

# **Daiichi Sankyo Group Marketing Code of Conduct**

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## 1. PURPOSE

The purpose of this Daiichi Sankyo Group Marketing Code of Conduct (the “Group Marketing Code”) is to establish the principles and policies for interactions with Healthcare Professionals, medical institutions and Patient Organizations, and the Promotion of Pharmaceutical Products.

## 2. SCOPE

As set forth in the related Implementation Guide dated September 3, 2018, this Group Marketing Code applies to all Executives, Employees and Contingent Workers of the Company who interact with Healthcare Professionals, medical institutions and/or Patient Organizations, and/or are involved in the design, development and implementation of promotional and/or professional activities related to Pharmaceutical Products for Healthcare Professionals, medical institutions and/or Patient Organizations.

## 3. TERMS

<b>Term</b>	<b>Definition</b>
Commercial Employee	Employees who promote Pharmaceutical Products, develop promotional materials or engage in other activities intended to promote Pharmaceutical Products and may in their job responsibilities interact with HCPs on the Company's behalf, including home-based or field based Employees (line personnel as well as their management).
Company	Each company of Daiichi Sankyo Group (Daiichi Sankyo Co., Ltd. and its affiliates).
Contingent Workers	All individuals who provide services to the Company subject to a contingency. Typically, the contingency is a temporary need for services for a limited period of time, a select service, or a specific result/outcome. Contingent Workers include agency temporary workers, independent contractors, consultants, vendors, contract workers and fellows.
Employee	An individual hired directly by the Company and paid through the Company payroll as an employee for an ongoing period to perform work for the Company.
Executives	Board members and audit and supervisory board members (as applicable) of the Company.
Grant Support	Provision of unrestricted funds to help educate or raise awareness of shared disease or scientific objectives such as the funding for the continuing medical education (CME), non-CME education and awareness events, screening programs, medical scholarships, medical fellowships and investigator initiated study programs.
Health Care Professional (HCP)	Any member of the medical, dental, pharmacy or nursing professions or any other person who in the course of his or her professional activities may prescribe, recommend, purchase, supply, sell or administer a Pharmaceutical Product or recommend or grant a Pharmaceutical Product

	for placement on a formulary, approved reimbursement list or similar payment status.
Patient Organization	Typically a not-for-profit institution that primarily represents the interests and needs of patients, their families and and/or caregivers.
Pharmaceutical Product	All pharmaceutical or biological products (irrespective of patent status and/or whether they are branded or not) which are intended to be used on the prescription of, or under the supervision of, a HCP, and which are intended for use in the diagnosis, treatment or prevention of disease in humans, or to affect the structure or any function of the human body. For the avoidance of doubt, over-the-counter medicines are not Pharmaceutical Products.
Promotion	Any activity undertaken, organized or sponsored by the Company which is directed at HCPs to promote the prescription, recommendation, supply, administration or consumption of its Pharmaceutical Product(s) through all methods of communications, including the internet.

#### **4. COMPLIANCE WITH LOCAL LAWS, REGULATIONS AND INDUSTRY CODES**

This Group Marketing Code defines minimal standards for the common practices. In addition, any practice must comply with all applicable laws, regulations, and industry codes, as well as with local/ regional Company's standards, which may impose more stringent requirements.

#### **5. BASIS OF INTERACTIONS**

The Company's relationships with HCPs are intended to enhance the practice of medicine. Interactions must be focused on informing HCPs about Pharmaceutical Products, providing scientific and educational information and supporting medical research and education. Material relating to Pharmaceutical Products and their uses, whether promotional in nature or not, which is sponsored by the Company, should clearly indicate by whom it has been sponsored. Promotion should not be disguised. Commercial Employees and Contingent Workers may engage with HCPs in a variety of situations that are promotional in nature. Such situations could include sales calls, promotional speaker programs, conference or other industry events held by professional organizations.

#### **6. PRE-APPROVAL COMMUNICATIONS AND OFF-LABEL USE**

No Pharmaceutical Product of the Company shall be promoted for use in a specific country until the requisite approval for marketing for such use has been given in that country. This provision is not intended to prevent the right of the scientific community and the public to be fully informed concerning scientific and medical progress. It is not intended to restrict a full and proper exchange of scientific information concerning a Pharmaceutical Product, including appropriate dissemination of investigational findings in scientific or lay communications media and at scientific conferences. Nor should it restrict public disclosure of information to stockholders and others concerning any Pharmaceutical Product, as may be required or desirable under law, rule or regulation.

