

D. The Fair Competition Code and the Working Guidelines

KRPIA Fair Competition Code

CHAPTER 1. GENERAL

Article 1(Purpose)

The purpose of this “Code of Fair Competition in Pharmaceutical Trade” (hereinafter referred to as this “Code”) is to ensure public order of fair competition in distributing pharmaceuticals, and to maintain and improve the health of the public by curbing unfair customer solicitation activities prohibited by Item 3 of Paragraph 1 of Article 23 of the Monopoly Regulation and Fair Trade Law (hereinafter referred to as the “Fair Trade Law”).

Article 2 (General Principles)

Member companies shall observe the provisions of this Code according to the following general principles:

- 1 Marketing activities of pharmaceuticals shall be conducted to the extent that it does not violate relevant laws such as the Fair Trade Law and within the boundaries of acceptable normal commercial practice;
- 2 Member companies shall make efforts to deliver scientific and educational information of a product to healthcare professionals and try to maximize benefits to patients, provided that such efforts by member companies shall not interfere with the independent prescription rights of healthcare professionals;
- 3 Member companies’ activities under Paragraph 2 shall be conducted in appropriate venues in accordance with the purpose of such activities; and
- 4 Financial management including accounting records shall be recorded and managed precisely and transparently based on facts according to the relevant laws and generally accepted accounting principles.

Working Guideline

Article 1(Purpose)

1 The purpose of this Working Guideline (hereinafter referred to as “this Guideline”) is to set forth the details necessary for the implementation of the Code of Fair Competition in Pharmaceutical Trade (hereinafter the “Code”).

Article 2 (General Principles)

Member companies’ support for the continuing medical education of HCPs shall be provided to maximize the benefit of patients through continued provision of up-to-date domestic/overseas information on medicines/pharmaceuticals to the HCPs.

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Article 3 (Definitions)

The definitions of terms used in this Code are as follows:

- 1 "Pharmaceuticals" shall refer to prescription drugs and reimbursable over-the-counter drugs among those pharmaceuticals as designated under Item 4 of Article 2 (Definition of Pharmaceuticals) of the Pharmaceutical Affairs Law ("PAL");
- 2 "Member Company(ies)" shall refer to entities that carry on the business of manufacturing or importing, and selling pharmaceuticals after having obtained a manufacture business license and/or filing an import business notification pursuant to Article 31 or 42 of the PAL, and have qualifications as regular members or associate members of the Korean Research-based Pharmaceutical Industry Association ("KRPIA") under the regulation
- 3 "Wholesaler(s) of pharmaceuticals" ("Wholesaler(s)") shall refer to an entity which engages in the sale of pharmaceuticals after obtaining a pharmaceutical wholesaler's license pursuant to Article 45 of the PAL.;
- 4 "Medical institution(s)" shall refer to institutions other than Korea Orphan Drug Center as designated under Paragraph 1 of Article 42 of the National Health Insurance Act;
- 5 "Healthcare professional(s)" ("HCP(s)") shall refer to doctors, dentists, doctors of oriental medicine, pharmacists or herbal pharmacists;
- 6 "Sample(s)" shall refer to finished products of pharmaceuticals produced for the purpose of introduction;
- 7 "Donation" shall refer to any money or other valuables presented free-of-charge by member companies to medical institutions, schools, institutions or organizations which conduct academic or scientific researches on medicine or pharmacy, or academia- industry joint projects (hereinafter "medical institutions, etc."), irrespective of its title such as welcome contribution, support, sponsorship, or donation, etc.;
- 8 "Academic Conference(s)" shall refer to any event held to serve the purpose of supporting medical or pharmaceutical research and education of HCPs by providing HCPs with medicine/pharmacy-related scientific or educational information, irrespective of titles or forms, such as conferences,

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Article 3 (Definitions)

- 1 The terms used in this Guideline not defined otherwise shall have the same meaning as defined in the Code.
- 2 In the event goods, etc., under Article 3, Paragraph 12, Item 1 of the Code are lent free of charge with the rights of use associated therewith, money or other valuables equivalent to the rent at the fair market value of such goods, etc., shall be deemed to have been provided.

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symposia, seminars, academic events, etc., while events hosted by a member company shall practically be excluded. Among such academic conferences, “domestically-held international academic conferences” shall refer to those domestically-held academic conferences of an international scale for two (2) or more days, attended by HCPs from five (5) or more countries (HCPs from five (5) or more countries attending as audience, not as presenter, chair or panelist, must come to Korea.) or attended by participants of whom 150 or more are foreigners, and approved by medical doctors’ association, dentists’ association, oriental medical doctors’ association under Paragraph 1 of Article 28 of the Medical Services Act or the Korean Pharmaceutical Association, the Korea Oriental Pharmacy Association under Articles 11 and 12 of PAL as international academic conferences. “International Academy(ies)” shall refer to those academies approved by medical doctors’ association, dentists’ association, oriental medical doctors’ association under Paragraph 1 of Article 28 of the Medical Services Act or the Korean Pharmaceutical Association, the Korea Oriental Pharmacy Association under Articles 11 and 12 of PAL, 100 or more of whose regular members are foreigners from five (5) or more countries;

9 “Product Presentation(s)” shall refer to domestically-held events targeting multiple medical institutions and HCPs belonging thereto held by a member company for the purpose of providing information on its own pharmaceuticals, and the visiting of individual medical institutions thereby providing information on its pharmaceuticals to HCPs belonging thereto;

