Nippon Kayaku Code of Practice

Code type: Work regulations

Established: 2013-07-23

Established by: The President

Revised: 2024-02-01

Effective from: 2024-02-01

(The Process for Establishment and Revision)

March 2012 saw the International Federation of Pharmaceutical Manufacturers and Associations (hereafter: IFPMA) announce its IFPMA Code of Practice, covering relations with medical professionals, medical institutions and patient groups, and promotional activities for prescription drugs. In line with the purpose of that Code did the Japan Pharmaceutical Manufacturers Association (hereafter: JPMA) develop its existing Promotion Code for Prescription Drugs into the JPMA Code of

Practice (hereafter: JPMA Code) established in April 2013.

As a JPMA member, Nippon Kayaku (hereafter: we) undertakes the obligation to repay society's trust by forever ensuring high standards of ethicality and transparency in the conduct of its pharmaceutical-related corporate activities, and by holding itself accountable for the important interactions aimed at sharing information with all executives and staff, and all external stakeholders (hereafter: stakeholders) including researchers in the fields of medicine, dentistry and pharmacology, medical professionals, wholesalers and patient groups. We recognize the essential nature of integrity to such interactions, as well as the constant demand for ethical decision-making from the standpoint of a patient. As such, to ensure that our actions follow the aims of the JPMA Code, we have established and implemented our own Nippon Kayaku Code of Practice (hereafter: this Code).

As the JPMA, in response to IFPMA Code revisions and the application of newly-fixed Presentation Activity Guidelines for Prescription Drug Marketing Information (hereafter: Marketing Information Presentation Activity Guidelines), revised its own code in September 2019, so did we revise our company code based on the JPMA revisions in the manner expressed below.

We have already established a Nippon Kayaku Group Charter of Conduct and Code of Conduct in order to clarify our corporate ethics – the foundation of all corporate activities – and provide the guiding model image of a company holding high ethical standards at both an organizational and individual-employee level.

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In line with the JPMA Promotion Code for Prescription Drugs have we also established, among our internal regulations, a Nippon Kayaku Pharmaceuticals Group Prescription Drug Promotion Code (hereafter: Drug Promotion Code) with respect to promotional activities for prescription drugs.

Going forward, we shall operate this Code in tandem with the Nippon Kayaku Group Charter of Conduct and Code of Conduct.

(Pharmaceutical Company Ethics)

Generally, competition between companies has a tendency to overstep the bounds of moderation and overheat. It cannot be denied that, in days gone by, such a state of affairs applied to the promotion of prescription drugs. Today, in order to rectify that, we have, starting with the Pharmaceutical and Medical Device Act (hereafter: PMD Act), a number of regulatory and self-regulatory requirements, including Notes on the Revision of Standards for Appropriate Advertising of Prescription Drugs (hereafter: Standards for Appropriate Advertising of Prescription Drugs), Guidelines for Information Presentation Activities Pertaining to Prescription Drugs, Fair Competition Regulations on the Giving of Gifts in the Manufacture and Sales Industry for Pharmaceutical Goods (hereafter: Fair Competition Regulations), Key Points on the Production of Outline Information on Prescription Drug Products (hereafter: Key Production Points) and the MR Education and Training Guidelines.

As is well-known, when it comes to prescription drugs:

- (1) Their external appearance alone tells us nothing of their true nature
- (2) They have both effects and side-effects, whose manifestations are different
- (3) Hence prescription drugs based on faulty information cannot function as prescription drugs
- (4) That as these drugs are only used by patients with a need for them, it is impossible to increase demand through sales promotions

The above four points constitute the reasons why we must observe and respect the various legal regulations and self-regulations listed above.