## **7. STANDARDS OF PROMOTIONAL INFORMATION**

### **7.1. Consistency of Product Information**

It is understood that national laws and regulations usually dictate the format and content of the Pharmaceutical Product information communicated on labeling, packaging, leaflets, data sheets and in all other promotional materials. Promotion should not be inconsistent with locally approved Pharmaceutical Product information. Respecting the requirement that Promotion should be consistent with the label and approved uses locally, HCPs in developing countries should have access to similar data to those being communicated in developed countries.

### **7.2. Accurate and Not Misleading**

Promotional information should be clear, legible, accurate, balanced, fair, and sufficiently complete to enable the recipient to form his or her own opinion of the therapeutic value of the Pharmaceutical Product concerned. Promotional information should be based on an up-to-date evaluation of all relevant evidence and reflect that evidence clearly. It should not mislead by distortion, exaggeration, undue emphasis, omission or in any other way. Every effort should be made to avoid ambiguity. Absolute or all-embracing claims should be used with caution and only with adequate qualification and substantiation. Descriptions such as “safe” and “no side effects” should generally be avoided and should always be adequately qualified.

### **7.3. Substantiation**

Promotion should be capable of substantiation either by reference to the approved labeling or by scientific evidence. Such evidence should be made available on request to HCPs. The Company should deal objectively with requests for information made in good faith and should provide data which are appropriate to the source of the inquiry.

### **7.4. Direct-To-Consumer Promotion**

In most countries direct-to-consumer Promotion of the Pharmaceutical Product is not allowed. Where such Promotion is allowed, all Pharmaceutical Product-related information must be in appropriate language for lay persons. The same applies to information targeted at the general public.

## **8. PRINTED PROMOTIONAL MATERIAL**

### **8.1. Necessary Content**

All printed promotional material, including advertisements, other than “reminder advertisements” (which is covered in section 8.2. below) shall include:

- The trade name and generic name of the Pharmaceutical Product;
- The active ingredients, using approved names where they exist;
- The name, logo and address of the Company or its agent responsible for marketing the Pharmaceutical Product;
- Date of production of the advertisement (month/year); and

- “Abbreviated prescribing information” which should include an approved indication or indications for use together with the dosage and method of use; and a succinct statement of the contraindications, precautions, and side-effects.

## **8.2. Reminder Advertisements**

A “reminder advertisement” is defined as a short advertisement containing no more than the name of the Pharmaceutical Product, and may also include a simple statement of indications to designate the therapeutic category of the Pharmaceutical Product. For “reminder advertisements”, “abbreviated prescribing information” referred to above may be omitted.

## **9. ELECTRONIC MATERIALS, INCLUDING AUDIOVISUALS**

The same requirements shall apply to electronic promotional materials, including audiovisuals, as those applied to printed promotional material. Specifically, in the case of Pharmaceutical Product related websites:

- The identity of the Company and of the intended audience should be readily apparent;
- The content should be appropriate for the intended audience;
- The presentation (content, links, etc.) should be appropriate and apparent to the intended audience; and
- Country-specific information should comply with local laws and regulations.

## **10. INTERACTIONS WITH HEALTHCARE PROFESSIONALS**

### **10.1. Events and Meetings**

#### **10.1.1 Scientific and Educational Objectives**

The purpose and focus of all symposia, congresses and other promotional, scientific or professional meetings (each individually referred to as an “Event”) for HCPs organized or sponsored by the Company should be to provide scientific or educational information and/or inform HCPs about Pharmaceutical Product.

#### **10.1.2 Events Involving Foreign Travel**

Each Company may organize or sponsor an Event for HCPs (including sponsoring individuals to attend such an Event as described in section 10.2. below) that takes place outside of the HCP’s country of practice if it is appropriate and justified to do so from the logistical or security point of view. International scientific Events that derive participants from many countries are therefore justified and permitted.

#### **10.1.3 Promotional Information at Events**

Promotional information which appears on exhibition stands or is distributed to participants at international scientific Events may refer to Pharmaceutical Products which are not registered in the country where the Event takes place, or which are

registered under different conditions, provided that the following requirements are observed:

- Host country regulations should permit such an arrangement;
- The meeting should be a truly international, scientific Event with a significant proportion of the speakers and attendees from countries other than the country where the Event takes place;
- Promotional material (excluding promotional aids as described in section 10.5.2 below) for a Pharmaceutical Product not registered in the host country of the Event should be accompanied by a suitable explanatory statement indicating the countries in which the Pharmaceutical Product is registered and make clear that such Pharmaceutical Product is not available locally; and
- Promotional material which refers to the prescribing information (indications, warnings, etc.) authorized in a country or countries other than the host country of the Event but where the Pharmaceutical Product is also registered, should be accompanied by an explanatory statement indicating that registration conditions differ internationally.

