to ensure the quality, efficacy, and safety of pharmaceuticals, quasi-drugs, cosmetics, medical devices, and regenerative medicine products and prevent the occurrence and spread of health hazards caused by their use while at the same time establishing measures for the promotion of designated drugs as well as measures necessary for the promotion of research and development of pharmaceuticals, medical devices, and regenerative medicine products for which there is an especially high level of medical need.

In particular, when disseminating information, member companies are expected to comply with the provisions of the Pharmaceuticals and Medical Devices Act, that is, parts of Chapter 10, “Advertisement of Pharmaceuticals, etc.,” that pertain to “exaggerated advertising, etc.” (Article 66); “limitations on advertising of drugs and regenerative medicine products for designated diseases” (Article 67); and “bans on advertising of pharmaceuticals, medical devices, and regenerative medicine products that have not yet been approved” (Article 68). For violators of the provisions of “exaggerated advertisements, etc. (prohibition of false or exaggerated advertisements),” an administrative monetary penalty payment system (Article 75-5(2)) was newly enforced in August 2021.

Standard for Adequate Advertisement of Pharmaceutical Products

The “Standard for Adequate Advertisement of Pharmaceutical Products,” was entirely revised based on the notification issued by the Pharmaceutical Safety and Environmental Health Bureau: “Re-revision of the Standard for Adequate Advertisement of Pharmaceutical Products” (PSEHB 0929 Notification No. 4, dated September 29, 2017). Accordingly, we are called upon to not only comply with the Pharmaceuticals and Medical Devices Act but also engage in information dissemination activities with a full understanding of the content and tenor of this notification.

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 the Pharmaceutical Affairs Bureau, Ministry of Health and Welfare, “Council on the Proper Role of Drugs in 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.”

Unless drugs are used properly, they are not expected to exert their efficacy. The effects they exhibit can even be dangerous. Proper use is something essential to 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.

WHO Ethical Criteria for Medicinal Drug Promotion

(Ethical Criteria for Medicinal Drug Promotion)

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

The main objective of the WHO criteria is to “support and encourage the improvement of healthcare through the rational use of medicinal drugs.” The WHO criteria 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.”

The WHO criteria apply to both prescription and non-prescription medicinal drugs (over-the-counter drugs), and it is recommended that they be adopted by governments, healthcare professionals, patients, consumer organizations, educational organizations, and the general public.

Risk Management Plan (RMP)

(Risk Management Plan)

To ensure the safety of drugs, it is important to assess measures for appropriate management of the risks of drugs consistently, from the development phase to the regulatory review and post-marketing phases. The risk management plan (RMP) is a document that describes the risk management of drugs from the development phase to the post-marketing phase. The RMP aims to evaluate the drugs' risks at regular intervals, or in response to the progress of post-marketing surveillance and pharmacovigilance activities, to minimize these risks. It is expected that further enhancements of post-marketing safety measures will be ensured by publishing the RMP and sharing the information on risk management with healthcare professionals.

Healthcare professionals

"Healthcare professionals" refers to "persons who are engaged in medical care with certain qualifications such as physicians, dentists, pharmacists, nurses, public health nurses, midwives, 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 workers), and nursing care support specialists (care managers)."

Moreover, if it is necessary to cooperate with officers and employees of the government and medical institutions or provide medical information from the viewpoint of access to medical care or prevention of diseases, such officers and employees shall be handled similarly to healthcare professionals.

Elsewhere, the Medical Service Law uses the term "healthcare professionals," the Fair Competition Code uses the term "healthcare service providers," and the IFPMA Code uses the term "healthcare professional" as follows according to the intent of the establishment:

(1) Medical Service Law: The term "healthcare professionals" is used in the sense of "doctors, dentists, pharmacists, nurses, and other persons engaged in medical service."
(2) 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."
(3) IFPMA Code: "Healthcare professional" means any member of the medical, dental, pharmacy, or nursing profession or any other person who in the course of his or her professional activities may prescribe, recommend, purchase, supply, sell, or administer a pharmaceutical product," and this term is used in essentially the same sense as in the JPMA Code.

Medical institutions

"Medical institutions" signify facilities that provide medical care under the Medical Service Law, such as hospitals, clinics, long-term care facilities, and other facilities that provide medical care.