On the other hand, the increasingly diversified and complicated environment surrounding pharmaceutical companies gives rise to a succession of cases that cannot be tackled with traditional thinking and methods. It is also the case that society demands higher degrees of fairness and transparency in relations between pharmaceutical companies and medical professionals. Against this backdrop, to engage in conduct which ignores the true essence of prescription drugs risks triggering health hazards and unnecessary dosages, thereby causing serious damage to patients and society at large. We would thus, by our own hand, end up greatly damaging public trust in both prescription

drugs and the industry as a whole, with clearly calamitous consequences for our company and wider society. It must therefore be said that our company has nothing to gain from such reckless conduct, and merely everything to lose. In other words, it is incumbent upon our company too, as a JPMA member, not to simply view the various regulations and self-regulations as "things to be observed," but to be prepared, with a grasp of their objectives and the backdrop against which they were set, to interpret them on a bigger scale, and make them our own through reflecting the model image of a pharmaceutical company carrying society's expectations.

It can be easily understood how corporate activities based on such an ethical standpoint can construct the irreplaceable bedrock known as "public trust" in pharmaceutical companies and their products. This can be yet more easily understood if we place ourselves in the shoes of a patient or member of society and observe pharmaceutical companies from their point of view. Every individual, as a member of the society or community to which they belong (be that family, workplace, or region), has the role of naturally commanding expectations from those around them. Society itself is formed around the premise of two parties endeavoring to meet each other's expectations. Once that premise is damaged, no kind of society can survive.

This very analysis can be applied to any type of industry. Applied to prescription drugs, it tells us that regardless of the legal regulations and self-regulations listed above, members of society accept medical treatment on the premise that superb-quality medicines are being appropriately used. This is a proposition that pharmaceutical companies must especially accept, not least in the field of Corporate Social Responsibility (CSR).

The first kanji character of the Japanese word for ethics (♠) means "companion," and refers to the human companionship and societal companionship that produce our relationships of mutual expectation. As a JPMA member, we must not only observe legal regulations and self-regulations, but understand our status as a company which must proactively work to meet the demands and expectations of society.

(Principles for Basic Corporate Activities)

Our company, in view of the fact it conducts corporate activities related to human life under the public medical insurance system, has a core obligation to observe the following basic principles.

Basic Principles

- That in the conduct of corporate activities, a contribution to patient health and human life should be the priority standard against which our decisions should be referenced
- That progress in the fields of medicine, pharmaceutics and medical technology, and improvements in public health, stem from the information-sharing interactions with stakeholders and JPMA members across the entire medical world. As integrity is essential to such interactions, we shall take our

decisions ethically and from the patient's standpoint.

o That to ensure appropriate interactions with stakeholders we shall observe a code of conduct

grounded in high ethical standards, and carry out our mission to contribute to public health

improvements not only in Japan but across the wider world

o That in the conduct of corporate activities, in addition to obviously complying with the PMD Act

and related regulations, we shall comply with the standards of the Pharmaceutical Industry Code of

Practice, the JPMA Charter of Conduct, and the JPMA Compliance Program Guidelines, and act with

high ethical propriety.

o In the conduct of corporate activities, we shall, in a transparent manner, appropriately carry out our

duty of accountability to society in line with company policies fixed according to the JPMA

Relationship Transparency Guidelines for Corporate Activities and Relations with Medical Institutions

(hereafter: Transparency Guidelines) and the Transparency Guidelines for Corporate Activities and

Relations with Patient Groups (hereafter: Patient Group Transparency Guidelines).

o In order to contribute to the advancement of medicine, pharmaceutics and medical technology, and

the development of life sciences, as well as promote appropriate academic-industrial collaboration, we

shall build relationships of trust with stakeholders and refrain from actions which could lead to adverse

effects.

Chapter 1: Defining Promotions and their Scope

1.1 Scope

The JPMA Code not only applies to the promotion of prescription drugs but to every form of

interaction between JPMA members and researchers, medical professionals, medical institutions,

patient groups, wholesalers and others. In line with this JMPA Code, we establish and observe this

Code as the Code of Conduct for every executive and employee, as well as observe the Code of the

IFPMA, to which the JPMA belongs. Whether guidance is specifically written down or not, we will

constantly check our actions against the aims of this Code.

1.2 The Definition of a Promotion

A promotion is not defined as a so-called "sales promotion," but as "the act of aiming to achieve the

appropriate use and popularization of prescription drugs based on the presentation, gathering and

conveyance of medical information to medical professionals."

