# Nippon Kayaku Code of Practice

（Background to code establishment and revisions）

The Japan Pharmaceutical Manufacturers Association (hereafter: “JPMA”), in line with the spirit of the International Federation of Pharmaceutical Manufacturers and Associations (hereafter: “IFPMA”) Code of Practice (hereafter: “IFPMA Code”) announced in March 2012 and covering drug promotions as well as relations with medical professionals, medical institutions and patient organizations, built upon its existing Promotion Code for Prescription Drugs to determine its JPMA Code of Practice (hereafter: “JPMA Code” in April 2013.

In relation to the above business activities, JPMA member Nippon Kayaku (hereafter: “our company”) forever ensures high standards of ethics and transparency. We are accountable for forging appropriate relations for the benefit of information-sharing by all our executives and employees with society’s stakeholders, such as medical researchers involved in medical, dental and pharmacological research, medical professionals, wholesalers and patient organizations (hereafter: “stakeholders”), and thereby undertakes the responsibility to repay public trust.

Integrity is essential to such relationships, with trust in decision-making that prioritizes patient benefits being constantly demanded. Hence, so as to determine whether our company’s actions are in line with the spirit of the JPMA Code, we have determined and implemented our own Nippon Kayaku Code of Practice (hereafter: “this code”).

As the JPMA, in September 2019, revised its JPMA Code in response to IFPMA Code updates and the application of newly-fixed Guidelines for Provision of Sales Information for Prescription Drugs (hereafter: “Sales Information Provision Guidelines”), our company also made revisions and implementations in accordance with this new JPMA Code.

Thus, on this occasion, in order to achieve coherence with the IFPMA Code and Sales Information Provision Guidelines, we have revised our own code by reassessing the JPMA Code’s definition of “promotion”, and reorganizing contents so as to eliminate duplications with JPMA Code regulations.

Our company has also clarified its Corporate Ethics, which serve as the bedrock of business activities, and has already fixed its Nippon Kayaku Group Charter of Conduct and Code of Conduct to serve as a code to ensure high ethical standards at both organizational and individual employee level.

In relation to prescription drug promotion activities, we have also made our Nippon Kayaku Pharmaceuticals Division Promotion Code for Prescription Drugs (hereafter: "Promotion Code") conform to the JPMA Promotion Code for Prescription Drugs, and have already installed this among our internal regulations.

Our company shall continue to operate this code in tandem with its Nippon Kayaku Group Charter of Conduct and Code of Conduct and the above-mentioned Promotion Code.

(Pharmaceutical company ethics)

Generally, there are times when competition between companies tends to become immoderate. It cannot be denied that in previous times such tendencies were observed in drug promotions. That is why, starting with the Act on Securing Quality, Efficacy and Safety of Products Including Pharmaceuticals and Medical Devices (hereafter: the "Pharmaceuticals and Medical Devices Act" (PMD Act)),the industry of today has witnessed the fixing of various laws, regulations and standards such as: the Revision of the Fair Practice Standards for the Advertising of Drugs and Related Products, etc. (hereafter: "Fair Practice Drug Advertising Standards"), the Sales Information Provision Guidelines, the Fair Competition Code on the Restriction of Provisions of Premiums in the Pharmaceutical Drugs Industry (hereafter: "Fair Competition Code"), the Guidelines for Preparation of Prescription Drug Product Outlines (hereafter: "Preparation Guidelines"), and the MR Accreditation Guidelines.

As is commonly known, drugs can be described as follows:

（1） Their true nature cannot in any way be known simply from their appearance

（2） They produce both effects and side-effects, whose manifestation reveals their individual differences

（3） Consequently, they cannot possibly function as drugs without proper information

（4） They are used solely by patients who are undergoing necessary treatment

As such, it is necessary to observe the numerous laws, regulations and standards with respect to the aforementioned points.

