Nippon Kayaku Pharmaceuticals Group

Promotion Code for Prescription Drugs

The Nippon Kayaku Pharmaceuticals Group Promotion Code for Prescription Drugs (hereafter: “this code”) was designed with the objectives of promoting, and widening appropriate use of, prescription drugs, and of specifying both the duties and basics pertaining to prescription drug promotion activities, so that all Nippon Kayaku executives and employees can carry out promotions appropriately while upholding high ethical standards.

“Promotion” shall be defined as “an action which aims to promote and widen appropriate use of prescription drugs based on the provision, collation and transmission of medical information to medical professionals.” The term shall cover all actions that may affect the prescription decisions of medical professionals.

Nippon Kayaku shall uphold such laws and voluntary standards as The Act Securing Quality, Efficacy and Safety of Products Including on Pharmaceuticals and Medical Devices (hereafter: the “Pharmaceuticals and Medical Devices Act” (PMD Act)), the Antimonopoly Act, the Fair Practice Standards for the Advertising of Drugs and Related Products, the Guidelines for Provision of Sales Information for Prescription Drugs (issued Apr 1st 2019), (hereafter: Sales Information Provision Guidelines), the JPMA Code of Practice, the Fair Sales Activities Policy, the Fair Competition Code in the Ethical Pharmaceutical Drugs Marketing Industry (hereafter: the “Fair Competition Code”). Actions conflicting with these laws and standards, even if not specifically noted within this code, shall be taken to be code contraventions.

Furthermore, information regarding money matters and funding to medical institutions falling under these regulations shall be disclosed on the Nippon Kayaku homepage based on our Policy for Transparent Relationships between Nippon Kayaku and Medical Institutions (hereafter: “Transparency Policy”).

1. Nippon Kayaku duties with regard to promotion activities

Based on the Pharmaceutical Industry Ethics Code, the JPMA Charter for Good Corporate Conduct, and our own Nippon Kayaku Group Charter of Conduct and Code of Conduct, Nippon Kayaku takes all responsibility for promotions pertaining to its own prescription drugs. In recognition of that, we have established internal systems within our Pharmaceuticals Division to conduct appropriate promotions and thoroughly ensure that all executives and employees comply without exception.

Furthermore, both the Nippon Kayaku Code of Compliance and this code shall be applied

to not only promotion activities but activities deemed to be promotions, regardless of whether such activities are carried out by the Marketing and Sales Division.

(1) We shall continually set up education and training opportunities for executives and employees in order to promote and widen appropriate use of drugs.
(2) We shall not adopt any evaluation or remuneration systems that induce executives or employees towards unethical actions.
(3) We have set up a Pharmaceuticals Division Code Compliance Committee to help ensure observation of related laws and voluntary standards, ready internal systems, and fix, revise and disseminate operating rules.

2. The basics of promotion activities

Promotion activities conducted by Nippon Kayaku executives and employees should demonstrate sufficient awareness of our social mission as a component of the medical care, and of our positions as company representatives undertaking medical information provision activities. Executives and employees shall earnestly adhere to the following points.

(1) No form of promotional activity shall be carried out until a drug is domestically approved, and no off-label drug use encouraged.
(2) While knowledge of our company's digitalized attached documents and Drug Risk Management Plan (hereafter: "RMP") is a given, we shall also work to acquire knowledge of the medical and pharmacological basis behind the above so as to foster our ability to provide accurate and scientifically-grounded information.
(3) Promotions shall be undertaken in line with the contents and methods determined within the Nippon Kayaku Code of Practice and internal regulations.
(4) Information pertaining to efficacy, effects, usages, dosages and safety shall, within the bounds of approval for use as a drug, shall be fairly and impartially presented based on the latest scientifically-grounded data.
(5) Collation and transmission of medical information shall be done accurately and rapidly.
(6) We shall not slander or libel other companies or their products.
(7) When visiting medical institutions, we shall uphold the rules of the institution concerned and be disciplined in our actions.
(8) We shall observe related laws, voluntary standards and internal regulations, and take sensible actions.