Advertisement of prescription drugs

False or exaggerated advertisement of drugs, advertisement of anticancer agents and the like to ordinary persons, and advertising of drugs before they have been approved are prohibited by Articles 66 through 68 of the Pharmaceuticals and Medical Devices Act. The text is summarized as follows:

Article 66 of the law: No one may, explicitly or implicitly, make false or exaggerated advertisements regarding the drugs, etc. No one may make advertisements in editorial articles that could be misinterpreted as a guarantee of indications or effects by a doctor or other person. No one may imply that a drug, etc., may be used to perform an abortion, or use obscene text or images in connection with a drug.

Article 67 of the law: No one may make advertisements of drugs for the treatment of cancer and other specific diseases specified by government ordinance to the general public other than healthcare-related personnel.

Article 68 of the law: No one may make advertisements of unapproved drugs, etc.

Member companies

Refers to the member companies that belong to JPMA. The member companies of JPMA consider it their mission to contribute to improvements in the health and welfare of people in Japan and throughout the world through the development of safer, innovative, and highly useful pharmaceuticals. To support appropriate medical care that is ethical and patient-oriented, JPMA calls upon member companies to build mutual relationships of trust with researchers, healthcare professionals, and patient organizations through appropriate industry-academia collaborations.

Patient organizations

"Patient organizations" refer to patient associations or patient support groups that are composed mainly of patients, their families, and supporters, irrespective of their operating structure and whether or not they have corporate status. They represent the voice of the patients with the goal of mutual support for patients and their families as well as improvement of the care environment; in principle, their roles and objectives are defined by their articles of incorporation and regulations.

International Federation of Pharmaceutical Manufacturers & Associations (IFPMA)

(International Federation of Pharmaceutical Manufacturers & Associations)

The International Federation of Pharmaceutical Manufacturers & Associations (IFPMA: Geneva, Switzerland) is a non-profit non-governmental organization established in 1968 representing industry organizations and research-oriented global pharmaceutical companies located in developing and industrialized nations throughout the world. JPMA acts as one of the key members of the IFPMA.

The IFPMA has adopted the IFPMA Code of Practice (defined below), which 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.

JPMA Compliance Program Guidelines

JPMA presented the 2001 JPMA Compliance Program Guidelines to member companies as guidelines to instruct their executives and employees in how to comply with corporate ethics and laws and conduct themselves properly so as to prevent corporate scandals. Each member company is also required to establish its own compliance program. The JPMA Compliance Program Guidelines were revised in 2005, 2011, 2018, and 2023 to reflect the revision of the Keidanren Charter of Corporate Behavior and newly enforced or revised laws and ordinances.

A compliance program is a "program or system for complying with laws and ordinances and adopting behavior that is in line with corporate ethics". The JPMA Compliance Program Guidelines are to be utilized by member companies as "guidelines for reviewing laws/ordinances, code of conduct on corporate ethics, and compliance-related regulations that executives and employees should obey" from the standpoint of compliance, and they have the objective of minimizing risk to businesses from misconduct and to enhance corporate value.

Company code

Pharmaceutical companies engaged in research & development, production, and supply of drugs as life-related products are required to have high ethical values. This means that member companies are called upon to comply with laws and ordinances and self-regulations, as well as to adopt the attitude of spontaneously responding to the society's demands and expectations. This attitude of voluntary compliance is clarified by the "company code". It is important for each member company to establish its own "company code" that reflects the JPMA Code while adding elements of its own management philosophy and other unique provisions to make it more concrete and specific. The "company code" also has the character of basic guiding principles for the company's exchange with all stakeholders, beginning with healthcare professionals, medical institutions, patient organizations, and wholesalers.

Post-marketing studies

"Post-marketing studies" refer to 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, Paragraph 1 or Paragraph 139 (including cases where it is applied mutatis mutandis to Article 19-2, Paragraph 5), or Article 19-2, Paragraph 1, of the Pharmaceuticals and Medical Devices Act. The aim is to verify the assumptions, etc., obtained by the marketing approval holder as a result of clinical trials, clinical experience investigations, or post-marketing database survey, or to collect information on quality, efficacy, and safety that cannot be obtained through routine clinical practice.

World Health Organization (WHO)

(World Health Organization)

It is one of the United Nations' specialized agencies. It was established in 1948 to take charge of the field of health with the goal of enabling all people to achieve the highest possible level of health. WHO has 190 member nations throughout the world, and it is composed of a general assembly, which meets annually in Geneva, Switzerland, and a board of directors and secretariat. Japan has been a member of WHO since 1951.