On the other hand, the increasingly diversified and complicated environment in which pharmaceutical companies operate has given rise to phenomena which cannot be properly managed by conventional ways of thinking and methods. Additionally, when it comes to relations between pharmaceutical companies and medical professionals, society demands ever more fair, impartial and transparent actions. Against such a backdrop, blind pursuit

of actions which ignore the essence of drugs lead to health hazards and unnecessary dosages, in turn liable to cause significant damage to patients and society at large. Consequently, we will, by our own hand, greatly damage overall public trust in drugs and the wider industry, leading to undesirable outcomes for both businesses and society. We can only conclude that businesses have nothing to gain from such actions, and everything to lose. That is why our company, as a JPMA member, cannot be a mere observer of laws and voluntary standards, but must be prepared to place added importance on the background and objectives of policy to reflect the image of a pharmaceutical company that society expects.

It is therefore easy to grasp why business activities based on such ethical perspectives form an irreplaceable base on which to build public trust for drugs and their manufacturers. You can grasp this yet more easily from the standpoint of an individual patient or citizen looking at a pharmaceutical company. The individual, as a member of the community to which they belong (be that the household, the workplace, or the locality) naturally assumes a role in which others expect things of them. Society is therefore constructed on the premise that individuals mutually fulfil roles expected of them by each other, and any society in which that principle is damaged faces breaking down.

This very concept can be applied to a company. When it comes to drugs, regardless of whether there are laws or voluntary standards such as those mentioned above, society's individuals undergo medical treatment on the premise that high-quality drugs will be appropriately used. Which is why Corporate Social Responsibility (CSR) must be accepted as an important proposition, especially in the pharmaceuticals industry.

The character 倫 in the Japanese word for "ethics" represents the mutual expectations tied up in human relations and social relations. As a JPMA member, our company is not demanded to be a mere observer of laws and voluntary standards, but to proactively respond to society's demands and expectations.

**The basic principles of business activities**

As part of the life science industry, our company shall acknowledge that it operates under the public medical insurance system and therefore has a core responsibility to observe the following basic principles.

**Basic principles**

○ Progress in medicine, pharmacology and bioengineering, and improvements in public health are derived from interactions between stakeholders, JPMA member companies, and the entire medical community which are conducted with the objective of providing

information. As integrity is indispensable to such interactions, we shall ensure ethical decision-making occurs with the top priority placed on patient benefits.

○ So as to guarantee appropriate interactions with stakeholders, we shall observe a Code of Conduct based on high ethical standards as we carry out the mission of greatly contributing to public health both domestically and internationally.

○ When conducting business activities, while observation of the PMD Act and related legislation, the Fair Practice Drug Advertising Standards and the Sales Information Provision Guidelines is a given, we shall also comply with voluntary standards such as the Fair Competition Code, the Pharmaceutical Company Ethical Guidelines, and the JPMA's Code of Conduct and Compliance Program Guidelines, as we conduct our business activities with high ethical standards.

## Chapter 1: Definition of "scope" and "promotion"

### 1．1 Scope

The JPMA Code not only covers prescription drug promotion activities but applies to all interactions between JPMA member companies and researchers, medical professionals, medical institutions, patient organizations and wholesalers. Based on the JPMA Code, our company has fixed this code to serve as a code of conduct for all executives and employees, and observes it in addition to the Code of the IFPMA, to which the JPMA subscribes. Whether specifically mentioned in this code or not, our company constantly judges its actions based on whether they conform to the spirit of this code.

### 1．2 Definition of "promotion"

A "promotion" shall be defined as: "seeking to expand the appropriate use of prescription drugs through the provision, collation and transmission of medical information to medical professionals," and covers all company actions that may influence the prescription decisions of medical professionals.

## Chapter 2: Responsibilities of Top Management

Top management shall:

（1） Demonstrate an awareness that their role is to act based on the Basic Principles of this code, and, leading by example on matters determined in this code, assume top management responsibility for all executive and employee actions, as well as

improve awareness among related persons and prepare the relevant internal company systems

（２） In situations in which the spirit of this code has been violated, see it as their responsibility to involve themselves in problem-solving, root cause investigations and reoccurrence prevention measures

（３） Undertake companywide activities that ensure compliance with the spirit of this code even in sections outside of those responsible for drugs

（４） Ensure compliance with this code from domestic subsidiary companies involved in the manufacture and sale of drugs

