Nippon Kayaku Pharmaceuticals Group
Promotion Code for Prescription Drugs

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Compiled by: Medical Information Supervision Department Manager

As an entity involved in the manufacture and sale of pharmaceutical drugs, Nippon Kayaku, guided by ever-increasing awareness of ethical issues, seeks to voluntarily observe the Regulations for Enforcement of the Act on Securing Quality, Efficacy and Safety of Products including Pharmaceuticals and Medical Devices (hereafter: laws on pharmaceuticals and medical devices etc.); antitrust laws and related legislation; Presentation Activity Guidelines for Prescription Drug Marketing Information (effective as of 2019-04-01) (hereafter: Marketing Information Presentation Activity GL); the Japan Pharmaceuticals Manufacturers Association (JPMA) Code of Practice; and the Fair Competition Code for the Manufacture and Sale of Prescription Drugs (hereafter: Fair Competition Code). The company also seeks to present, gather and convey medical information via appropriate processes and in an accurate and prompt manner, while seeking to promote the appropriate use of pharmaceutical drugs under the following Nippon Kayaku Pharmaceuticals Group Promotion Code for Prescription Drugs.

These regulations were adopted internally by the company based on the JPMA Code of Practice, in turn derived from the IFPMA Code of Practice, and the Fair Marketing Activity Guidelines established to help ensure compliance with related laws and regulations.

Nippon Kayaku shall also publish on its company homepage information related to Promotion Code provisions on money matters and funding for medical institutions based on the Transparency Guidelines for Nippon Kayaku's Relationships with Medical Institutions etc. (hereafter: transparency-related guidelines).

1. Nippon Kayaku's obligations

In line with the Guidelines on Pharmaceutical Company Ethics, the JPMA Charter of Corporate Behavior, and the Nippon Kayaku Group Charter of Conduct and Code of Conduct, we shall require our Pharmaceuticals Group to devise an internal system geared towards appropriate promotion conduct which takes full responsibility for our company's prescription drug promotions. Nippon Kayaku shall also require its group companies (in which its shareholding exceeds 50%), both

domestically and overseas, to observe this Promotion Code, and request that our partner companies do likewise.

(1) To ensure observation of related laws and regulations, and voluntary standards, we shall set up a Nippon Kayaku Pharmaceuticals Group Code Compliance Committee to devise, disseminate and instill various internal operational standards and relevant instruction manuals.
(2) We shall also continually set up education and training programs for our Medical Representatives (hereafter: MR) related to appropriate use of pharmaceutical drugs.
(3) Our evaluation and remuneration system shall not incentivize MRs to act unethically.
(4) With respect to the efficacy, effectiveness, usage and dosage of pharmaceutical drugs, we shall, within the bounds of approval, provide information based on the latest scientifically-backed data via appropriate methods.
(5) We shall gather and convey pharmaceutical drug information both accurately and promptly.

2. Top management obligations

In order to meet the responsibilities entrusted to us by society as a company connected with human life, our top management shall exhibit the requisite awareness and responsibility demanded of their roles when carrying out the following.

(1) Recognizing that their role is to bring the aims of these regulations into reality, and leading by example when preparing dissemination activities and readying internal company systems.
(2) Proactively taking responsibility for solving problems related to situations in which the aims of the rules have been violated, conducting the relevant work on root-cause investigations and recurrence prevention measures.

3. MR obligations

Tasked with the mission of taking on part of society's medical care duties, MRs should have sufficient awareness of their positions as company representatives exercising the function of providing medical information as they faithfully seek to implement the following.

(1) In addition to gaining knowledge of the documents accompanying our company's medical products, which goes without saying, cultivating the requisite ability to present these documents by working to acquire the underpinning medical and scientific knowledge.
(2) Conducting product promotions in line with the contents and methods determined by the company's Pharmaceuticals Group.
(3) Fairly and impartially presenting information on the efficacy, safety, usage and dosage of pharmaceutical drugs within the boundaries of the drug's approval as a medical product.
(4) Gathering and conveying medical information both accurately and promptly.
(5) Refraining from making slanderous or libelous statements about other companies' products.

