

# I. Kissei Code of Practice

## Fundamental Rules of Conduct of Kissei Pharmaceutical Co., Ltd.

Kissei Pharmaceutical Co., Ltd. (“we,” “our,” “the Company”) engages in corporate activities under the public health insurance system as a member of the life sciences industry in accordance with the provisions of “3. Basic Philosophy” in the preamble of the Japan Pharmaceutical Manufacturers Association (JPMA) Code of Practice (“JPMA Code”) summarized below. As such, it complies with the Act on Securing Quality, Efficacy and Safety of Products Including Pharmaceuticals and Medical Devices (“Pharmaceuticals and Medical Devices Act”) and other relevant laws, the Standard for Adequate Advertisement of Pharmaceutical Products, and the Guidelines for Provision of Sales Information on Prescription Drugs, as well as with voluntary codes including the Fair Competition Code Concerning Restriction on Premium Offers in Ethical Pharmaceutical Drugs Marketing Industry, the Code of Ethics for Pharmaceutical Companies of the Federation of Pharmaceutical Manufacturers’ Association of Japan, the JPMA Charter of Corporate Behavior, and the JPMA Compliance Program/Guideline, and conducts itself maintaining high ethical standards.

- (a) **Importance of interaction throughout the entire healthcare industry**  
The progress of the medical and pharmaceutical sciences and the improvement of public health are supported by the sharing of information and interaction among researchers, healthcare professionals, patients, wholesalers, pharmaceutical manufacturers, and other relevant parties.
- (b) **Emphasis on trustworthy rules of conduct and ethics**  
Highly trustworthy rules of conduct are essential to such interactions, calling for ethical decision-making that prioritizes the interests of patients.
- (c) **Role of the Code**  
We present the Kissei Code of Practice (“the Code”) as the fundamental principles for our officers and employees to interact appropriately with all interested parties.
- (d) **Contribution to global public health**  
The Code provides the rules of conduct for making contributions to public health in Japan and internationally and is the standard for all our interaction activities.
- (e) **Responsibility and transparency of corporate activities**  
We bear a responsibility to pursue corporate activities with high ethical standards and transparency.
- (f) **Recognition and promotion of the Code**  
We strive to have the Code recognized by society and promote activities on that basis.
- (g) **Standard for judgment**  
If there are no specific provisions in the Code, the standard of judgment for our actions will be compliance with the letter, underlying principles, and spirit of laws and regulations, the Corporate Philosophy, the Code of Conduct, and other policies.
- (h) **Flexible action in emergencies**  
At times of major disaster or other emergencies, we will act flexibly, giving highest priority to respect for human life.

## 1 Scope and Definition of Promotion

### 1.1 Scope

The Code applies not only to the promotion of prescription drugs but to all our interactions with researchers, healthcare professionals, medical institutions, patient groups, wholesalers, and other relevant parties. Based on the Code, we comply with the JPMA Code and the International Federation of Pharmaceutical Manufacturers and Associations (IFPMA) Code, which is the code of practice of the organization to which the JPMA belongs. In addition, regardless of whether or not the Code contains specific provisions, the standard of judgment for our actions is whether or not they are consistent with the purpose and intent of the 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 drug information to facilitate the proper use and broader adoption of prescription drugs based on those interactions. It includes all acts performed by us that could potentially influence prescribing decisions made by healthcare professionals.

## 2 Responsibilities of Top Management

Our top management executives are to execute the following.

- (1) With the awareness that their role is to conduct themselves on the basis of the fundamental rules of conduct of Kissei Pharmaceutical Co., Ltd., they set an example by implementing the provisions of the Code. They also make the Code known to all and strive to maintain and improve the internal system, perceiving the conduct of all officers and employees to be the responsibility of top management.
- (2) When circumstances arise that run counter to the spirit of the Code, they take responsibility for resolving the problems, investigating and identifying the causes, and taking measures to prevent recurrence.
- (3) They ensure that departments other than those that handle pharmaceuticals also conduct corporate activities in a manner that observes the spirit of the Code.
- (4) They ensure compliance with the Code by subsidiaries that manufacture and market pharmaceuticals in Japan.
- (5) They express the Company's compliance with the Code to affiliates, subsidiaries, etc. that manufacture and market pharmaceuticals, whether in Japan or overseas, and seek their understanding.