（５） In observing this code, provide relevant explanations and demand relevant understanding from parent, partner and subsidiary companies involved in the manufacture and sale of drugs both domestically and overseas

## Chapter 3: The basis for relations

### ３．１ The basis for relations

The development of medicine, pharmacology and bioengineering, and improvements to public health are built upon interactions (relations) between the entire medical profession (researchers, medical professionals, patients, wholesalers) conducted with the aim of sharing information. Integrity is indispensable to such relations. As society demands that such relations can be trusted to yield ethical decision-making that prioritizes patient benefits, our company acts in ways as to be constantly trusted by authorities, medical professionals and patients to conduct ethical activities.

### ３．２ Transparency of relations

As the pharmaceuticals industry, being a life science industry, is demanded to have high ethical standards, our company must be accountable for the sincerity and ethicality of its relations with researchers and medical professionals, and its collaborations with patient organizations.

Our company shall therefore appropriately fulfil its accountability to society through ensuring business activity transparency in accordance with our own policy based on the JPMA Transparency Guidelines on Relations between Business Activities and Medical Institutions (hereafter: Medical Institution Transparency Guidelines), the Guidelines on Collaboration with Patient Organizations (hereafter: Patient Organization Collaboration Guidelines), and the Transparency Guidelines on Relationships between Business Activities and Patient Organizations (hereafter: Patient Organization Transparency

Guidelines).

## Chapter 4: Relations with Medical Professionals

Our company's relations with medical professionals shall be deemed to prioritize contributions to patient benefits, health and welfare, with the objective of aiding the development of medicine, pharmacology, bioengineering, and the improvement of public health. Such relations shall involve placing emphasis on the provision of drug information, academic exchanges related to medicine, pharmacology and bioengineering, and support for research. Furthermore, in order to aid the development of medicine, pharmacology and bioengineering, our company, even in instances of industrial-academic collaboration, shall construct relationships of trust with researchers, medical professionals and patients. We shall conduct no business activities which inappropriately affect prescription decisions.

## Chapter 5: Outlawing the provision of information pre-approval and encouragement of off-label use

Inside Japan, no drug promotions shall be conducted at a pre-approval stage. It is also forbidden to promote off-label use.

## Chapter 6: Transmission of Information

As a life science industry company, we shall provide, as appropriate, scientific and objective information related to prescription drugs. When presenting such information, we shall not only strive for reader-friendly contents and expressions, but ensure we comply with laws and voluntary standards. Additionally, the PMD Act and Fair Practice Drug Advertising Standards forbid the advertising of prescription drugs to anyone other than medical professionals. Accordingly, it is incumbent on our company, whether issuing press releases, conducting disease awareness activities directed at the general public, or presenting information to investors, to conduct careful examination of contents from the planning stage to ensure there is no advertising of prescription drugs or of off-label use for non-approved drugs within. The Promotion Code for Prescription Drugs governs our information transmissions to medical professionals.

### 6．1　Promotion Materials（including digital ones）

Our company shall create promotion materials (including digital ones) (hereafter: "promotion materials") in line with related laws, regulations and voluntary standards such as creation guidelines.

### 6．2　Social Media

When making use of digital communications such as so-called social media, our company shall take full responsibility for the contents communicated. Accordingly, in tandem with related subsidiaries, parent companies, partner companies, planning companies, agencies and employees, we shall only conduct such activities after confirming their compliance with this code.

## Chapter 7:　Staging seminars and conferences

Our company is able to stage seminars with the objective of presenting medical, pharmacological, or disease awareness information. Furthermore, in order to gain useful academic observations on our business activities, we are able to convene conferences which gather medical professionals. When setting up seminars or conferences for medical professionals, we shall observe related laws, the Fair Competition Code, and the Promotion Code for Prescription Drugs.

## Chapter 8:　Subcontracting

Our company is allowed to pay remuneration and expenses to researchers, medical professionals, medical institution and patient organizations in circumstances concerning the subcontracting of research, clinical trials, postmarketing surveillance, consultation or advisory services, participation in conferences, chairmanship or guest speaker roles at seminars, and work to research professors. However, such subcontracting must involve the exchange of contracts which shall meet the standards expressed below.