Social Media

"Social media" refers to media formed through 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 a large, unspecified number 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 has 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 light of the Pharmaceuticals and Medical Devices Act, the Standard for Adequate Advertisement of Pharmaceutical Products, the Guidelines for Provision of Sales Information, the JPMA Code, etc., to ensure that no untoward consequences are invited.

Clinical trials

Clinical trials are clinical studies performed in order to obtain marketing approval for drugs, medical devices, extracorporeal diagnostic agents, regenerative medicine products, etc. It refers to conduct of studies for the purpose of collecting data on the outcome of clinical studies among the materials to be submitted to the reviewing authority in connection with an approval application (Pharmaceuticals and Medical Devices Act, Article 2-17).

Transparency

[Transparency of relationship with medical institutions, etc.]

Industry-academia collaboration between pharmaceutical companies and medical institutions, etc., is essential for the development of medicine and pharmacy and the spread of proper use. However, the more this collaboration flourishes, the more deeply medical institutions and healthcare professionals may become involved in specific companies and products, raising suspicion that pharmaceutical companies may have some sort of influence on the judgment of medical institutions, healthcare professionals, etc.

Since pharmaceutical companies represent a life-related industry conducting activities under the public health insurance system, the Medical Institutions Transparency Guidelines were approved at the General Assembly of JPMA in January 2011 based on the concept that transparency of activities is more important in the pharmaceutical industry than in any other industry. In response, member companies have also formulated their own guidelines based on which they have disclosed information. The Medical Institutions Transparency Guidelines were revised in October 2018 in line with the enforcement of the Clinical Trials Act which stipulates mandatory publication of information on provision of research funds or other benefits, which led to further improvement of transparency. As social conditions change, there will be a need for every greater transparency.

[Transparency of clinical study information]

The IFPMA Code, revised in 2012, calls for transparency of clinical study information in "9. Clinical Studies and Transparency." Moreover, the provisions of both the "Joint Position on the Disclosure of Clinical Trial Information via Clinical Trial Registries and Databases" (revised in 2018) and "Joint Position on the Publication of Clinical Trial Results in the Scientific Literature" (revised in 2017) issued by IFPMA, PhRMA, EFPIA, and JPMA require transparency of clinical study information. The IFPMA Code also specifies in "9. Clinical Studies and Transparency" that all research including clinical studies and observation research conducted on human subjects, not limited to post-marketing surveillance, etc., must have a legitimate scientific purpose and must not be disguised as promotion. Member companies of JPMA need to comply with the above two joint guidelines in their approach to transparency of clinical studies.

[Transparency of relationship with patient organizations]

In 2007, EFPIA adopted the "Standards of Conduct for the Relationship Between the Pharmaceutical Industry and Patient Organizations." The revised 2012 version of the IFPMA Code also includes provisions that elucidate the nature of alliances with patient organizations under Section 11, "Exchange 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 are also 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 increase transparency by complying with the "Guidelines on Collaboration with Patient Organizations" (established in January 2013) and "Guidelines on Transparency of the Relationship Between Corporate Activities and Patient Organizations" (established in March 2012).

Guidelines on Provision of Sales Information

The supervision and monitoring of prescription drug advertising (supervision of the provision of prescription drugs' sales information since 2019) has been conducted since 2016 as a commissioned project of the Compliance and Narcotics Division of the Ministry of Health, Labour and Welfare's Pharmaceutical Safety and Environmental Health Bureau ("Compliance and Narcotics Division of the Ministry of Health, Labour and Welfare's Pharmaceutical Safety Bureau" since September 2023). This project has reported activities that affect or could affect the proper use of prescription drugs. In response to these reports, the Ministry of Health, Labour and Welfare issued the "Guidelines for Provision of Sales Information on Prescription Drugs" (PSEHB Notification No. 0925-1, dated September 25, 2018) to promote the improvement of environmental health by regulating advertising and activities similar to advertising that are conducted while providing sales information on prescription drugs.

Member companies are called upon to comply with these guidelines when engaging in the provision of sales information on prescription drugs (activities that either actively or passively provide information on prescription drugs with the expectation of promoting sales by improving name recognition of a specific prescription drug or awareness of its efficacy and safety).