10 “Market Survey” shall refer to the activity of collecting data by a member company on the market and the scope and characteristics of its components, including consumer demands;

11 “Post-Market Surveillance Study” (“PMS”) shall refer to study conducted by one who has obtained product approval during a period of re-examination, including usage data collections, special investigations, post-market clinical trials, etc., to collect, review, validate or verify the data necessary for safety, effectiveness and appropriate usage of pharmaceuticals subject to re-examination pursuant to Article 32, and Paragraph 5 of Article 42 of PAL; and

12 “Money or other valuables”, irrespective of their means, shall refer to goods, money or other economic benefits offered by member companies to medical institutions, etc., or HCPs, including, but not limited to, the following:

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1. Goods, machines, devices, land, buildings, other constructions (right of use included);
2. Money, certificate of money deposit, gift certificates, other securities or written promises of payment under various titles;
3. Entertainment (food & beverages, invitations or privileged treatment to any performance or entertainments including movies, plays, sports, tour, golf, skiing, etc.);
4. Provision of convenience services, such as transportation, lodging and registration for academic conferences;
5. Provision of labor or other services; or
6. Discounts, premiums or sales incentives (but excluding "discount according to conditions of payment" and "accumulated points from the use of credit cards or debit cards" which fall under permissible economic benefits, etc., under the Enforcement Regulations of the Medical Service Act or Pharmaceutical Affairs Act), etc.

13 Electronic documents refer to information which was created in electronic format using an electronic device with information processing capabilities, such as computers, and transmitted, received, and/or saved and which expresses thoughts or ideas through commonly-used text and/or special signs, symbols, etc. that can be recognizable by people (excluding electronic video and sound).

Article 4 (Working Guideline)

- 1** KRPIA may prescribe working guideline ("Guideline") providing detailed rules of this Code.
- 2** Korean Fair Trade Commission ("KFTC") may recommend establishment of or amendment to the Guideline under Paragraph 1 if deemed necessary to ensure public order of fair competition.

Working Guideline

Article 4 (Working Guideline)

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CHAPTER 2. PERMISSIBLE SCOPE REGARDING PRESENTING MONEY OR OTHER VALUABLES

Article 5 (Limitation on Presenting Money or Other Valuables)

1 Member companies shall neither provide money or other valuables to medical institutions or HCPs nor respond to demands made by medical institutions or HCPs to provide money or other valuables. However, an exception is made for those that fall under Articles 6 through 16, and those that can be recognized as being normal commercial practice according to social norms.

2 Notwithstanding Paragraph 1, in addition to money and other valuables whose provision is permitted under the conditions of the same Paragraph, a member company may provide money and other valuables to HCPs as an exception when the provision of such money and other valuables has been confirmed to be possible by the authoritative interpretation of MOHW, the competent authority in relation to Paragraph 1 of Article 23-2 of the Medical Service Act and Paragraphs 2 and 3 of Article 47 of PAL.

3 In each of the following cases, a member company shall be deemed to have directly provided money or other valuables to medical institutions, etc., or HCPs:

1. When the domestic or overseas headquarters, branches, or affiliated companies of a member company provides money and other valuables to medical institutions, etc. or HCPs, or when a member company provides money and other valuables to a wholesaler or marketing agency (a company that is delegated by a member company to carry out sales promotion activities for pharmaceuticals) and asks such wholesaler or marketing agency to deliver them to medical institutions, etc., or HCPs; or

2. When a member company provides money or other valuables to a wholesaler or marketing agency even though it could have known that such money or other valuables were going to be delivered to medical institutions, etc., or HCPs.

4 Presenting money or other valuables to family members, relatives or others in special ties with HCPs, or individuals, company or other entities with special ties with medical institutions, etc., shall be considered the same as being presented to that specific HCPs or medical institutions, etc.

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Article 5 (Limitation on Presenting Money or Other Valuables)

1 Gift for HCPs' personal benefits, even when provided as social courtesy, shall not be deemed "those that can be recognized as being normal commercial practice pursuant to social norms" mentioned in Article 5, Paragraph 1 of the Code. "When the domestic or overseas headquarters, branches, or affiliated companies of a member company provide money or other valuables to medical institutions, etc. or HCPs" under Article 5, Paragraph 3, Item 1 of the Code shall refer to the case in which a member company, while providing money or other valuables to its domestic or overseas headquarters, branches, or affiliated companies, demands that such money or other valuables be provided to medical institutions, schools, institutions or organizations which conduct medical and/or pharmaceutical related academic or scientific research or industry-university collaboration, etc. (hereinafter referred to as "medical institutions, etc.") or HCPs, or the case in which a member company did not prevent its domestic or overseas headquarters, branches, or affiliated companies from independently providing money or other valuables to medical institutions, etc. or HCPs due to its willful or gross negligence when it was aware or could have been aware of such provision taking place.

2 Article 5, Paragraph 3, Item 2 of the Code shall refer to instances where money or other valuables have been provided to wholesalers or marketing agencies, although member companies knew or, due to gross negligence did not know although they could have known, that the wholesalers or marketing agencies would provide them to medical institutions, etc. or HCPs.