3. Creation and use of promotion materials

When it comes to creating our own printed promotion materials, advertisements for

(paper) academic journals, and visually informative websites, slides and videos for medical professionals, Nippon Kayaku shall retain awareness of these being key medical information provision methods. When creating and using such materials, we shall follow the PMD Act, communications from the authorities, Sales Information Provision Guidelines and related voluntary standards such as our Creation Guidelines for Prescription Drug Product Outline Information and our Pharmaceuticals Division's Handling Guidelines for the Creation and Use of Information Materials pertaining to Prescription Drugs and Medical Devices. We shall thereby ensure that the contents we publish are scientifically-grounded, accurate and impartial. Furthermore, we shall only use contents examined and approved by our internal management system centered upon the Pharmaceutical Division's Prescription Drug Product Outline Information Manager.

4. Staging seminars and conferences

When staging seminars aimed at medical professionals with the objective of diffusing medical, pharmacological, bioengineering and disease awareness information, Nippon Kayaku shall assume ultimate responsibility for such seminars and ensure that attendees are presented with information that is specialist, academic and scientific.

The locations and venues selected for such seminars shall be in line with, and appropriate to, the objectives of the event, and, in principle, be inside Japan. When offering food and drink alongside such seminars, we shall follow our Internal Guidelines on Provision of Food and Drink, and make no luxurious or excessive offers. We shall forever check our provisions against our latest internal standards.

For the provision of monies in connection with seminars, we shall set limits on the travel expenses (for transport and accommodation) and amount of remuneration awarded to the professor, or such like, serving as guest speaker. Remuneration amounts shall also be deemed a reasonable reflection of the contents of work offered. Furthermore, we shall neither accept travel expenses claims from the guest speaker's retinue nor permit such retinue to participate in networking events.

When providing gifts, we shall observe both the Fair Competition Code and Nippon Kayaku Group Code of Practice, and shall not offer goods to medical professionals or institutions that are liable to either affect appropriate drug use or damage drug quality. Provision of goods shall be made in line with our Internal Standards on Social Formalities: Provision of Gifts, Monies and Participation in Events, and upon confirmation of the latest such standards.

The planning of seminars for the general public with the objective of increasing disease awareness shall be conducted with cognizance of the PMD Act and the Fair Practice Standards for the Advertising of Drugs and Related Products. Furthermore, Nippon Kayaku, when convening advisory meetings or follow-up conferences to medical

trials to gain expert academic opinion for, for example, the drafting its product strategy plans, shall not use such events as promotional methods.

5. Provision and management of trial drugs

Trial drugs, which represent a method of providing information on prescription drugs, come in two forms. “Preparations” exist for medical professionals to confirm the external appearance of prescription drugs, while “clinical trial drugs” exist for doctors to confirm quality, efficacy, safety and material characteristics before they enter use.

When providing either of the above, we shall, in line with information pertaining to the drug confirmed, always provide no more than the minimum necessary amount of the drug. In particular, regarding clinical trial drugs to be deployed in actual clinical practice, we shall observe the Fair Competition Code, and provide and manage them in accordance with the Guidelines for Trial Drugs and the Management Guidelines for Trial Medical Devices fixed by our Pharmaceuticals Division. Our provision of drugs shall always be checked against the latest internal company standards.

6. Relationship to the Fair Competition Code

Nippon Kayaku shall go above and beyond in its proactive and strict observation of the Fair Competition Code. We shall not only seek to observe this Code but conduct our activities with high ethical standards.

7. Convening briefing sessions

When staging briefing sessions for medical professionals on its own pharmaceutical products, Nippon Kayaku shall observe the Fair Competition Code and the Guidelines for Handling Briefing Sessions established by our own Pharmaceuticals Division. Furthermore, provision of food, drink and bento lunches shall be made according to our Internal Standards on Provision of Food and Drink, and Internal Guidelines on the Provision of Goods, Monies and Food and Drink to Wholesalers. We shall also confirm all the latest regulations and guidelines on each such occasion.

8. Handling medical devices

With respect, also, to the medical devices we manufacture and sell, Nippon Kayaku shall operate according to this code’s regulations.