Chapter 2: Top Management Obligations

Top Management shall:

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- (1) Exhibit awareness of their role as leaders who act in line with this Code's Basic Principles, and lead by example in this Code's wider implementation, taking responsibility for all executives and employees, preparing to disseminate information to all relevant persons, and readying internal company systems
- (2) When situations against the aims of this Code arise, take responsibility for working towards problem-solving, root-cause investigations and recurrence prevention
- (3) Conduct corporate activities in line with the aims of this Code even when in charge of departments other than those pertaining to prescription drugs
- (4) Enforce compliance with this Code from Japan-based subsidiaries involved in the manufacture and sale of prescription drugs
- (5) Declare the need to understand and comply with this Code to parent companies, partner companies and subsidiaries involved in the manufacture and sale of prescription drugs both within Japan and overseas

Chapter 3: The Basics of Interaction

3.1 The Basics of Interaction

Progress in the fields of medicine, pharmaceutics and medical technology, and improvements in public health, stem from the information-sharing interactions among researchers, medical professionals, patients, wholesalers and pharmaceutical companies across the entire medical world. Integrity is essential to such interactions, with respect to which society demands that we can be trusted to take our decisions ethically and from the patient's standpoint. Hence, working with authorities, medical professionals and patients shall we endeavor to build the trust that comes with constantly acting in an ethical manner.

3.2 Transparency in Interactions

Concerned as they are with human life, pharmaceutical companies are demanded to have high ethical standards. As such, we must be held accountable for sincerity and ethicality in our interactions with researchers and medical professionals, and in our collaborations with patient groups.

We shall be accountable to the public, and transparent with our corporate activities, in line with company policy based on the Transparency Guidelines, the Guidelines for Collaborating with Patient Groups (hereafter: Patient Group Collaboration Guidelines) and the Patient Group Transparency Guidelines.

Chapter 4: Interactions with Medical Professionals

When interacting with medical professionals, we shall prioritize contributing to patient benefits, health

and welfare, and aim to contribute to the development of medicine, pharmaceutics and medical technology as well as the improvement of public health. We will also place importance on the presentation of prescription drug information, exchanges with academia related to medicine, pharmaceuticals and medical technology, and research support. Furthermore, when promoting academic-industrial collaboration for the development of medicine, pharmaceutics and medical technology, we will build relationships of trust with researchers, medical professionals, patients and others, and concurrently refrain from actions which may adversely affect decisions on prescriptions.

Chapter 5: Forbidding the Presentation of Information Prior to Approval and Recommendation of Off-Label Use

Until a prescription drug is granted approval for use in Japan, we must not undertake any promotional activities. We must also not recommend any off-label use.

Chapter 6: Information-disseminating Activities

As a company involved with human life, we shall appropriately present scientific and objective information on prescription drugs and, while doing so, strive to make use of contents and expressions which are easy-to-understand, and in observance of both legal regulations and self-regulations. Furthermore, the PMD Act and Standards for Appropriate Advertising of Prescription Drugs forbid us from advertising prescription drugs to anyone who is not a medical professional (i.e. the general public). It therefore follows that, right from the planning stage, we shall subject to detailed examination the contents of press releases, disease education activities vis-à-vis the general public and patients, and communication activities such as those aimed at investors, so as to confirm the presence of neither prescription drug advertising activities nor anything that could be misinterpreted as recommending either non-approved drugs or off-label uses. Furthermore, we shall observe our Medical Promotion

6.1 Promotional Materials (including digital ones)

Code when disseminating information to medical professionals.

We shall produce our promotional materials (including digital ones) by observing related laws and voluntarily complying with the Key Production Points mentioned above.

6.2 Social Media

When making use of so-called "social media" to conduct digital communication for work purposes, we shall take full responsibility for the contents we post. Consequently, as with related subsidiaries, parent companies, partner companies, planning companies, agencies and employees, we will confirm

whether contents conform to this Code prior to posting.