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Article 6 (Presenting Samples)

A member company may provide, free of charge, to medical institutions or HCPs pharmaceuticals in minimum packing unit marked „sample’ in either Korean or English so as to enable the identification of features such as form, color, taste, smell, etc., in which case a member company shall not provide samples exceeding the minimum amount required to confirm the form, etc., of the pharmaceutical concerned.

Article 7 (Donations)

1 Member companies can make donations to medical institutions, etc., for medical, pharmaceutical, educational or charitable purposes within the scope acknowledged by social norms, based on the principles set forth in each of the following principles:

1. Donations that fall under any of the following are not allowed:

A. Where a promise has been made for profits in relation to the selection, prescription, trading of pharmaceuticals of the member company making the donation;

B. When a member company responds to donation requests made by medical institutions, etc., in consideration of its positive influence on the selection, prescription, trading of pharmaceuticals;

C. Donations that are used as funds to make payments that the medical institution, etc., should bear with its own funds according to social norms, such as funds used for purchasing real estate or fixtures, expanding or remodeling facilities, or preserving fund for management; or

D. When a member company repeatedly and continuously provides donations to the same medical institutions, etc., without any justifiable reasons thereof.

2. Member companies shall, by stating the purpose, amount, etc., of a donation in the form designated by KRPIA, request KRPIA to select the medical institutions, etc., to which such donation will be delivered (hereinafter referred to as “beneficiary”), after which member companies shall donate directly to the beneficiary upon the decision of KRPIA.

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Article 6 (Presenting Samples)

1 Minimum packaging unit under Article 6 of the Code shall mean the minimum packaging unit of each member company.

2 When marking the word “sample” in either Korean or English, a member company shall do so on the exterior of the container so that it is well-recognizable.

Article 7 (Donations)

1 The medical institutions, etc. to which donations may be made pursuant to Article 7, Paragraph 1 of the Code (excluding entities falling under Article 7, Paragraph 4 of the Code) shall mean institutions or organizations referred to in Items 1 through 4 of Paragraph 1 of Article 9 of the Code. Institutions or organizations under Article 9, Paragraph 1, Item 4 of the Code shall mean institutions or organizations which satisfy all of the following requirements, and institutions or organizations approved by the Code Deliberation Committee (hereinafter referred to as “CDC”) even if not satisfying all of the following requirements.

1. A non-profit organization founded for the purpose of medical or pharmaceutical researches, such as publishing researches of medicine or pharmacology, etc;

2. [The organization] should have operating regulations in place;

3. [The organization] should collect membership dues on a regular basis;

4. [The organization] should have financial or accounting regulations in place for spending membership dues, other incomes and research funds; [the organization should] have accounting regulations independent of medical institutions, etc., to which individual members or medical institution members belong; and [the organization] should not be for profits but use incomes only for research activities;

5. [The organization] should have in place an executive structure such as a general meeting, board of directors, auditors, etc.;

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3. Notwithstanding Item 2, when medical institutions, etc., request KRPIA for donations in order to execute projects such as academic awards, campaigns, etc. (However, in the case of international academies the secretariat of which are domestically-based, notwithstanding Sub-Item C of Item 1, support funds for the operation of such secretariat are included), member companies shall donate directly to the beneficiary in accordance with the procedure set forth in each of the following items:

A. Medical institutions, etc., request KRPIA for donations by stating in the form designated by KRPIA the name, outline of the project, requesting amount, etc., and attaching annexed documents such as a detailed project proposal, budget plan, etc.

B. KRPIA reviews the propriety of the project proposal and, based on the result thereof, solicits by announcement member companies which wish to donate and notify the result of such solicitation to the academic conference concerned and the donating member companies.

C. Member companies donate directly to the beneficiary following KRPIA's notice.

4. Member companies shall not be allowed to donate directly to medical institutions or HCPs, except for donations made in accordance with Items 2 and 3.

5. Once the delivery of money and valuables being donated has been completed, member companies shall notify KRPIA the date, beneficiary, purpose, amount, etc., of such donation in the form designated by KRPIA within ten (10) days from the day of such delivery.

6. Member companies shall attach detailed evidentiary materials regarding the date, beneficiary, purpose, amount, etc., of donations for accounting purposes.

2 Regarding provisions of Item 2 of Paragraph 1, KRPIA, on behalf of member companies, shall select a beneficiary within the scope conforming to the provisions of Item 1 of Paragraph 1 and notify the member company concerned, while verifying whether such donation by the member company has been made in an appropriate manner in accordance with KRPIA's decision. KRPIA shall respect the member company's purpose for making such donation and, if needed, may have the member company concerned attend the Code Deliberation Committee (hereinafter referred to as "CDC") to express its opinion.

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6. [The organization] should have executive officers, such as president, directors and auditors;

7. [The organization] should be engaged in medical research activities through regular or irregular meetings;

8. [The organization] should have periodic publications publishing medical research activities; and

9. [The organization] should not be a subordinate organization of a medical institution, and the beneficiaries of its public funds should be many and unspecified public.

2 In the case of Article 7, Paragraph 1, Item 2 of the Code, a member company shall implement donations according to each of the following items:

1. The request to select beneficiaries shall be made to KRPIA sixty (60) days before the date when the member company wishes to make the donation.

2. KRPIA shall select beneficiaries by making a public announcement of solicitation to medical institutions, etc. for two (2) weeks or longer.