（1） Contracts exchanged shall take the form of a document which states the objective of the work and the basis for the relevant remuneration and expenses

（2） The justification for the work in question must be clearly specified prior to subcontracting.

（3） The subcontractor must be directly related to the specified need, and must possess the necessary specialist knowledge for the work in question.

（4） The number of persons subcontracted shall be that which is reasonable for

meeting the specified needs in question

（５） There shall be no inducement to prescribe, purchase or promote specified drugs

（６） Remuneration for the subcontracted work shall consist of a reasonable price for such work commensurate with the market rate.

Furthermore, the subcontracting of work shall involve observing the rules of the subcontractor in addition to related laws and the Fair Competition Code. Remuneration and expenses disbursed for the work in question shall be publicly released in line with our company's policy based on the Medical Institution Transparency Guidelines and Patient Organization Transparency Guidelines.

## Chapter 9: Provision of goods and money

Whether directly or indirectly, our company shall not offer the following goods or monies to stakeholders such as researchers, medical professionals, medical institutions, patient organizations and wholesalers.

（１） Goods or monies liable to inappropriately influence decision-making (including items which affect appropriate use of drugs)

（２） Goods which damage drug quality

（３） Goods and monies for which the company would struggle to gain public understanding or agreement

## Chapter 10: Setting up trials, research activities, postmarketing safety management work and postmarketing surveillance

### １０．１ Trials and research activities

Trials and research activities in the form of, for example, epidemiology, non-clinical trials, clinical research and clinical trials (clinical trials and postmarketing clinical trials) must, at the various stages, exhibit high ethical standards and justifiable scientific objectives that conform to laws and ethical policies. Research expenses and academic research grants arising from such trials and research are covered by the Medical Institution Transparency Guidelines, and appropriate accountability must be shown in line with those guidelines.

Furthermore, so as to ensure the transparency of clinical trial information, our company shall publish such information in line with the joint policy issued by the JPMA, IFPMA, and the European Federation of Pharmaceutical Industries and Federations (hereafter: EFPIA), along with the Pharmaceutical Research and Manufacturers of

America（hereafter: “PhRMA”）, namely: the Joint Position on the Disclosure of Clinical Trial Information via Clinical Trial Registries and Databases (revised 2018 and the Joint Position on the Publication of Clinical Trial Results in the Scientific Literature (revised 2017).

In order to minimize as best as possible the side-effects of drugs, we shall not only develop safer and effective drugs, but demonstrate appropriate self-management from an animal welfare perspective of animals necessary for testing during such development, and move forward with yet better preparation of our R & D system.

**10.2: Postmarketing safety management work and postmarketing surveillance**

Our company properly recognizes the objective of establishing appropriate use of drugs postmarketing, and that postmarketing safety management work and postmarketing surveillance must have scientific grounding as well as be observant of laws and voluntary standards. Such activities must not, however, serve as methods for sales promotion.

## Chapter 11: Collaboration with patient organizations

Our company, in its various collaborations with patient organizations, shall conduct itself with high ethical standards and respect the independence of said organizations. We must also work towards mutual understanding of the aims and contents of collaboration with patient organizations. To that end, in instances of collaboration with patient organizations, our company shall sincerely operate our own internal policy decided in line with Patient Organization Collaboration Guidelines.

Our company shall also openly disclose information pertaining to financial support provided to patient organizations, so as to gain widespread understanding of the fact that these actions contribute to both the activities and development of those organizations in line with guaranteed high ethical standards. Our company therefore discloses such information according to the Patient Organization Transparency Guidelines.

Regarding activity types and provision of funding when collaborating with patient organizations, we first exchange contract documents and agreements stating objectives and contents so as to guarantee transparency records.