(6) Respecting house rules and regulations and behaving in a disciplined way when visiting other institutions.
(7) Showing the common sense expected of a Nippon Kayaku Pharmaceuticals Group MR when observing or voluntarily complying with related laws and regulations.

4. On the creation and use of promotional materials and advertising

Nippon Kayaku recognizes that its printed promotional materials, adverts in specialist print magazines, websites aimed at healthcare professionals, and visual and audio materials such as slides, videos and other related promotional materials all constitute important vehicles for presentation of medical information. These materials shall be created and used in voluntarily compliance with laws on pharmaceuticals and medical devices, Marketing Information Presentation Activity GL, and related Key Points on the Creation of Information Overviews for Prescription Drugs Products. Such materials shall also be in line with Nippon Kayaku Pharmaceuticals Group Regulations on Handling the Creation and Use of Outline Information Materials on Prescription Drugs and Medical Devices, thereby guaranteeing that their contents are scientifically-grounded, accurate, impartial and objective.

(1) Promotional materials and advertisements are screened and approved in accordance with the Regulations on Handling the Creation and Use of Outline Information Materials on Prescription Drugs and Medical Devices. Only materials gaining approval from our management system centered upon our Person in Charge of Outline Information Materials on Prescription Drug Products shall ultimately be used.
(2) Printed materials and website contents aimed at healthcare professionals, patients and the general public shall only be used subject to approval by our internal screening committee.
(3) We shall not print information pertaining to efficacy, efficiency, usage and dosage that falls outside the scope of approval.
(4) We shall neither make false or exaggerated claims about the efficacy and safety of products, nor use expressions, indications or layouts likely to cause misunderstanding. Expressions which emphasize or guarantee product safety are strictly forbidden.
(5) We shall provide unbiased information on product efficacy, as well as impartially publish information pertaining to side effects and safety.
(6) We shall only make comparisons with other drugs by using objective data and, in principle, generic names.
(7) We shall not print anything slanderous or libelous about other companies or their products.
(8) We shall not use expressions which lead our audience to believe that outlying data is actually the norm.
(9) We shall not use photographs or illustrations which either provoke misunderstanding or seek to harm the image of medical products.

5. Setting up Postmarketing Surveillance

Nippon Kayaku recognizes the importance of Postmarketing Surveillance, which is linked to the essence of the product. In drawing together its Postmarketing Surveillance documents for its own medical products, Nippon Kayaku observes GVP ministerial ordinances, laws and self-regulations related to GPSP ministerial ordinances, and establishes and implements a management system based on the Pharmaceuticals Group's Safety Management Task Manual for Prescription Drugs, Medical Device Safety Management Task Manual, and the Task Manual for Postmarketing Surveillance for Prescription Drugs and Medical Devices. Such surveillance shall not be used as a sales promotion method.

(1) Postmarketing Surveillance and Testing shall be carried out based on the Postmarketing Surveillance and Testing Implementation Plan for the products in question.
(2) Postmarketing Surveillance and Testing shall be carried out on medical institutions that have adopted the products in question.
(3) Postmarketing Surveillance and Testing shall be carried out on medical institutions that are able to guarantee the required number of case studies for the products in question.
(4) Postmarketing Surveillance and Testing shall only be requested for the necessary number of case studies.
(5) Requests for Postmarketing Surveillance and Testing shall be lodged with the relevant medical institution in writing, and conducted based on the terms of a contract.
(6) Postmarketing Surveillance and Testing which pertain to reevaluation needs and other such mandatory requirements associated with the product in question shall be prioritized over other surveys.
(7) Posmarketing Surveillance and Testing shall be remunerated in accordance with fair competition regulations and medical institution regulations.
(8) The results of Postmarketing Surveillance and Testing shall be reported to the participating medical institution.
(9) We shall receive medical institution reports on side-effects and infections based on task manual guidelines.
(10) We shall effectively, promptly and comprehensively convey information of relevance to the correction of product instruction documents and warnings.
(11) In order to guarantee the reliability of Postmarketing Surveillance and Testing, we shall take extra care not to offer unfair inducements to trade or cause misunderstandings.