## 3 Fundamentals of Interaction

### 3.1 Fundamentals of interaction

Advances in the 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 the Company, and integrity is essential for these interactions. Society relies on pharmaceutical companies to make ethical decisions that prioritize the interests of patients when engaging in such interactions. We conduct ourselves in such a manner that the government, healthcare professionals, patients, etc. will trust us to engage in ethical activities at all times.

### 3.2 Transparency of interactions

Pharmaceutical manufacturers, as life sciences companies, are called on to maintain high ethical standards. We must also bear accountability for interactions with researchers, healthcare professionals, and others and ensure that collaboration with patient groups is conducted ethically and in good faith. We maintain transparency in our corporate activities and bear appropriate accountability toward society in accordance with our own guidelines, which are based on the JPMA's Transparency Guideline for the Relation between Corporate Activities and Medical Institutions ("Medical Institutions Transparency Guideline"), Guideline for Collaboration with Patient Organizations ("Patient Organizations Collaboration Guideline"), and Transparency Guideline for the Relationship between Corporate Activities and Patient Organizations ("Patient Organizations Transparency Guideline").

## 4 Interactions with Healthcare Professionals

In our interactions with healthcare professionals, we give the highest priority to being of benefit to patients and contributing to patient health and welfare. With the goal of contributing to the development of the medical and pharmaceutical sciences and the improvement of public health, our interactions focus on the provision of drug information, as well as academic exchanges and support for research in the medical and pharmaceutical sciences. Further, when promoting industry-academia collaboration for the development of the medical and pharmaceutical sciences, we will make efforts to build relationships of

trust with researchers, healthcare professionals, patients, etc., while at the same time avoiding activities that could exert an inappropriate influence on prescribing decisions.

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

We do not engage in promotion until approval for the prescription drug is received in Japan. We also refrain from endorsing off-label uses.

## **6 Information Dissemination Activities**

As a life sciences company, we provide scientific and objective information on drugs as needed. When providing information, we strive to make the content and mode of expression easy for users to understand, while complying with laws, regulations, and voluntary codes. Advertisement of prescription drugs to the general public other than medical industry professionals is prohibited by the Pharmaceuticals and Medical Devices Act and the Standard for Adequate Advertisement of Pharmaceutical Products. Accordingly, even in the cases of press releases, education activities targeting the general public or patients, or the provision of information to investors, it is necessary to take such steps as closely examining the content from the planning stages to ensure that there will be no suspicion that such 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 Section II. Kissei Promotion Code for Prescription Drugs.

### **6.1 Promotional materials (including digital media)**

We prepare promotional materials (including digital media; hereinafter referred to as “promotional materials”) in accordance with related laws and regulations and with voluntary codes including the Guideline for Preparation of Product Overview for Prescription Drug (“Preparation Guideline”).

### **6.2 Social media**

We bear all responsibility for content when utilizing digital communication via social media, etc. Accordingly, compliance with the Code must first be confirmed with related subsidiaries, affiliates, planning companies, agencies, employees, and other relevant parties.

## **7 Seminars and Conferences, Etc.**

We may hold seminars, etc. for the purpose of providing medical and pharmaceutical information, disease education information, and other information. We may also hold conferences, etc. convening healthcare professionals and other experts for the purpose of obtaining professional insights that will benefit our activities. When holding seminars, etc. and conferences, etc. convening healthcare professionals and other experts, we comply with relevant laws and regulations, the Fair Competition Code, and II. Kissei Promotion Code for Prescription Drugs.

## **8 Fee for Services**

We may engage researchers, healthcare professionals, medical institutions, patient groups, etc. for service arrangements such as research, clinical studies, post-marketing surveys, consultants and advisories, involvement in meetings, chairing or lecturing at seminars, etc., and training instructor services, where such participation involves payment of remuneration, expenses, and other fees. However, when making such arrangements for these services, we must first enter into a written agreement that fulfills all of the following criteria.

- (1) A written agreement must be made in advance to specify the purpose of the service to be provided and the basis of payment of remuneration, expenses, and other fees for those services.
- (2) A legitimate need for the services must be clearly identified in advance.
- (3) The service provider must be directly related to the identified need and 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, recommend, or take other action for

any specific drug.

- (6) Remuneration for the services must be reasonable and reflect the fair market value of the services provided.

Further, in fee-for-service arrangements, we respect the rules and other requirements of the contracted party and comply with relevant laws and regulations and the Fair Competition Code. We also disclose appropriately the remuneration, expenses, and other fees associated with the contracted services, in accordance with our Guidelines for Transparency in the Relationship between Corporate Activities and Medical Institutions and Guidelines for Transparency in the Relationship between Corporate Activities and Patient Groups, which are based respectively on the Medical Institutions Transparency Guideline and Patient Organizations Transparency Guideline.