#### **10.1.4 Appropriate Venue**

All Events organized by the Company must be held in an appropriate venue that is conducive to the scientific or educational objectives and the purpose of the Event. The Company must avoid using renowned or extravagant venue.

#### **10.1.5 Limits**

Refreshments and/or meals incidental to the main purpose of the Event can only be provided:

- Exclusively to participants of the Event; and
- If they are moderate and reasonable as judged by local standards.

#### **10.1.6 Entertainment**

Entertainment or other leisure or social activities must not be provided or paid for by the Company.

### **10.2. Sponsorships**

The Company may sponsor HCPs to attend Events provided such sponsorship is in accordance with the following requirements:

- The Event complies with the requirements in this Group Marketing Code as described in section 10.1 ;
- Sponsorship to HCPs is limited to the payment of travel, meals, accommodation and registration fees;
- No payments are made to compensate HCPs for time spent in attending the Event; and

- Any sponsorship provided to individual HCPs must not be conditional upon an obligation to prescribe, recommend, purchase, supply, administer or promote any Pharmaceutical Product.

### **10.3. Guests**

The Company must not pay any costs associated with individuals accompanying invited HCPs, except in cases of medical necessity for the HCP.

### **10.4. Fees for Services**

HCPs may be engaged as consultants and advisors for services such as speaking at and/or chairing Events, involvement in medical/scientific studies, clinical trials or training services, participation in advisory board meetings, and participation in market research where such participation involves remuneration. The arrangements which cover these genuine consultancies or other services must, to the extent relevant to the particular arrangement, fulfill all the following criteria:

- A written contract or agreement must be signed in advance of the commencement of the services which specifies the nature of the services to be provided and the basis for payment of those services;
- A legitimate need for the services must be clearly identified and documented in advance;
- The criteria for selecting consultants must be directly related to the identified need and the consultants must have the expertise necessary to provide the service;
- The number of consultants retained must not be greater than the number reasonably necessary to achieve the identified need;
- The hiring of the consultant to provide the relevant service must not be an inducement to prescribe, recommend, purchase, supply, and/or administer any medicine; and
- The compensation for the services (which may include the travel time) must be reasonable and reflect the fair market value of the services provided. The compensation arrangement may include reimbursement of reasonable expenses including travel, meals and accommodation.

### **10.5. Gifts and Other Items to HCPs**

#### **10.5.1 Prohibition of Cash and Gifts**

Cash, cash equivalents (such as gift certificates) or personal services must not be directly or indirectly provided or offered to HCPs. For these purposes, personal services are any type of service unrelated to the HCP's profession and that confer a personal benefit to the HCP. Other gifts for the personal benefit of HCPs (such as sporting or entertainment tickets, electronics items, social courtesy gifts, etc.) must not be directly or indirectly provided or offered.



### **10.5.2 Promotional Aids**

A promotional aid is a non-monetary item given for a promotional purpose, which does not include printed or electronic promotional materials as defined in sections 8 and 9 above. Providing or offering them to HCPs is prohibited. Notwithstanding the prohibition, pens and notepads can be provided or offered to HCPs in the context of company organized or third-party events as long as they are company branded only, of minimal value and only the necessary quantity for the purpose of the event are distributed.

### **10.5.3 Items of Medical Utility to enhance the Provision of Medical Services and Patient Care**

Items of medical utility may be offered or provided if such items are of modest value, infrequent, do not offset routine business practices and are beneficial to enhancing the provision of medical services and patient care. Items of medical utility must not have a value outside of the HCP's professional responsibilities. For example, a DVD player is not appropriate as it may have independent value to an HCP outside of his/her professional responsibilities. Items of medical utility can include the company name, but must not be product branded, unless the product's name is essential for the correct use of the item by the patient.

### **10.5.4 Informational or Educational Items that enhance Patient Care**

Informational or educational items provided to HCPs for their own education or for the education of patients on disease and its treatments may be provided or offered provided that the items do not have independent value except their educational purposes. Informational and educational items provided to HCPs for patient use can include the company name, but must not be product branded, unless the product's name is essential for the correct use of the item by the patient. The value of books and subscriptions must be reasonable. Other informational or educational items must be of modest value.

## **11. SAMPLES**

In accordance with local/ regional laws and regulations, free samples of a Pharmaceutical Product may be supplied to HCPs authorized to prescribe that Pharmaceutical Product in order to enhance patient care. Samples should be marked as such so that they cannot be resold or otherwise misused. Adequate systems of control and accountability for samples provided to HCPs must be utilized, including how to look after such samples whilst they are in possession of the Company representatives.