3. When making a public announcement of solicitation, KRPIA shall receive materials such as detailed business proposals (research proposals) and budget plans stating expense items and costs submitted by medical institutions, etc., review the content as to whether it is in accordance with the principle under Article 7, Paragraph 1 of the Code and the member company's purpose of making the donation, then select the beneficiaries.

4. KRPIA shall select the beneficiaries and notify the member company accordingly within 60 days of receipt of the request to select beneficiaries from the member company.

KRPIA shall notify the member company in advance if the selection cannot be made within the designated period due to unavoidable circumstances.

5. If the member company, which was notified of the selected beneficiaries, has an objection to the decision of KRPIA, it may withdraw the request for selection of beneficiaries within five (5) business days from the receipt of the notification.

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3 Regarding provisions of Item 3 of Paragraph 1, in reviewing the propriety of the project proposal by a medical institution concerned, etc., or selecting the donating member company, KRPIA shall consider whether such review or selection is in conformity with the provisions of Item 1 of Paragraph 1, and verify whether the donation by the member company has been made in an appropriate manner in accordance with KRPIA's notice.

4 Notwithstanding the provisions of Items 2 through 4 of Paragraph 1, when a member company wishes to donate pharmaceuticals to medical institutions, etc., for charitable purposes, such member company may donate directly to the beneficiary by notifying KRPIA in advance by stating in the form designated by KRPIA the beneficiary, purpose, amount, etc., of such donation. Even in such a case, member companies shall comply with the principles set forth in Sub-Items A through C of Item 1, and Items 5 and 6 of Paragraph 1, and KRPIA shall verify whether such donation by the member company has been made in an appropriate manner.

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3 In the event that KRPIA has approved the donation request by institutions or organizations established for academic, research purposes related to medicine or pharmacy (hereinafter "academic societies, etc.") pursuant to Article 7, Paragraph 1, Item 3 of the Code, KRPIA shall make a public announcement to member companies for a period of two (2) weeks or longer, thereby soliciting member companies that wish to donate and determine the donation amount depending on the amount of donation each such member company wishes to make. In the event that the sum of the donations that member companies wish to make exceed the requested amount of donation, the member companies that wish to donate shall divide among themselves the donation amount in proportion to the amount of donation that each of them wishes to make. However, academic societies, etc. shall request KRPIA for donations, sixty (60) days before the date desired for such donations to be made.

4 Pursuant to Article 7, Paragraph 1, Item 5 of the Code, a member company shall attach evidentiary materials such as the donation invoice and submit them to KRPIA within ten (10) days from the date delivery of the donation has been completed.

5 Pursuant to Article 7, Paragraph 3 of the Code, KRPIA shall receive from medical institutions, etc. a statement of accounts including itemized expenses and copies of invoices proving such expenses and verify whether the donation was executed in an appropriate manner, within one (1) month from the completion of the project concerned.

6 In the case of Article 7, Paragraph 4 of the Code, a member company shall report to KRPIA thirty (30) days before the act of donation takes place and attach evidentiary materials such as the donation invoice and submit them to KRPIA within ten (10) days from the date delivery of the donation has been completed. In such a case, KRPIA shall verify whether the member company's donation was executed in an appropriate manner.

7 The evidentiary materials such as the donation invoice referred to in Paragraph 6 of this Article refer to materials such as receipts issued by the organizations receiving the pharmaceuticals, documents confirming receipt of the pharmaceuticals, etc. that can be used to verify receipt by the recipient organization, the received pharmaceuticals and their quantity.

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Article 8 (Support for the Hosting or Operation of Academic Conferences)

1 Member companies may support the hosting and operation of domestically-held academic conferences hosted by institutions or organizations of each of the following Items through a variety of means such as donations, provision of food & beverages, souvenirs, booth lease or advertisements, etc..

1. Medical doctors' association, dentists' association, oriental medical doctors' association under Paragraph 1 of Article 28 of the Medical Service Act, association of medical institutions under Paragraph 1 of Article 52 of the same Act, or the Korean Pharmaceutical Association, the Korea Oriental Pharmacy Association under Articles 11 and 12 of the Pharmaceutical Affairs Act, and academic conferences (including overseas academic conferences), academic conference institutions/organizations or research institutions/organizations approved or recognized by the preceding associations

2. Academic conferences (including overseas academic conferences), academic conference institutions/organizations or research institutions/organizations recognized by KRPIA.

2 When a member company wishes to support a domestic academic conference, it shall follow the procedure of the following Items:

1. Institutions/Organizations of Paragraph 1 that host academic conferences request KRPIA support by stating in the form designated by KRPIA the name/outline of the academic conference, requested amount of support and by attaching annexed documents such as a detailed conference proposal, budget plan, etc.;

2. KRPIA reviews the propriety of the conference proposal and, based on the result thereof, solicits by announcement member companies which wish to provide support and notify the result thereof to the institutions/organizations and member companies concerned;

3. Member companies support the academic conference in question following KRPIA's notice; and

Within one (1) month of conclusion of the academic conference in question, member companies shall notify KRPIA the details of the support provided in accordance with the form designated by KRPIA and KRPIA shall verify whether the support by member companies was provided in an appropriate manner.