## **9 Provision of Gifts, Cash, or Cash Equivalents**

We do not directly or indirectly provide researchers, healthcare professionals, medical institutions, etc., patient groups, wholesalers, or other stakeholders with the following gifts, cash, or cash equivalents.

- (1) Gifts, cash, or cash equivalents that could exert inappropriate influence on the decision-making of the recipient (including those that could affect the proper use of pharmaceuticals)
- (2) Gifts that would be inappropriate for a pharmaceutical product
- (3) Gifts, cash, or cash equivalents that are unlikely to gain the understanding or acceptance of society

## **10 Implementation of Studies, Research Activities, Post-Marketing Safety Management Operations and Post-Marketing Surveillance, Etc.**

### **10.1 Studies and research activities**

At every phase, studies and research activities, including epidemiological research, non-clinical studies, and clinical research/clinical studies (clinical trials and post-marketing studies, etc.) must have highly ethical and appropriate scientific objectives that conform to national laws and ethical guidelines, etc. Moreover, as information on R&D expenditures and public research subsidies for such studies and research is subject to disclosure under the Medical Institutions Transparency Guideline, we bear appropriate accountability in accordance with that Guideline.

Further, to ensure transparency of information on clinical studies, we publicly disclose clinical study information in conformity with such guidelines as 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, the European Federation of Pharmaceutical Industries and Associations (EFPIA), and the Pharmaceutical Research and Manufacturers of America (PhRMA).

Additionally, to minimize harm from adverse reactions to pharmaceuticals, we 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 R&D will be further improved.

### **10.2 Post-marketing safety management operations and post-marketing surveillance, etc.**

We accurately understand that the objective of post-marketing safety management operations and post-marketing surveillance is to establish the proper methods of use for post-launch drugs. We therefore conduct these activities based on scientific evidence and in compliance with laws, regulations, and voluntary codes, and do not use them as tools for sales promotion.

## **11 Collaboration with Patient Groups**

In all types of collaboration with patient groups, we act with high ethical standards and integrity and respect the independence of the patient groups. We also strive to ensure sufficient mutual understanding regarding the purpose and content of our collaboration with patient groups. To achieve this, referring to the Patient Organizations Collaboration Guideline, we establish guidelines when collaborating with patient groups and implement them in good faith. When we provide financial or other support to a patient group, we make our involvement known to the public to foster a broad understanding that our efforts

contribute to the activities and advancement of the patient group while ensuring high ethical standards. We disclose information after establishing guidelines for those disclosures based on the Patient Organizations Transparency Guideline. In collaborations with patient groups, we ensure transparency by exchanging contracts or agreements in writing or other means regarding the objectives, content, and other details of specific activities, funding, and other matters prior to the collaboration, and retaining records of those matters.

## **12 Relationship with Wholesalers**

Relationships between pharmaceutical manufacturers and wholesalers are maintained as fair trading relationships in compliance with the Act on Prohibition of Private Monopolization and Maintenance of Fair Trade (“Anti-Monopoly Act”) and other relevant laws and regulations, as well as voluntary codes. In addition, since such relationships take place under the public health insurance system, they require higher ethical standards and transparency than similar relationships in other industries. For this reason, in cases where we offer cash or cash equivalents, goods, food and drink, or similar gifts to wholesalers or receive them from wholesalers, we draw up and comply with our own appropriate standards.

## **13 Internal Procedures and Education**

We establish and maintain appropriate internal procedures for the purpose of complying with the relevant laws and regulations and the Code. We also ensure that all officers and employees receive appropriate education according to their roles.

## **14 Inquiries, complaints, and corrective actions**

We handle inquiries and complaints about the Code and suspected violations of the Code with procedures set forth in our whistleblowing regulations. With respect to any matter deemed to be in violation of the Code, we will take disciplinary action or other corrective measures against the officers and employees involved.

## **15 Activities Outside Japan**

### **15.1 Rules applied to activities outside Japan**

Even in our activities overseas, we observe the Code and also comply with the laws and regulations of the relevant country and any laws and regulations that apply to that country, in addition to the pharmaceutical organization code in the relevant country or the IFPMA Code in the absence of such a code.