## Chapter 12: Relationships with wholesalers

Relationships between pharmaceutical companies and wholesalers must conform to

laws and voluntary standards such as the Act on Guaranteed Antimonopoly Practices and Fair Trading (hereafter: the “Antimonopoly Act”). They must also take into account the fact that trading takes place under the public health insurance system and therefore requires the guaranteeing of relations that exhibit higher ethical and transparency standards than those of other industries. Accordingly, when either offering or receiving monies, goods and food and drink to or from wholesalers, our company shall determine and observe its own voluntary standards in the form of the Guidelines on Provision of Goods, Monies and Food and Drink to Wholesalers.

## Chapter 13: Internal procedures and education

Our company shall ensure the establishment of appropriate internal processes for observing related laws and this code, and provide role-appropriate education for all executives and employees in order to maintain such compliance.

## Chapter 14: Improvement measures in response to code violations

On any matters deemed to be in contravention of this code, our Pharmaceuticals Division Medical Information Supervision Department shall take remedial measures in response to offending employees.

## Chapter 15: Overseas activities

### １５．１　Standards applied to overseas activities

Our company shall observe this code even when conducting activities overseas, and also, in addition to host country laws, respect any code issued by the host country’s pharmaceuticals association. Should such a code not exist, our company shall revert to observing the IFPMA Code.

### １５．２　Provision of medical information overseas

When providing medical information to overseas medical professionals, whether directly or via an agency, we shall ensure that information is internationally consistent. In such cases, in addition to host country laws, we shall respect any code issued by the host country’s pharmaceuticals association. Should such a code not exist, our company shall

revert to observing the IFPMA Code.

### １５．３ Dealing with domestic medical professionals overseas, and with overseas medical professionals in Japan

Our company shall observe this code even when dealing with domestic medical professionals at overseas seminars or academic conferences. Furthermore, when staging seminars inside Japan and inviting overseas medical professionals, in addition to relevant laws, we shall observe any code issued by the relevant country's pharmaceuticals association. Should such a code not exist, our company shall revert to observing the IFPMA Code.

### １５．４ Dealing with overseas subsidiaries, licensees and agencies

When a subsidiary conducts business overseas, our company shall, in addition to host country laws, observe any code issued by the relevant country's pharmaceuticals association. Should such a code not exist, we shall revert to observing the IFPMA Code. Furthermore, when enlisting overseas licensees and agencies based on licensing and agency agreements, we shall, in addition to local laws, observe any code issued by the relevant country's pharmaceuticals association. Should such a code not exist, our company shall revert to observing the IFPMA Code.

## Chapter 16: Revisions and Abolitions

Any determinations, revisions or abolitions of this code shall be made via consultation between the Pharmaceuticals Division Medical Information Supervisory Department Chief and the relevant departments, and with the president's final decision.

(History)

| Edition | Date | Contents of revisions |
|---|---|---|
| 1st | Jul 23rd, 2013 | The code was newly determined |
| 2nd | Oct 1st, 2017 | In line with JPMA Code revisions, we created more up-to-date contents and rewrote the text and better organized items to aid understanding. |
| 3rd | Oct 1st, 2019 | In line with IFPMA Code revisions, and taking on board the application of the Sales Information Provision Guidelines, the JPMA Code was also revised, causing us to revise wording and phrasing. The revision status for guidelines, standards and joint-policies cited in this code was confirmed, and titles brought up-to-date.<br>Also, in line with organizational restructuring, we made |

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| | | the Medical Information Supervision Department responsible for overseeing this code. |
| 4th | Oct 1st, 2023 | In line with revised organizational naming, the "Pharmaceuticals Division Head Office" was altered to the "Pharmaceuticals Division." |
| 5th | Feb 1st 2024 | Minor formatting revisions were made. |
| 6th | Oct 1st, 2025 | In order to ensure consistency between the IFPMA Code and Sales Information Provision Guidelines, the JPMA Code's definition of "promotion" was revised, with any duplications of JPMA Code regulations eliminated as part of a document reorganization process. This code was therefore revised accordingly. |

## Glossary of Terms

### The International Federation of Pharmaceutical Manufacturers and Associations (IFPMA)

Established in 1968, the IFMPA (headquartered in Geneva, Switzerland) is a non-profit, non-governmental organization whose members comprise industrial organizations and pharmaceutical companies engaged in research and development, and based in both developed and developing countries. The JPMA operates as one of the leading members of the IFPMA.