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Article 8 (Support for the Hosting or Operation of Academic Conferences)

1 The required budget and details of account settlement, each of which is to be submitted by the host of an academic conference pursuant to Article 8, Paragraph 2, Items 1 and 3 of the Code shall be in accordance with each of the following Items, and the host of an academic conference shall also submit copies of invoices which can prove the expenses when submitting the details of account settlement

1. Total income shall refer to the total sum of economic gains received in relation to the hosting/operation of an academic conference and shall include registration fees (or participation fees), the academic society's own budget, booth fees, income from the sale of print media and Internet advertisements, donations (support funds) received from HCPs or medical institutions, and donations (support funds) received from healthcare organizations, all in connection with the academic conference.

2. Total expenditure shall refer to the total sum of expenses in relation to the hosting/operation of an academic conference, such as food & beverages, invitation costs regarding the presenters, chairs, and panelists invited by the host of the academic conference, agency commission, venue rental fees, short-term hired labor cost, and printing and advertising fees, all in connection with the academic conference

2 Income items which fall under costs to be supplied by the sponsor of an academic conference under Article 8, Paragraph 3 of the Code are registration fees (or participation fees) in relation to the academic conference and the institution or organization's own budget, of which are not economic gains provided by pharmaceutical or medical device companies, etc., (e.g. membership fees from members) and are for the purpose of providing support for the academic conference concerned.

3 A member company that wishes to support a domestically-held international academic conference pursuant to Article 8, Paragraph 4 of the Code shall report to KRPIA thirty (30) days before the opening day of the conference in accordance with the form designated by KRPIA with evidentiary material(s) attached proving that the academic conference concerned is an international academic conference. However, when a member company wishes to support an academic conference that KRPIA

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3 Regarding Paragraph 2, KRPIA shall approve member companies' support of academic conferences on condition that the sponsor of the academic conference supplies 30% or more (30% or more from 2015) of the total costs (excluding the costs required for Product Presentations held during the academic conference) required for the conference in question through registration fees (or participation fees) collected from participants or membership fees from the members of the institution/organization sponsoring the conference in question.

To confirm that the above conditions have been met, KRPIA shall request, prior to member companies' support for the conference, the sponsor of the academic conference to report the details of expenses for the conference to KRPIA within one (1) month of the conclusion of the conference and KRPIA may cease to continue the support process of the conference in question when the sponsor of the conference rejects such requests by KRPIA. KRPIA shall have the right to reject the supporting of future academic conferences held by sponsors of the conference in question when the above conditions are not met or KRPIA does not receive the details of expenses.

4 When a member company wishes to support a domestically-held international academic conference, it shall follow the procedure set forth in each of the following Items:

1. A member company, by notifying KRPIA in advance by stating in the form designated by KRPIA the name of the academic conference, scope of support, details of support, etc., may directly support the academic conference in question.

2. The member company notifies KRPIA the details of support provided to the academic conference in accordance with the form designated by KRPIA within one (1) month of the conclusion of the academic conference; KRPIA then verifies whether such support by the member company was executed in an appropriate manner.

5 Regarding Paragraphs 2 and 4, member companies shall not engage in deciding the agenda, proceedings, participants and related materials of the academic conference which they support, and attach detailed evidentiary materials on the support provided when handling the accounting of expenses on the holding operation of the academic conference.

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listed on its website from the list of domestically-held international academic conferences it received from the Korean Medical Association, etc., evidential materials proving that the academic conference concerned is an international academic conference need not be attached.

4 Provisions under Article 8, Paragraph 5 of the Code shall not apply to product presentations held during academic conferences.

5 Support funds (including for product presentations occurring during an academic conference) provided by a member company must be directly provided by the member company to the host of the academic conference pursuant to Article 8, Paragraph 2, Item 3 of the Code. However, among details of support that has completed the process stipulated in Article 8, Paragraph 2, Item 1 to Item 2, costs (traveling expenses and speaker fee, etc.) associated with an overseas speaker (who is not an HCP under the Code and is employed overseas when the academic conference is held and whose medical and/or pharmaceutical knowledge and expertise is recognized) invited by a member company for a product presentation held during an academic conference may be provided by the member company directly to the overseas speaker.

6 Among costs associated with hosting and operating an academic conference under Article 8 of the Code, costs that fall under any of the categories below are not included in the total costs for the academic conference under Paragraph 3, Article 8 of the Code.

1. Administrative costs not directly related to the academic conference such as personnel expenses for employees at the institution or organization hosting the academic conference, equipment purchase expenses, and other fees associated with managing the operational office.

2. Costs that occur during an academic conference associated with non-academic content that does not fall under the definition of an academic conference under Article 3, Paragraph 8 of the Code.

7 Costs in each Item below are not added to the self-pay costs under Article 8, Paragraph 3 of the Code.

1. Registration or participation fees received from individuals (or corporate bodies) that are not HCPs or officers or employees of medical institutions, etc.

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6 Support as set forth in Paragraph 1 does not set a limit on the amount of support provided by a member company in terms of voluntary support through booth lease or advertisements. When Article 8 (Support for the Holding or Operation of Academic Conferences), Article 7 (Donations) or Article 15 (Exhibition/ Advertisement) conflict, Article 8 shall take precedence in application.