### **15.2 Provision of Information on Drugs Overseas**

When we provide drug information to overseas healthcare professionals, we provide globally consistent information, whether directly or indirectly through agents, etc. At such times, we comply with the laws and regulations of the relevant country, in addition to the pharmaceutical organization code in the relevant country or the IFPMA Code in the absence of such a code.

### **15.3 Attending to Japanese healthcare professionals overseas and foreign healthcare professionals in Japan**

We comply with the Code also when attending to Japanese healthcare professionals participating in seminars or scientific meetings overseas. When we invite healthcare professionals from overseas to seminars, etc., held in Japan, we comply with the laws and regulations of the relevant country, in addition to the pharmaceutical organization code in the relevant country or the IFPMA Code in the absence of such a code.

### **15.4 Activities by overseas subsidiary companies, licensees, and agencies**

When an overseas subsidiary conducts activities in the relevant country, we ensure that the overseas subsidiary complies with the laws and regulations of the relevant country and any laws and regulations

that apply to that country, in addition to the pharmaceutical organization code in the relevant country or the IFPMA Code in the absence of such a code. When we have an overseas licensee or agency conduct activities in the relevant country based on a licensing or agency agreement, we require that the overseas licensee or agency complies with the laws and regulations of the relevant country, in addition to the pharmaceutical organization code in the relevant country or the IFPMA Code in the absence of such a code.

## **16 Committee in Charge of Guidelines for Provision of Sales Information on Prescription Drugs**

The Committee for the Review and Oversight of Sales Information Provision Activities supports the Company's compliance with the Guidelines for Provision of Sales Information on Prescription Drugs.

## **17 Management and Implementation**

### **17.1 Management of the Code**

- (1) The Code is managed by the Legal Department.
- (2) Upon notification from the JPMA Code Compliance Promotion Committee, the Legal Department makes matters related to this Code known to all officers and employees.
- (3) The Legal Department revises the Code as appropriate in line with revisions to the JPMA Code. However, the revision of the Code requires the approval of the Board of Directors.

### **17.2 Implementation of the Code**

- (1) The Legal Department has declared November as the month to promote understanding of the Kissei Code of Practice and conducts activities to raise awareness of the Code.
- (2) The responsible officers of the relevant departments support the Legal Department and cooperate with activities for compliance with and understanding of the Code.

## II. Kissei Promotion Code for Prescription Drugs

The Kissei Promotion Code for Prescription Drugs (“Promotion Code”) sets forth the obligations when conducting promotions of prescription drugs and the basics of promotional activities. It mandates that all officers and employees conduct appropriate promotions. The word *promotion* as it is used here means to engage with healthcare professionals in the provision, collection, and communication of pharmaceutical product information to facilitate the proper use and broader adoption of prescription drugs based on those interactions. Regardless of whether or not the Promotion Code contains specific provisions or descriptions, the standard of judgment of our actions will be whether or not they are consistent with the spirit of the Promotion Code. Acts during promotions that infringe laws and regulations, the Standard for Adequate Advertisement of Pharmaceutical Products, the Guidelines for Provision of Sales Information on Prescription Drugs, or voluntary codes are deemed to be violations of the Code even if there are no specific descriptions in the Code.

### 1 Responsibility of Kissei Pharmaceutical Co., Ltd. in Promotional Activities

We bear all responsibility for our promotions and, with this recognition, establish the following internal frameworks for conducting proper promotions. We also ensure that measures are put in place so that no officers or employees are excluded from the application of those frameworks.

Although the Promotion Code obviously applies to promotions, it similarly applies to other activities that are regarded as promotion, irrespective of whether it is the sales department or another organization that performs those activities.

- (1) We strive to continuously provide officers and employees with education and training to support the proper use and broader adoption of pharmaceutical products.
- (2) We ensure that the evaluation and remuneration systems for officers and employees do not induce unethical acts.
- (3) We establish the internal systems necessary to comply with laws, regulations, and voluntary codes.

### 2 Basics of Promotional Activities

In conducting promotional activities, our officers and employees perform the following duties in a sincere and honest manner with a full awareness of both their social mission as persons who play a role in healthcare and their positions of providing drug information as our representatives.