## **12. CLINICAL RESEARCH AND TRANSPARENCY**

### **12.1. Transparency**

The Company is committed to the transparency of clinical trials which it sponsors. It is recognized that there are important public health benefits associated with making clinical trial information more publicly available to HCPs, patients, and others. Such disclosure,

however, must maintain protection for individual privacy, intellectual property and contract rights, as well as conform to legislation and current national practices in patent law. The Company discloses clinical trial information as set out in the Joint Position on the Disclosure of Clinical Trial Information via Clinical Trial Registries and Databases (2009, with minor revisions as of October 30, 2017) and the Joint Position on the Publication of Clinical Trial Results in the Scientific Literature (2010, with minor revisions as of October 30, 2017) issued by the International Federation of Pharmaceutical Manufacturers and Associations (IFPMA), the European Federation of Pharmaceutical Industries and Associations (EFPIA), the Japanese Pharmaceutical Manufacturers Association (JPMA) and the Pharmaceutical Research and Manufacturers of America (PhRMA).

### **12.2. Distinct from Promotion**

All human subject research must have a legitimate scientific purpose. Human subject research, including clinical trials and observational studies, must not be disguised Promotion.

## **13. GRANT SUPPORT**

The Company may provide Grant Support to HCPs, Patient Organizations and medical institutions, including hospitals and institutions of higher learning that provide medical education programs that may be of interest to the Company, in accordance with sections 13.1 and 13.2.

### **13.1. Basic Concepts for Grant Support**

- Grant Support to HCPs, medical institutions and Patient Organizations by the Company shall be focused on medical and scientific endeavors consistent with its scientific and therapeutic areas of interest and are not be used as an opportunity to promote Pharmaceutical Products to HCPs, medical institutions and Patient Organizations;
- Executives, Employees or Contingent Workers may not solicit, suggest, or recommend that any individual or entity seek Grant Support from the Company;
- Grant Support provided by the Company shall always be clearly acknowledged and documented in a written agreement between the Company and the HCPs, medical institutions and/or Patient Organizations;
- The Company shall disclose financial relationships with HCPs, medical institutions and Patient Organizations, as well as any attendee, faculty, speaker, or organizer of any program funded by the Company, as required by applicable law and regulation and shall require HCPs, medical institutions and Patient Organizations, as well as any attendee, faculty, speaker, or organizer of any programs funded by the Company, to disclose and/or agree for the Company to disclose any financial relationships with the Company as a condition of funding whenever asked or expected by legislation, codes of conduct or any third person to do so locally; and

- The Company encourages multi-sponsor support and does not require that the Company be the sole supporter of any HCP, medical institution, Patient Organization or program. The objectives and scope of any interactions are to be transparent to the Company and to the HCP, medical institution and Patient Organization.

### **13.2. Prohibited Matters for Grant Support**

The Company should not engage in activities designed to affect the independent judgment of HCPs, medical institutions and Patient Organizations such as;

- offering or providing any Grant Support in a manner or on conditions that such support would interfere with the independence of the HCP, medical institution or Patient Organization;
- utilizing its Grant Support opportunities to promote its Pharmaceutical Products to a HCP, medical institution and Patient Organization or requesting that HCP, medical institution or Patient Organization promote its Pharmaceutical Product. This is not intended to restrict an Executive, Employee or Contingent Worker from purchasing exhibit or display space at fair market value and promoting Pharmaceutical Products at a hospital or a conference or other Event organized by a HCP, medical institution and/or Patient Organization; and
- providing and/or engaging in arrangements of Grant Support to HCPs, medical institutions and Patient Organizations as a means or method to:
  - Influence the registration, review or approval of Pharmaceutical Products in any country,
  - Influence HCPs, medical institutions and Patient Organizations services they provide for developing or disseminating branded or promotional materials of the Company,
  - Create a favorable formulary or reimbursement decision,
  - Reward past, present or future prescriptions, referrals or recommendations of Pharmaceutical Products,
  - Influence or directly support the development of clinical practice guidelines.

## **14. INTERACTIONS WITH PATIENT ORGANIZATIONS**

The Company may have common interests with Patient Organizations. All interactions with Patient Organizations must be ethical and the independence of Patient Organizations must be respected. When working with Patient Organizations, the Company must ensure that the involvement of the Company, and the nature of that involvement, is clear from the outset. The Company may provide Grant Support for Patient Organization meetings provided that the primary purpose of the meeting is professional, educational, and scientific in nature, or otherwise supports the mission of the Patient Organization. Venues and locations selected for the meetings for Patient Organizations must be appropriate and conducive to informational communication. In addition, any meals or refreshments provided by the Company must be modest as judged by local/ regional Company's standards.