Article 9 (Sponsorship for Participation in Academic Conferences)

1 A member company may sponsor HCPs participating in domestic or overseas academic conferences hosted by an institution or an organization of the followings Items:

1. Non-profit legal entity founded for the purpose of medical or pharmaceutical research;
2. Medical doctors' association, dentists' association, oriental medical doctors' association under Paragraph 1 of Article 28 of the Medical Service Act, association of medical institutions under Paragraph 1 of Article 52 of the same Act, or the Korean Pharmaceutical Association, the Korea Oriental Pharmacy Association under Articles 11 and 12 of the PAL, and academic societies (including overseas academic societies), academic institutions/organizations or research institutions/organizations approved or recognized by the above associations;
3. Universities under Item 1 of Article 2 of the Higher Education Act or industry- academic cooperation foundations under Paragraph 1 of Article 25 of the Promotion of Industrial Education and Industry-Academic Cooperation Act; or
4. Academic societies (including overseas academic societies), academic institutions/organizations or research institutions/organizations approved or recognized by KRPIA.

2 A member company which wishes to provide sponsorship shall follow the principles in each of the following Items:

1. Domestic and overseas academic conferences shall be limited to those held at an appropriate venue and in compliance with the academic or educational purposes;

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2. Economic benefits received from member companies, medical device companies, and pharmaceutical (or medical device) wholesalers (or sales agents).

8 "Souvenirs" in Article 8, Paragraph 1 of the Code shall mean goods made under the own names of those institutions/organizations numerated in each subgraph of Article 8, Paragraph 1 of the Code for the purpose of commemorating academic conferences and purposes unrelated to promotion activities of members companies. While member companies may donate money to manufacture such souvenirs, in kind donations of souvenirs are prohibited.

Article 9 (Sponsorship for Participation in Academic Conferences)

1 The presenter (including poster presenter and e-poster presenter whose presentation time is clearly stated), chair, and panelist under Article 9, Paragraph 2, Item 2 of the Code shall mean the HCPs selected by the host of an academic conference, and sponsorship for these HCPs shall be made through cost reimbursement. In case of presenters, only the main author and one (1) co-author may be sponsored. (for e-poster presenter, only one person may be sponsored.)

2 In the event that a HCP under Paragraph 1 receives whole or partial support from an entity other than a member company in relation to his or her participation in the academic conference, KRPIA shall try to prevent the provision of support from a member company pursuant to the provisions of this Article so as to prevent repeated support from being provided.

3 Member companies shall submit to KRPIA the application designating the academic conference to which the donation will be made sixty (60) days before the academic conference, and KRPIA shall request the host of the academic conference to select the participants.

4 Within 30 days after completion of an academic conference, the host of the academic conference shall submit to the KRPIA evidential materials regarding the participant's qualifications under Article 9, Paragraph 2, Item 2 of the Code and participation in the academic conference,, and receipts of actual expenses incurred along with sponsorship application details, and the KRPIA shall review the materials and notify the member companies of the confirmed sponsorship amounts, compile the same and deliver the same to the host of the academic conference

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2. Support for HCPs shall be limited to transportation costs, registration fee, meals and lodging expenses equivalent to the actual expense provided to the presenter, chair, and panelist from the host of the academic conference;

3. A member company shall support HCPs by depositing the fund to the KRPIA for the designated academic conference that it intends to support. Any support directly made to institutions/organizations hosting the academic conference or related persons thereto, or individuals participating in the academic conference, other than support through KRPIA, shall not be allowed;

4. Support to participate in the academic conference shall not be combined with pleasure or treatment, such as tour, sightseeing and leisure activities. The support for HCPs' companion shall not be allowed; and

5. A member company shall attach the evidentiary documents that detail the host of the academic conference, agenda, participants and supporting amount, etc., when it handles accounting for the expenses in relation to the support of the academic conference participation.

2 KRPIA shall carry out the following undertakings regarding the support for academic conference participation:

1. KRPIA shall provide the funding to the academic conference designated by the member company in lieu of the member company provided that KRPIA shall designate the purpose and use under Item 1 and Item 2 of Paragraph 2 only, and shall not designate individuals participating in the academic conference;

2. After the completion of the academic conference, KRPIA shall receive the evidentiary materials as required from the host of the academic conference or participating HCPs, and disclose through its website the host of the academic conference, agenda, support amount and usage of the support amount, etc.;

3. KRPIA shall faithfully manage the entire materials regarding expense payment, and have the supporting member company always able to peruse and copy the relevant materials upon request.

3 KRPIA shall carry out the following undertakings regarding the support for academic conference participation:

1. KRPIA shall provide the funding to the academic conference designated by the member company in lieu of the member company provided that KRPIA shall designate the purpose and use under Item 1 and Item 2 of Paragraph 2 only, and shall not designate individuals participating in the academic conference;

2. After the completion of the academic conference, KRPIA shall receive the evidentiary materials as required from the host of the

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5 Transportation costs, registration fees, meals and lodging expenses equivalent to the actual expense under Article 9, Paragraph 2, Item 2 of the Code shall be each of the following Items:

1. In the case of participation in academic conferences held overseas, transportation costs shall mean the return fare for economy class of an international airline for the shortest route to destination, which shall be determined by the confirmed price for the date of return. In the case of participation in domestically-held academic conferences, transportation fees shall mean the economy class fare of a domestic airline, KTX, bus fare to destination, or public transportation fares equivalent to the aforementioned fares, which can be proven at the time of expense calculation by item statements stating the itinerary, invoices, boarding passes;

2. Registration fees shall be pre-paid in principle and the amount in Korean Won calculated by the exchange rate on the date of remittance or the amount as it appears on credit card bill shall apply;