Chapter 7: Lectures and Meetings

There are occasions on which we set up lectures to disseminate information pertaining to medicine, pharmaceutics, medical technology and disease education. When setting up such lectures, we shall provide contents which befit ourselves as a pharmaceutical company, select a suitable location and venue, and observe Fair Competition Regulations and related laws.

We shall ensure that meetings set up for the purpose of receiving academic advice on our company activities, and to which medical professionals are invited, are not used as vehicles for sales promotion activities. We shall select attendees based on their appropriateness for the aims of the meeting, and in the smallest numbers necessary.

Chapter 8: Subcontracting

There are instances in which we subcontract work, remunerate, and pay expenses to researchers, medical professionals, medical institutions and patient groups for research, clinical trials, postmarketing surveillance surveys, consulting or advisory roles, participation in meetings, lecturing, chairing seminars, or serving as workshop instructors. However, such subcontracting arrangements can only be made upon the exchanging of contracts fulfilling the following criteria.

- (1) The exchanging of contracts based on a document listing the objectives of the work, and the reasons for remuneration and expenses
- (2) Clear identification of the legitimate necessity of the work in question prior to subcontracting
- (3) The subcontractor having a direct relationship to the necessity identified, and the requisite specialist knowledge
- (4) The number of people subcontracted being of a reasonable number required to achieve the necessary outcomes identified
- (5) The contract not inducing the prescription, purchase or recommendation of specific pharmaceutical products
- (6) The remuneration amounts are reasonable in relation to the subcontracted work

Chapter 9: On the Offering of Goods and Money

We shall not offer to researchers, medical professionals, medical institutions, patient groups, wholesalers, or stakeholders across the medical world, any goods or money, directly or indirectly, that may adversely affect their decision-making.

Even in instances not applicable to the above, we shall offer neither goods which tarnish the image of a pharmaceutical product, nor goods or money which the public may find unconvincing or struggle to understand.

Chapter 10: Preparation Examples of Pharmaceutical Products

Preparation examples of pharmaceutical products serve as a method of presenting medical information,

allowing us to convey to medical professionals the outward features of the relevant product, while

helping us confirm and evaluate product quality, efficacy and safety.

Consequently, when presenting preparation examples do we follow the information given on the

product concerned, and supply only the minimum necessary dose.

Chapter 11: Trials and Research Activities

Nonclinical trials, clinical research, epidemiological studies, and testing and research activities

pertaining to clinical trials (trial cases, postmarketing clinical trials), must, at their various stages, be

based on government-determined legislation and ethical policies, exhibit high ethical standards, and

have legitimate scientific objectives. As R&D expenses and academic research grants for such trials

and research form part of Transparency Guidelines disclosure requirements, we must be appropriately

accountable with respect to said guidelines.

Furthermore, with respect to ensuring transparency of clinical trial information and the publication of

clinical trial information, we shall follow both the Joint Position on the Disclosure of Clinical Trial

Information via Clinical Trial Registries and Databases (revised in 2017) and the Joint Position on the

Publication of Clinical Trial Results in the Scientific Literature (revised in 2017) collectively agreed

by the JPMA, the IFPMA, the European Federation of Pharmaceutical Industries and Associations

(EFPIA), and the Pharmaceutical Research and Manufacturers of America (PhRMA).

Also, in order to reduce prescription drug side-effects to the maximum extent possible, we shall

develop safer and more effective prescription drugs and advance R&D system preparation to the next

level by conducting self-regulation with respect to, for example, offering greater care to animals used

for experiments necessary to product development.

Chapter 12: Patient Group Collaboration

In our relations with patient groups shall we hold high ethical standards, respect the independence of

such groups, and work towards sufficient mutual understanding of the objectives and contents of our

collaboration. Consequently, when working with a patient group shall we refer to our internally-fixed

Patient Group Collaboration Guidelines as a code of behavior.

To help gain a wider understanding of our monetary support activities for patient groups as

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contributions to the activities and development of the groups concerned, we shall clarify the extent and type of our involvement. We shall also agree upon those aims and contents in document form, and keep records of such documents to ensure transparency. In instances where we send monetary support to a patient group, we shall refer to our own internal policies based on the Patient Group Transparency Guidelines and publish information accordingly.