- (1) They refrain from conducting promotions until approval for manufacture and sale of the pharmaceutical product is received in Japan. They also refrain from endorsing off-label uses.
- (2) They strive to acquire knowledge not only of the content of the digitized package inserts of our products, pharmaceutical product risk management plans (RMP), and other relevant information, but also familiarity with the medical and pharmaceutical science on which such information is based, and to cultivate the ability to present such information accurately.
- (3) They conduct promotions according to the rules and methods that we have established.
- (4) They provide information on indications or effects, dosage, and administration, etc. within the range approved as a drug and in a proper manner based on the most up-to-date data backed by clear scientific evidence, ensuring that both efficacy and safety are presented fairly and without bias.
- (5) They collect and communicate drug information as accurately and promptly as possible.
- (6) They refrain from slandering or defaming competitors or competitors’ drugs.
- (7) They maintain discipline when visiting a medical institution and abide by the rules of the institution.
- (8) They strictly abide by laws, regulations, and voluntary codes and behave sensibly.

### 3 Production and Use of Promotional Materials, Etc.

In recognition of the fact that promotional brochures, advertisements in medical journals, etc., websites targeting healthcare professionals, audiovisual promotional materials such as slides and videos, and other promotional materials are important media for the provision of drug information, we produce and use

those materials in compliance with the Pharmaceuticals and Medical Devices Act, relevant administrative notifications, and other relevant laws and regulations, as well as the Preparation Guideline and other voluntary codes. We also ensure that the statements contained therein are correct, objective, fair, and based on scientific data.

We also establish an internal management framework centered on the officer responsible for the management of product overviews for prescription drugs (director, Legal Department) and use only product overviews that have been approved.

#### **4 Seminars and Conferences, Etc.**

When we hold seminars, etc. for the purpose of providing medical and pharmaceutical information, disease education information, etc. to healthcare professionals and others, we do so at our own responsibility, and we ensure that we provide attendees with specialized, academic, and scientific information. We hold seminars, etc. in appropriate locations and venues to suit their objective, within Japan in principle. If we offer food and drinks in association with a seminar, such offerings will be modest and kept within the bounds of social norms, so as not to undermine our dignity as a pharmaceutical company. We limit payments in cash or cash equivalents that are made in connection with holding a seminar to travel expenses (transportation and accommodation expenses) and remuneration such as honoraria for the lecturer, after concluding a contract in advance. Remuneration is set at a reasonable level within the bounds of social norms, commensurate with the value of the services requested. Payment of the travel expenses of individuals accompanying the lecturer and the participation of such individuals at social-gathering events are not permitted. If providing premiums, we will comply with the Fair Competition Code.

In planning seminars for providing disease awareness information to the general public other than healthcare professionals, we pay particular attention to such laws and standards as the Pharmaceuticals and Medical Devices Act and the Standard for Adequate Advertisement of Pharmaceutical Products.

If holding advisory conferences convening healthcare professionals and other experts for the purpose of obtaining professional insights that will benefit our activities, such as when developing product strategies, or conferences, etc. associated with clinical trials and other studies, we will not use such meetings and conferences, etc. for promotional purposes.

#### **5 Provision and Management of Samples**

Samples are a means of providing drug information. There are two types of samples: product samples, which are intended for healthcare professionals to confirm the external features of prescription drugs, and trial-use samples, which are intended for physicians to confirm and evaluate the quality, efficacy, safety, and other pharmaceutical particulars of drugs prior to adopting them for use. When providing either of these types of samples, we make sure that relevant prescription drug information accompanies them, and we provide only the minimum necessary amount.

In particular, since trial-use samples are used in actual clinical practice, we construct and appropriately implement a strict system of management.

#### **6 Relationship to the Fair Competition Code**

We proactively and rigorously comply with the Fair Competition Code. We conduct ourselves according to high ethical standards, without limiting ourselves to mere compliance with the Fair Competition Code.

If any doubt arises regarding applicability and other aspects between the Promotion Code and the Fair Competition Code, we will give precedence to and apply the Fair Competition Code.

### **III. Supplementary Provisions**

The Code incorporates the former Kissei Code of Practice for the Promotion of Ethical Drugs as Section II.  
Kissei Promotion Code for Prescription Drugs.

Established April 1, 2013  
Revised November 25, 2014  
Revised April 1, 2020  
Revised October 1, 2025

Section II. Promotion Code

Established April 1, 1993  
Revised October 1, 1993  
Revised October 1, 1995  
Revised June 1, 1998  
Revised June 1, 2000  
Revised April 1, 2001  
Revised April 1, 2004  
Revised April 1, 2005  
Revised January 1, 2007  
Revised September 1, 2012  
Revised April 1, 2020  
Revised October 1, 2025