So as to ensure ethical promotions of drugs to medical professionals, and that member companies conduct appropriate relations with medical professionals, the IFPMA has adopted a Code of Practice to serve as its relevant standards. The IFPMA demands observance of its code from member associations, member companies and companies belonging to member associations.

### Japan Pharmaceutical Manufacturers Association (JPMA)

A Japanese industrial organization whose members comprise pharmaceutical companies engaged in research and development.

### Medical professionals

Refers to individuals with a specific qualification who are involved in the practice of medicine: doctors, dentists, pharmacists, nurses, public health nurses, midwives, dental hygienists, dental technicians, medical radiographers, physiotherapists, occupational therapists, clinical lab technicians, medical lab technicians, orthoptists, clinical engineers, prosthetists, paramedics, nutritionists, dieticians, care workers and care managers. The term also covers related government officers and the staff of medical institutions when it is necessary to share information with them from the standpoints of medical access and disease prevention.

### Medical information

“Medical information” refers to the information exchanged between pharmaceutical companies and medical professionals to promote appropriate use of drugs. Medical information comes with strong demands for accuracy, impartiality and objectivity based on medical, pharmaceutic and scientific evidence. It is vital that such information is always current.

### Medical Representatives (MR)

The accreditation guidelines of the MR Accreditation Center, a public interest incorporated foundation, contain the following definition: “An MR is a company representative whose work chiefly consists of providing, gathering and transmitting information pertaining to drug quality, efficacy and safety, and who, so as to contribute to improvements in appropriate use of prescription drugs and drug treatment, exchanges information with medical professionals via meetings and/or electronic tools.” The same center’s website also refers to an MR as: “a medical information specialist who handles information pertaining to drug quality, efficacy and safety, so as to contribute to improvements to appropriate use of their own company’s prescription drugs and drug treatment.”

Additionally, Order 2: Clause 4 issued by the GVP Ministry contains the following definition: “Under this order, a Medical Information Manager is someone who, in order to contribute towards appropriate use of drugs, chiefly concerns themselves with the visiting of medical professionals and the collection and provision of safety management information.”

### Medical institutions

A term referring to institutions which provide medical services under medical law, such as hospitals, clinics, geriatric health service facilities, and others.

### Patient organizations

A term referring to organizations chiefly comprised of patients, families and advocates which represent patient voices, facilitate relationships of mutual support with patients and families, and aim for improvements in the medical environment. In principle, they are patient organizations and patient support groups with roles and objectives defined by articles of incorporation and regulations. They need not have corporate status nor a specific form of establishment.

### Transparency

### Transparency in relations with medical institutions

Industrial-academic collaborative activities between pharmaceutical companies and medical institutions are indispensable to the development of medicine, pharmacology, and bioengineering as well as appropriate use of drugs. However, the more these activities thrive, the more likely it is that medical institutions and medical professionals become deeply involved with specific firms and products, undeniably giving rise to doubts over

whether their decision-making is subjected to certain influences.

Furthermore, as pharmaceutical companies are part of the life science industry operating under the public health insurance system, their need for transparency is greater than that of other industries. Based on this, the 2011 AGM of the JPMA approved the Transparency Guidelines for Relationships between Business Activities and Medical Institutions, with each member company then fixing its own policies and moving ahead with releases of information in that vein. Furthermore, as the Clinical Research Act made it a duty to publish all information related to research funding, the aforementioned Transparency Guidelines were revised in October 2018 to pursue further transparency improvements. Changes in the social landscape have necessitated yet higher degrees of transparency.

**Transparency of clinical trial information**

Chapter 9 of the revised IFPMA Code of 2012: Clinical Trials and Transparency, regulates the transparency of clinical trial information in line with the Joint Position on the Disclosure of Clinical Trial Information via Clinical Trial Registries and Databases (revised 2018), and the Joint Position on the Publication of Clinical Trial Results in the Scientific Literature (revised 2017), collectively issued by the IFMPA, PhRMA, EFPIA and JPMA. These joint positions also state that in areas not limited to post-marketing surveillance the various forms of clinical trials and observational research involving humans etc., must be conducted with justifiable scientific objectives, and should not be mere camouflaged promotions. On clinical trial transparency, it is vital for JPMA members to adhere to both aforementioned joint positions.