Chapter 13: Relations with Wholesalers

Relations between pharmaceutical companies and wholesalers must be conducted along the lines of fair trading and in compliance with antitrust laws (through respect for legal regulations and self-regulation). As such trading takes place under the public medical insurance system, our relations are demanded to exhibit a higher degree of ethicality and transparency than those within under industries. With that in mind have we fixed our own self-imposed standards (Internal Standards on the Offering of Goods, Money, Food and Drink to Wholesalers) for the offering of money, goods, food and drink to wholesalers, and for the acceptance of such offers from wholesalers. We shall duly comply with such standards.

Chapter 14: Company Procedures and Instruction

We shall establish and maintain appropriate procedures for observing relevant laws and the contents of this Code, and deliver appropriate instruction to all executives and employees commensurate with their roles.

Chapter 15: Measures to Correct Contraventions

In the emergence of cases which are thought to contravene this Code, our Medical Group's Medical Information Supervision Department shall, in line with internal regulations, take corrective measures against the offending employees.

Chapter 16: Overseas Activities

16.1 Criteria Applying to Activities Conducted Outside Japan

Even when conducting activities outside of Japan shall our company respect this Code, and in addition to related laws and regulations in the relevant country, follow the Code of that country's pharmaceutical federation. In cases where no such code exists, our company shall revert to following the IFPMA Code.

16.2 Presentation of Medical Information Outside Japan

When presenting medical information to medical professionals outside of Japan, be it directly or indirectly via an agency or such like, we shall ensure consistency, and, in addition to the relevant country's related laws, comply with the Code of that country's pharmaceutical federation. In cases where no such code exists, we shall present information in line with the IFPMA Code.

16.3 Handling Domestic Medical Professionals Overseas and Handling Overseas Professionals Inside Japan

This Code shall serve as our guide on how to handle domestic medical professionals at a lecture or conference being held overseas. When inviting overseas medical professionals to a lecture in Japan, we shall follow the relevant laws in the visitor's country and any pharmaceutical federation code that country might have. In cases where no such code exists, we shall revert to following the IFPMA Code.

16.4 Handling Overseas Subsidiaries, Licensees and Agencies

We shall ensure any subsidiary of ours respects the relevant laws of the overseas country in which it conducts business, as well as any pharmaceutical federation code that country might have. In cases where no such code exists, we shall ensure our subsidiary reverts to following the IFPMA Code. Furthermore, when engaging a licensee or agency to conduct business in another country based on a licensing or agency agreement, we shall demand that, in addition to that country's relevant laws, they also comply with any pharmaceutical code that country might have. If no such code exists, they will be made to comply with the IFPMA Code.

Chapter 17: Revisions and Abolitions

The fixing, revision or abolition of this Code shall only take place following consultation between the Medical Group's Medical Information Audit Chief and related departments, and the forwarding of proposals for approval by the president.

(Code History)

Version	Date	Contents revised
1	2013-07-23	Newly established
2	2017-10-01	Following amendments to the JPMA Code, we rewrote the text,
		updating the contents to fit the new era and reorganizing
		paragraphs to achieve better understanding.
3	2019-10-01	In response to JPMA Code amendments stemming from IFPMA

		Code revisions and the application of new Marketing Information
		Presentation Activity Guidelines, we reworded certain sentences
		and expressions. We also confirmed the guidelines, standards and
		Joint Positions cited within this Code and updated the title
		accordingly. Furthermore, following organizational changes, we
		transferred responsibility for this Code to our Medical
		Information Supervision Department.
4	2023-10-01	In response to an organizational name change, "The
		Pharmaceuticals Group Head Office" was rewritten as "The
		Pharmaceuticals Group."
5	2024-02-01	Minor modifications were made to the document format.

Glossary

o IFPMA (International Federation of Pharmaceutical Manufacturers & Associations)

The IFPMA (located in Geneva, Switzerland) is a non-profit, non-governmental organization established in 1968. Its membership consists of pharmaceutical federations and international pharmaceutical firms engaged in research and development in both developed and developing countries. Among its main members can be counted the JPMA.