3. Meal expenses shall be supported for three (3) meals per day and within KRW 50,000 per invoice per meal paid for with one's personal credit card or in cash during meal time at a local restaurant;

4. Lodging expenses shall be supported within KRW 200,000 per night for domestic accommodation and within KRW 350,000 per night for overseas accommodation, and can be supported from one (1) day before the day on which an academic conference begins to the day on which it ends. Lodging expenses shall not include incidental expenses such as mini-bar, movies, laundry, telephone costs, etc.;

5. In the case of participation in academic conferences held overseas, local transportation fees shall mean round-trip fares between the local airport and the hotel and fares between the accommodation and the venue of the academic conference (limited to one (1) round-trip per day) not exceeding KRW 150,000 per person during the academic conference period and shall be limited to those cases which can be proven by invoices that clearly state the time of use and the places of departure and arrival; and

6. At the time of expense calculation, the opening exchange rate at the time of purchase of Korea Exchange Bank on the day before the opening day of an academic conference (if this day falls on a weekend or holiday, the prior business day) shall be applied.

6 In connection with Article 9, Paragraph 3, Item 2 of the Code, KRPIA shall post on its website the details of support provided to academic conference participants (name of the academic conference, hosting academic society, names of sponsoring member companies, total amount sponsored, number of sponsored HCPs, names of medical

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academic conference or participating HCPs, and disclose through its website the host of the academic conference, agenda, support amount and usage of the support amount, etc.;

3. KRPIA shall faithfully manage the entire materials regarding expense payment, and have the supporting member company always able to peruse and copy the relevant materials upon request.

Article 10 (Product Presentation of Member Company's Product)

1 A member company may provide travel expenses, accommodation, food & beverages and souvenirs equivalent to the actual expense within the scope allowed by social norms to HCPs participating in product presentations it holds targeting multiple medical institutions in accordance with the principles of the following Items. However product presentations held during academic conferences are regarded as a part of the academic conference concerned and, accordingly, support thereof shall be provided in conformity with Articles 8 and 9.

1. Recipients of travel expenses, accommodation, food & beverages and souvenirs are limited to those HCPs directly related to product presentations and the provision of such to HCPs' companions shall not be allowed.

2. When holding a product presentation, a member company shall take caution to ensure that the venue, content, proceedings of the event may not be misunderstood as an unfair practice.

2 In the case where the provision of accommodation to HCPs participating in the product presentation of Paragraph 1 prior to its opening is prearranged, a member company shall file an application for KRPIA's approval sixty (60) days before the product presentation in question, by attaching annexed documents such as a detailed product presentation proposal, budget plans, etc., to the form designated by KRPIA, obtain KRPIA's prior approval, and report to KRPIA the details of expenses within one (1) month of the conclusion of the product presentation in question. KRPIA shall verify whether the member company operated the product presentation in an appropriate manner. For other product presentations under Paragraph 1, member companies shall notify KRPIA according to the form designated by KRPIA a week prior to the opening of such product presentations.

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institutions to which the sponsored HCPs belong, etc.) in the preceding quarter every January, April, July and October.

7 The host of an academic conference under Paragraph 3 of this Article shall include domestic academic societies that were delegated the tasks of this Article in written form by the international academic society hosting the relevant academic conference.

8 KRPIA shall set standards for the settlement of accounts for sponsoring participants in the academic conference, and the standards shall take effect upon approval by the CDC. If needed, the CDC may revise the standards for the settlement of accounts.

Article 10 (Product Presentation of Member Company's Product)

1 In the case of Article 10, Paragraph 1 of the Code, a member company may provide each HCP participating in its product presentation with travel expenses equivalent to the actual expense, accommodation, food & beverages of up to KRW100,000 for each meal (excluding tax and service charges, and including refreshments costs; hereinafter the same for food & beverages in this Guideline), and promotional materials (including taxes) of up to KRW 10,000. Member companies shall not provide any additional souvenirs other than the aforementioned promotional materials.

2 In the case of Article 10, Paragraph 2 of the Code, a member company shall request an approval or report to KRPIA according to the form designated by KRPIA with attachments and evidentiary materials attached.

3 In the case of Article 10, Paragraph 4 of the Code, a member company may provide each HCP with food & beverages of up to KRW 100,000 per day (four (4) times per month) and promotional materials of up to KRW 10,000 (including taxes). A member company may provide (i) promotional materials of a minimal value for product presentations organized for over-the-counter drugs of the member company and (ii) a pen and a notepad with the company's name, but not the product's name inscribed on them, for product presentations organized for prescription drugs of the member company for the purpose of facilitating transfer of medical information during the event. In any case, the member company shall not provide promotional materials exceeding the minimum quantity and economic value required for permitted use.

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3 A member company shall attach detailed evidentiary materials such as the date, venue, content, list of participants, expenses, etc., of product presentations when handling the accounting of its expenses.

4 When a member company presents on its pharmaceuticals by visiting individual medical institutions, the member company may provide HCPs with food & beverages and promotional materials of minimal value which include the name of its company or of its products.

5 A member company shall not hold product presentations for the purpose of providing food & beverages needed at meetings of HCPs.