**Transparency of relationships with patient organizations**

2007 saw the EFPIA adopt its "Code of Practice on Relations between the Pharmaceutical Industry and Patient Organizations." Furthermore, Chapter 11 of the revised IFPMA Code of 2012: Relations with Patient Organizations, stipulates that relations with patient organizations be openly disclosed. In order to understand and respond to the needs and concerns of patients and their families, opportunities for JPMA member companies to collaborate with patient organizations are growing inside Japan. On the other hand, in times when the voices and influence of patient organizations are strengthening vis-à-vis the authorities, it has become increasingly important for JPMA member companies, through the disclosure of information pertaining to financial support offered to patient organizations, to guarantee transparency and gain wider public understanding of the fact that donations to patient organization activities are made

according to high ethical standards. With respect to collaboration with patient organizations, JPMA member companies must further improve transparency based on the Guidelines for Collaboration with Patient Organizations of January 2013, and the Business Activity and Patient Organization Relationship Transparency Guidelines of March 2012.

### Prescription Drug Appropriate Advertising Standards

Sep 29th 2017 brought the issuing of Chapter 4 of Medical Directive 0929: "Revisions to Appropriate Advertising Standards for Prescription Drugs etc." which represented wholesale revision of the Prescription Drug Appropriate Advertising Standards." Our information transmission activities require that we not only observe the PMD Act, but to understand the contents and spirit of the directive concerned.

### Social Media

Refers to internet use mainly via social media, which is a medium constructed for users, including individuals, to transmit information and engage in two-way communication. Social media is characterized by its ability to allow individuals to easily and rapidly transmit information to the general public. The corollary is that false information and inappropriate contents can be widely distribute without their accuracy even being questioned. Consequently, when transmitting information via social media, individuals must properly reference and examine laws pertaining to drugs and medical devices, Fair Practice Drug Advertising Standards, and voluntarily standards such as Sales Information Provision Guidelines and this code, to confirm whether their activities comply and so as not to deliver undesirable results.

### Sales Information Provision Guidelines

The 2016 Prescription Drugs Advertising Activity Monitoring Project (from FY2019 known as the "Prescription Drugs Information Provision Activity Monitoring Project") commissioned by the Ministry of Health, Labor and Welfare's Medical and Environmental Health Bureau: Compliance and Narcotics Division (from Sep 2023, the Ministry of Health, Labor and Welfare's Pharmaceutical Bureau Compliance and Narcotics Division), saw the reporting of actions giving rise to concerns over appropriate use of prescription drugs. Accepting this report, and seeking to optimize advertising or resemblant activities for prescription drug sales information provision, and with the aim of improving health and safety, the Ministry of Health, Labor and Welfare issued its Guidelines on Sales Information Presentation Activities for Prescription Drugs on

September 25th 2018 (Pharmaceutical Instruction 0925, No. 1)

When carrying out sales information provision activities for prescription drugs (conducting, actively or passively, information provision activities designed to promote sales based on increasing awareness of drug efficacy, safety or specific name), JPMA member companies are required to observe these guidelines.

## Conflicts of Interest (COI)

In instances where medical research is conducted in the form of industrial-academic collaboration, it becomes incumbent on the pharmaceutical firm funding or deriving financial benefit (private benefit) from this research to ensure both the impartiality and credibility of the individual researcher, and guarantee the lives and safety of both patients and participants under the social responsibility (public benefit) of protecting human rights. When an individual researcher is inevitably and unavoidably faced with a conflict of duty, or conflicting or competing interests, we refer to this situation as a "Conflict of Interest (COI)." In so far as we can formally observe, medical research conducted in the form of industrial-academic collaboration can be construed as a COI, but not as one that need pose a problem. Problems only emerge when fair and impartial decision-making is impaired as a result of such COIs, making the key issue one of how to manage COIs so as to avoid such outcomes.