6. Supplying trial drugs and trial medical devices

Trial drugs constitute a method of presenting information and are available in two forms: Preparation

Examples, which convey information to medical professionals on the outward appearance of prescription drugs, and Clinical Trial Drugs, which doctors take the lead in using so as to ascertain and evaluate the quality, efficacy and safety of drug characteristics. In both cases, we shall follow the relevant drug information and supply only the minimum amount necessary. As Clinical Trial Drugs shall actually be put into medical use, we shall pay especial heed to fair competition regulations as well as our Pharmaceuticals Group's Key Points on the Management of Trial Drugs and Key Points on the Management of Trail Medical Devices when providing such drugs for clinical trial. We shall also ensure that these drugs are supplied in line with our most recent internal standards.

7. Setting up lectures and workshops

Nippon Kayaku shall set up its lectures and workshops for medical professionals on the prescription drugs it produces based on observance of fair competition regulations and its Pharmaceuticals Group's Regulations on Handling Seminars and Lectures – as well as its separate Internal Company Standards on Provision of Food and Drink. Each seminar and workshop shall be focused on confirming the latest product handling regulations and key points of note.

8. On the setting up of briefing sessions

Nippon Kayaku shall set up product briefing sessions for medical professionals on the prescription drugs it produces based on observance of fair competition regulations and its Pharmaceuticals Marketing Division's Key Points on the Handling of Briefing Sessions. The tea, cakes and bento boxes to be served at such briefing sessions shall be determined based on our Internal Standards for Provision of Food and Drink and our Internal Standards Related to the Provision of Commodities, Money, and Food and Drink. Each briefing session shall be focused on confirming the latest product handling regulations and key points of note.

9. Provision of goods

In instances where Nippon Kayaku offers goods to medical professionals or institutions, it shall do so in observance of Fair Competition Regulations and the JPMA Code of Practice. It shall offer neither goods which may affect the appropriate use of prescription drugs nor commodities which degrade those drugs. All goods are offered in accordance with our Internal Standards on the Provision of Social Courtesy Gifts or Money, and Attendance at Events. Each good will be given after consultation with the latest internal company standards.

10. Provision of money

In instances where Nippon Kayaku provides money to medical professionals and institutions, it shall follow the Operating Standards for Fair Competition Regulations and the JPMA Code of Practice, as

well as the National Public Service Ethics Code and Ethical Regulations, and any regulations put in place by the medical institution concerned. All money shall be provided in accordance with the Regulations on Handling the Provision of Money to Medical Institutions, and with reference to the latest internal company standards.

11. Provision of food and drink to medical professionals

In instances where Nippon Kayaku provides food and drink to medical professionals, it shall follow its Internal Standards on the Provision of Food and Drink, and refer to the latest internal company standards.

12. Conducting promotions overseas

In instances where Nippon Kayaku conducts promotions overseas, it shall adhere to the relevant country's regulations and IFPMA Code of Practice, and pay particular attention to the following points.

(1) Presenting medical information overseas

In instances where Nippon Kayaku provides medical information to overseas medical institutions, whether it be directly or through the offices of an agency, it shall do so with international consistency, and in line with the relevant country's regulations and IFPMA Code of Practice.

(2) Overseas subsidiaries

In instances where a promotion is conducted by a Nippon Kayaku subsidiary (in which shares or equity held by Nippon Kayaku exceed 50%), it shall follow the promotion code of the relevant country's pharmaceuticals federation, and in cases where no such code exists, refer to the IFPMA Code of Practice.

(3) Overseas licensing and agencies

In instances where Nippon Kayaku seeks an overseas licensing or agency agreement with a licensee or agency, it shall make such requests in accordance with the promotion code of the relevant country's pharmaceuticals federation and the IFPMA Code of Practice.

(4) Dealing with domestic medical professionals in overseas settings

In instances where Nippon Kayaku holds a workshop, lecture or conference overseas, domestic medical professionals involved should be treated in line with these regulations.

(5) Dealing with overseas medical professionals in domestic settings

When inviting overseas medical professionals to take part in a workshop, lecture or conference inside Japan, Nippon Kayaku shall follow the relevant country's promotion code, and in cases where no such code exists, refer to the IFPMA Code of Practice.

13. Handling medical devices

In the manufacture and sale of its own medical devices, Nippon Kayaku shall operate according

to these regulations.