Non-clinical studies

Non-clinical studies are usually performed to evaluate the safety and efficacy of a drug using animals, cell lines, etc., before the start of clinical studies (clinical trials) in the development of a drug. They include pharmacokinetic studies (ADME), pharmacological/effectiveness studies, and safety studies (toxicity studies). Their results must be in compliance with Article 43 of the Enforcement Regulations of the Pharmaceuticals and Medical Devices Act (Criteria for the Reliability of Application Materials). In particular, Good Laboratory Practice (GLP) standards are established for safety studies under the MHLW Ministerial Ordinance.

Medical science liaison (MSL)

(Medical Science Liaison)

An individual who belongs to an organization independent of the sales divisions and whose main role is to interact with external experts in the medical or scientific fields.

Conflict of interest (COI)

When medical research is conducted through industry-academia collaboration, individual researchers have the social responsibility to secure research integrity and protect the lives, safety, and human rights of patients and subjects (public interest); they also have an obligation to the pharmaceutical companies funding the research in terms of the financial benefit obtained through conducting medical research (private interest). “Conflict of interest” (COI) refers to the conflicting obligations or opposition/conflicts of interest that can inevitably occur for individual researchers. Medical research conducted through industry-academia collaboration can be said to involve conflicts of interest from the standpoint of form, and it is not the case that the conflict of interest itself is the problem. Rather, the issue is whether fair and appropriate judgment is compromised as a result of the conflict of interest. How the conflict of interest is managed is important in avoiding such lapses of judgment.

Clinical Trials Act

The Clinical Trials Act (2017 Law No. 16) was enforced on April 1, 2018, to contribute to the improvement of environmental health by promoting the conduct of clinical research and securing the trust of clinical trial participants and the greater public in clinical research through the establishment of procedures for clinical trials, measures for the appropriate review and stating of official opinion by the Certified Review Board, a system for the public announcement of information related to funding for clinical trials, etc.

This law obligates marketing authorization holders and other entities to enter into agreements for the funding of specified clinical trials as defined by the law, and to publicly announce information related to research funding, etc.

Ethical guidelines

The Ministry of Education, Culture, Sports, Science and Technology and the Ministry of Health, Labour and Welfare originally established the “Ethical Guidelines on Clinical Research” (MHLW Notification No. 415, dated July 31, 2008) and “Ethical Guidelines on Epidemiological Research” (Joint MEXT/MHLW Notification No. 1, dated April 1, 2013) to ensure that researchers protect the dignity of human beings and their human rights when conducting clinical research, epidemiological research, and other medical research involving human subjects, as well as enable the research to be conducted smoothly and properly. These two sets of guidelines were reviewed by the two ministries and integrated into the “Ethical Guidelines on Medical Research Involving People” (Joint MEXI/MHLW Notification No. 3, dated December 22, 2014), which came into effect on April 1, 2015 (the two original sets of guidelines were abolished as interim measures as of March 31, 2015). Moreover, It was specified that both the “Ethical Guidelines on Medical Research Involving People (Medical Guidelines)” and “Ethical Guidelines on Human Genome and Genetic Analysis Research (Genome Guidelines)” (Joint MEXT/MHLW/METI Notification No. 1, dated November 25, 2014) should be reviewed as needed or around five years after their enforcement. For this reason, the Ministry of Education, Culture, Sports, Science and Technology, the Ministry of Health, Labour and Welfare, and the Ministry of Economy, Trade and Industry, which are in charge of the guidelines, established a joint meeting for the review of these guidelines in August 2018, considered further improvement of the system, and prepared and released a summary of the review in January 2020. In response to the summary that stated that both guidelines can be integrated after considering the points to note as a result of examining the consistency of the items commonly prescribed in both guidelines, these guidelines were newly integrated as the “Ethical Guidelines for Medical and Biological Research Involving Human Subjects” (Guidelines for Life and Medical Sciences; MEXT, MHLW, METI Notification No. 1, dated March 23, 2021). (Both Guidelines were abolished on June 30, 2021.)

Depending on the content of clinical research, epidemiological research, or other medical research with human subjects, member companies may be required to comply with ethical guidelines such as the “Ethical Guidelines for Medical and Biological Research Involving Human Subjects” and “Guidelines on Clinical Research into Gene Therapy, etc.” (MHLW Notification No. 344, dated August 12, 2015).