Japan Pharmaceutical Manufacturers Association (JPMA)

The industrial organization for R&D-based pharmaceutical manufacturers inside Japan.

Medical professionals

Refers to doctors, dentists, pharmacists, nurses, public health nurses, midwives, dental hygienists, dental technicians, radiographers, physiotherapists, occupational therapists, clinical lab technicians, medical lab technicians, orthoptists, clinical engineers, prosthetists, paramedics, nutritionists, care workers and care managers.

o Medical institutions

Institutions that provide medical and healthcare services under medical law, such as hospitals, clinics and nursing homes.

Patient groups

o Patient groups or patient support groups, regardless of legal status or form of establishment, whose aims are, in principle, defined by articles of association and regulations. Such groups are chiefly

comprised of patients, patient families and other supporters who give representation to patient voices, have mutually-supportive relationships with patients and their families, and aim for reform and improvement of medical and healthcare environments.

o Prescription Drug Promotion Code

The self-imposed industry rules agreed by the JPMA and its member companies which serve as a code of conduct for the promotion of the pharmaceutical products demanded of pharmaceutical companies by the general public. JPMA member companies have a duty to observe this Code. "Promotion" in this sense does not mean "sales promotion," but rather refers to "the act of aiming to achieve the appropriate use and expansion of prescription drugs based on the presentation, gathering and conveyance of medical information to medical professionals."

*Appropriate use of prescription drugs

The Promotion Code views "appropriate use of prescription drugs" as a series of cycles which, in order to suitably function, requires pharmaceutical companies to conduct the promotional activities expected of them. In other words, pharmaceutical companies must ensure prescription drugs are appropriately used via the following set of basic actions: accurately presenting correct medical information to medical professionals; rapidly gathering information on product side-effects etc.; and promptly relaying the results of side-effect evaluations and analysis to the medical professionals concerned.

o Transparency in relations with medical institutions

Joint-activities between pharmaceutical companies and academia are essential to the development of medicine, pharmaceutics and medical technology, and widening appropriate usage. However, the more those joint activities flourish, the more likely medical institutions and medical professionals are to become deeply involved with specific companies and products, undeniably giving rise to concerns that their decision-making may thereby be impeded in some way. As pharmaceutical companies form an industry related to human life, and operate under the public medical insurance system, they require a yet higher degree of transparency in their activities than companies in other industries. As such, January 2011 saw a General Meeting of the JPMA approve new Transparency Guidelines for Corporate Activities and Relations with Medical Institutions, and saw JPMA members fix their own internal policies with the aim of improving transparency. Our company, starting with this very Code, is now also observing self-regulations due to the increasing importance of undertaking ethical corporate activities by placing ourselves in the shoes of the public. It is important to take transparency to the next level in response to changing social conditions.

o Transparency in relations with patient groups

2007 saw the EFPIA adopt its Code of Conduct on Relations Between Pharmaceutical Companies and Patient Groups. Furthermore, a 2012 revision to the IFPMA Code entitled "11. Interactions with Patient Groups" mandated the need to disclose links with such groups. Japan, too, is also seeing an increase in JPMA member-patient group collaborations in order to better understand and respond to the needs and concerns of patients and their families. However, with patient group voices becoming increasingly influential at government level, and with JPMA members now disclosing any monetary relations they may have with those patient groups, it has become increasingly important to ensure transparency and gain widespread understanding of the fact that we are contributing to these groups' activities from a high ethical standpoint. It is therefore important to further increase the transparency of JPMA member collaborations with patient groups by following the Guidelines on Collaborations with Patient Groups (revised in September 2017) and the Guidelines on Corporate Activities and Relations with Patient Groups (fixed in March 2012).