14. Confidentiality of customer information etc.

Regarding personal information and internal information gathered during the course of work from patients, clinical trials, and the subjects of contracted research, Nippon Kayaku shall in principle, and in line with Laws Concerned with the Protection of Personal Information (Personal Information Protection Laws) and its own internal Personal Information Protection Policy, neither disclose such information to third parties without the consent of the individuals concerned, nor use such information in promotions.

15. Operation

The operation of these regulations shall be conducted with appropriate reference to the most recent version decided by the Pharmaceuticals Group.

16. Revising or Abolishing these Regulations

In principle, the drafters of these regulations shall reassess them at the end of each financial year, and in cases where revisions or abolitions are deemed necessary, conduct such revisions or abolitions in consultation with the Pharmaceuticals Group Code Compliance Committee. Furthermore, revisions or abolitions to these regulations necessitated by updates to Ministry of Health, Labor and Welfare practices or new self-regulation practices by the industry itself shall be promptly made in consultation with the Pharmaceuticals Group Code Compliance Committee.

History of revisions

2004-06-01 Following revisions to the JPMA Promotion Code, these regulations were accordingly updated, with a new section added on Top Management Obligations and some sentences reworded.

2005-09-01 In response to the Revised Japanese Pharmaceutical Law, the Law for the Protection of Computer-Processed Personal Data Held by Administrative Organs, and new sales and marketing of medical devices, Paragraphs 11, 12 and 13 were added.

2007-01-01 Following revisions to the IFPMA Marketing Code, the JPMA Promotion Code and the Operating Standards for Fair Competition Regulations, these regulations were reassessed and accordingly revised.

2007-06-01 An upper limit for the value of goods given to individual medical professionals on

occasions of celebration or condolence was fixed for “Paragraph 8: Provision of Goods.”

2008-06-01 Two revisions were made to “Paragraph 4: On the Creation and Use of Promotional Materials and Advertising”, changing the expression “Operating Standards” to “Key Points on the Handling of.”

2012-09-01 Following on from the Revised Operating Standards on the Provision of Food and Drink issued by the The Fair Trade Council of the Ethical Prescription Drugs Marketing Industry, and the Revised JPMA Promotion Code, we updated our supplementary Internal Standards on the Provision of Food and Drink, and Internal Standards on the Provision of Goods and Money,” reflecting this in our Code. “Paragraph 11: Conducting promotions overseas” was also added and made to reflect the wording on Transparency Policies.

2016-01-01 Nov 25th 2014 saw the Pharmaceutical Affairs Law part-revised to become the Pharmaceutical and Medical Device Act. Furthermore, March 2012 saw the IFPMA Marketing Code updated into the IFPMA Code of Practice, which was further revised into the JPMA Code of Practice on April 1st 2013. In response, Jan 1st 2016 saw Nippon Kayaku determine its Regulations for Handling the Creation and Use of Promotional Materials Related to Prescription Drugs and Medical Devices. The Paragraph 6 item related to presentation had “Test Devices” added to it.

2016-04-01 The Key Points on the Handling of Lectures, Workshops and Briefing Sessions were split into separate sections for “Lectures & Workshops” and “Briefing Sessions.” Our Key Points for the Handling of Briefing Sessions were also revised and added to Paragraph 8. Furthermore, the Nippon Kayaku Pharmaceutical Group Head Office Promotion Code Committee was renamed the Nippon Kayaku Pharmaceutical Group Head Office Code Compliance Committee.

2019-11-01 An organizational change saw the Medical Information Supervision Department take over responsibility for drafting these regulations from the Compliance Promotion Office Manager. We also included wordage on basing certain sections on the Marketing Information Presentation Activity GL and the JPMA Code of Conduct.

2023-10-01 Following an organizational name change, “the Pharmaceuticals Group Head Office” was renamed “the Pharmaceuticals Group.”

2024-01-01 In Paragraph 4: The Creation and Use of Printed Promotional and Advertising Materials, the “Regulations on the Handling of the Creation and Use of Promotional and Advertising

Materials Providing Information on Prescription Drugs and Medical Devices" were retitled: "Regulations on the Handling of Creation and Use of Information Materials on Prescription Drugs and Medical Devices."