9. Confidentiality of customer information etc.

Regarding personal information connected to patients, trials and participants in subcontracted research gained in the conduct of business, and internal information held on customers, Nippon Kayaku shall, in principle, based on the Act on Protection

of Personal Information (APPI) and our own Personal Information Protection Policy, never engage in the disclosure of such information to third parties and the use of such information in promotions without the consent of the individual(s) concerned.

10. Operation

Operation of these regulations shall be conducted with reference as appropriate to the regulations determined by the Pharmaceuticals Division.

11. Revisions to, and abolitions of, these regulations

The drafters shall, in principle, meet at the end of every financial year to reassess this code. In the event said drafters deem revisions and abolitions to be necessary, they shall carry out such tasks in consultation with the Pharmaceuticals Division Code Compliance Committee. Furthermore, when receiving instructions to update the relevant sections of this code from the Ministry of Land, Labor and Welfare, or in response to revised industry voluntary standards, the Pharmaceuticals Division Code Compliance Committee shall be promptly consulted and the task promptly carried out.

〔Timeline〕

Jun 1st 2004	In line with JPMA Promotion Code revisions, the paragraph on "Top Management Duties" was added. The code was also given a more contemporary flavor, with some wording revised.
Sep 1st 2005	Paragraphs 11, 12 and 13 were added in line with the revised Pharmaceutical Affairs Act, the establishment of the Personal Information Protection Act, and newly-commenced sales of medical devices.
Jan 1st 2007	A reassessment was conducted and revisions made in accordance with the IFPMA Marketing Code, JPMA Promotion Code and Revised Operating Standards for the Fair Competition Code.
Jun 1st 2007	Paragraph 8 on "Provision of Goods" was updated to include an upper price limit on goods that can be provided to individual medical professionals on occasions of celebration or condolence.
Jun 1st 2008	Paragraph 4 on the "Creation and Use of Printed Promotional Materials and Advertising" had the words "operating standards"

rewritten as “handling guidelines” in two separate places.

Sep 1st 2012 — In accordance with the JFTC’s Revised Operating Standards on Food and Drink Provision and revisions to the JPMA Promotion Code, separate Internal Standards for Food and Drink Provision and Internal Standards for Provision of Goods and Monies were fixed and reflected in this code. Furthermore, Paragraph 11 on Overseas Promotions was added, and the wording of the Transparency Policy reflected.

Jan 1st 2016 — The Pharmaceutical Affairs Act was partially revised on Nov 25th 2014 to become the PMD Act. Furthermore, the IFPMA Marketing Code was updated to become the IFPMA Code of Practice in March 2012, and subsequently the JPMA Code of Practice in April 2013. The Handling Guidelines for the Creation and Use of Promotional Materials for Prescription Drugs and Medical Devices (first edition) were also fixed. Meanwhile, “Trial Medical Devices” was added to the Paragraph 6 item on “Provision”.

Apr 1st 2016 — The “Handling Guidelines for Seminars, Research Groups and Briefing Sessions” were divided into “Seminars and Research Groups”, and “Briefing Sessions.” The Guidelines on Handling Briefing Sessions were revised and added to Paragraph 8. Meanwhile, the Nippon Kayaku Pharmaceuticals Division HQ Promotion Code Committee was renamed the Nippon Kayaku Pharmaceuticals Division Code Compliance Committee.

Nov 1st 2019 — In line with organizational restructuring, the drafters updated the term “Compliance Manager” to “Medical Information Chief.” A postscript on conformity with Prescription Drug Sales Information Provision Guidelines and the JPMA Code of Practice was also added.”

Oct 1st 2023 — In line with organizational title changes, the “Pharmaceuticals Division Head Office” was renamed “the Pharmaceuticals Division”.

Jan 1st 2024 — The “Handling Regulations for the Creation and Use of Promotion Materials and Advertising for Prescription Drugs, and

	Information Materials for Medical Devices" contained in Paragraph 4: "Creation and Use of Printed Promotion Materials and Advertising" were retitled as the "Handling Regulations for the Creation and Use of Information Materials for Prescription Drugs and Medical Devices"
Oct 1st 2025	In line with revisions to the JPMA Code of Practice, the Nippon Kayaku Code of Practice was made the basis for our Code of Conduct, while the Promotion Code was made the basis for our Promotion Code of Conduct, with duplications ironed out.