The Fair Trade Council of the Ethical Pharmaceutical Drugs Marketing Industry

An organization established by Fair Competition Commission approval in 1984 for the purposes of industry self-regulation, responsible for operating the JPMA Promotion Code for Prescription Drugs as part of efforts to promote fairer distribution of such drugs under the Act against Unjustifiable Premiums and Misleading Presentations.

o JPMA Code for Fair Competition in the Manufacture and Sale of Prescription Drugs

Article 31 of the Act against Unjustifiable Premiums and Misleading Presentations seeks to outlaw the giving of unreasonable gifts and presentations to customers, ensure the general consumer is presented with voluntary and practical choices, and ensure fair trading between businesses. Although fixed as a set of voluntary rules by the Consumer Affairs Agency Commissioner and the Fair Trade Commission, these rules actually have legal backing.

(Transparency of Clinical Trial Information)

Joint Position on the Disclosure of Clinical Trial Information via Clinical Trial Registries and Databases (revised in 2017)

Joint Position on the Publication of Clinical Trial Results in the Scientific Literature (revised in 2017) With respect to "Paragraph 9: Clinical Trials and Transparency" of the revised IFPMA Code of 2012, the IFPMA, PhRMA, EFPIA and JPMA jointly fixed their transparency policies with respect to clinical trial information in two documents: the Joint Position on the Disclosure of Clinical Trial Information via Clinical Trial Registries and Databases (revised in 2017), and the Joint Position on the Publication of Clinical Trial Results in the Scientific Literature (revised in 2017). Furthermore, the regulations stipulate that, not only with respect to Postmarketing Surveillance, various types of research involving

human participants, such as clinical trials and observation studies, must have reasonable scientific objectives and must not be camouflaged as presentations. JPMA members must deal with matters of clinical trial transparency by following the two documents mentioned above.

Standards for Appropriate Advertising of Prescription Drugs

October 9th 1980 gave rise to Drug Development Notice 1339 from the Director of the Ministry of Health and Welfare. In order to prevent the emergence of health hazards stemming from prescription drugs, and take steps to ensure that prescription drug advertising does not include false or exaggerated claims, the notice provided instruction on how to achieve the aforementioned, serving as a supplement to the PMD Act. In addition to the obvious need to observe the latter, sufficient understanding of this notice's contents and key points has been henceforth demanded.

OSocial Media

Social media mainly refers to a form of internet media built around information transmission and two-way communication between users, including individuals. In the eyes of the general public, it has the key feature of allowing for easy transmission and conveyance of information, but this can lead to false or inappropriate contents being bandied around without their accuracy being questioned. Consequently, when transmitting information via social media, and checking our activities against the self-regulating sections of the PMD Act, the Standards for Appropriate Advertising of Prescription Drugs, and our Promotion Code for Prescription Drugs, we must carefully examine our contents so that they do not deliver inappropriate results.

oConflicts of Interest (COI)

Joint-medical research projects between pharmaceutical companies and academia give rise to a host of responsibilities and duties to be taken on by the researcher with respect to: protecting the life and human rights of the patients and participants (public benefit), the money earned from such research (private benefit), and the pharmaceutical company providing financial backing. It is inevitable that an individual researcher will experience conflict and collisions between these duties, and opposing interests; the general term for this is "Conflicts of Interest." Just as the joint format suggests, although not necessarily a problem, conflicts of interest nearly always accompany joint-medical research projects, and become a problem when they cause a loss of fair and impartial decision-making. In order to avoid this, the question of how to manage conflicts of interest takes on utmost importance.

Web sources:

IFPMA Code of Practice

https://www.jpma.or.jp/about/basis/code/ifpmacode.html

o JPMA Code of Practice

https://www.jpma.or.jp/about/basis/code/pdf/code.pdf

o JPMA Corporate Charter of Conduct

https://www.jpma.or.jp/about/basis/kensyo/kigyo/kensyo all.html

o JPMA Compliance Program Guidelines

https://www.jpma.or.jp/about/basis/kensyo/compliance/compliance0-a.html

- Transparency Guidelines for Corporate Activities and Relations with Medical Institutions https://www.jpma.or.jp/tomeisei/index.html
- Voluntary Standards for Relations with Patient Groups https://www.jpma.or.jp/patient/tomeisei/
- Key Implementation Points and Policies on the Disclosure of Clinical Trial Information https://www.jpma.or.jp/about/basis/rinsyo/