Article 11 (Provision of Pharmaceuticals for Clinical Activities)

A member company may provide HCPs or medical institutions with pharmaceuticals for clinical trials, free of charge, in the amount necessary for conducting clinical trials whose clinical trial plans have been approved by the Commissioner of the Ministry of Food & Drug Safety ("MFDS") pursuant to Paragraphs 1 or 7 of Article 34 of PAL (when falling under Paragraph 8, Article 24 of the Regulations on the Safety of Drugs, etc., clinical trials refer to those whose clinical trial plans have been approved by the Institutional Review Board), in which case non-clinical trials (animal testing, laboratory testing, etc.) pre-approved by relevant committees of the medical institution concerned shall be included.

Article 12 (Market Survey)

1 A member company must report to KRPIA the results of the market survey in a form designated by KRPIA every quarter and may provide money and other valuables as a consideration for market surveys within the scope allowed by social norms. However, if a member company directly conducts a market survey of HCPs, no money or other valuables may be provided as remuneration.

2 A member company shall conduct a market survey mainly for the purpose of collecting market data, and shall not utilize or disguise it as a means of price or compensation for prescriptions by HCPs.

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Article 11 (Provision of Pharmaceuticals for Clinical Activities)

Article 12 (Market Survey)

1 A member company shall not conduct by itself, a market survey which provides compensation. In the event that a member company conducts a market survey by entrusting it to a market survey institution, the market survey institution shall comply with each of the following items:

1. The market survey institution shall not disclose to the participating HCPs the member company entrusting the market survey, and vice versa.

2. The selection of the HCPs participating in the market survey shall be conducted independently by the market survey institution.

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- 3 A member company shall conduct a market survey as an activity to collect valuable information to promote the use of quality pharmaceuticals and enhance patients' benefit.
- 4 A member company shall clearly disclose to the participating HCPs the purport that it is a market survey from the initial stage of recruiting.

Article 13 (Post-Market Surveillance Study)

- 1 A member company shall conduct a PMS pursuant to the protocols and implementation guideline approved by MFDS, and shall comply with each of the following principles:
 - 1.PMS shall be carried out within the scope acknowledged as necessary for medicine or pharmacy based on the relevant provisions of the PAL and KFDA, and with a proper sample size considering the purpose and content of the surveillance;
 - 2.A member company shall not request a PMS to medical institutions which have not adopted or purchased the target pharmaceuticals;
 - 3.A member company shall not request a PMS on the condition of adopting, continuously purchasing, or increasing the amount of purchase of the target pharmaceuticals;
 4. Study fees to HCPs participating in the PMS shall be paid when survey of matters deemed necessary considering the purpose of the surveillance is fully completed, and the results thereof are reported to the member company;
 5. A member company shall not make full payment to the HCPs before receiving the reports set forth in Item 4, and the number of case reports subject to remuneration shall be the minimum number of case reports which shall be submitted under Articles 22 and 23 of the Regulations on the Safety of Pharmaceuticals, etc., the remuneration for which shall be reasonable according to social norms; and

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3. Food & beverages (excluding taxes and service charge) or compensatory gifts (including taxes) of up to KRW 100,000 may be provided to HCPs participating in the market survey.
4. An appropriate amount of compensatory payment of up to KRW 100,000 per HCP (including taxes) may be provided only to those HCPs participating in a market survey which requires thirty (30) minutes or more to answer.
- 2 Regarding matters to be reported quarterly to KRPIA pursuant to the provisos under Article 12, Paragraph 1 of the Code, member companies shall report to KRPIA details of payments made each quarter determined by the date on which each payment is made by the twentieth (20th) day of the following month (e.g. member companies shall report the details of payments made from January to March by April 20th to KRPIA each year).

Article 13 (Post-Market Surveillance Study)

- 1 Study fees under Article13, Paragraph 1, Item 5 of the Code shall be limited to up to KRW 50,000 per case report to HCPs participating in a PMS. An appropriate amount of remuneration of up to KRW 300,000 may be paid per case report in the event additional survey is required due to rare disease cases provided under the Pharmaceuticals Affairs Law or relevant regulations of the MFDS, long-term monitoring, or frequent and significant adverse effects.
- 2 In connection with Article 13, Paragraph 1, Item 5 of the Code, member companies shall pay HCPs remuneration for PMS according to a service agreement (including a detailed statement of expense calculation).
- 3 KRPIA may set forth guidelines on PMS and clinical activities besides such studies through resolution of the CDC. However, such guidelines shall not conflict with the Code.
- 4 For studies, regarding which normal drop-out rates are expected based on materials related to existing or similar studies, a member company shall provide remuneration based on the number of case reports that can satisfy the number of safety evaluation surveys when a company applies for reevaluation to the MFDS.

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6. Compensation for a PMS shall be independently managed from marketing or sales department activities.

2 A member company shall provide no economic benefit to patients participating in a PMS.

Article 14 (Clinical Activities other than PMS)

1 A member company may carry out clinical activities for the purpose of obtaining medically or pharmaceutically important information on clinical characteristics of pharmaceuticals, diseases or other healthcare fields of significant interest to it, pursuant to the PAL and relevant MFDS regulations, and shall comply with each of the following principles and rules:

1. Only those cases whose clinical trial plans have been approved by the Minister of MFDS pursuant to Paragraph 2 of Article 34 of PAL (when falling under Paragraph 3 of Article 31 of the Enforcement Regulations of the PAL, clinical trials refer to those whose clinical trial plans have been approved by the Institutional Review Board) shall be allowed. However, in the case of non-clinical trials (animal testing, laboratory testing, etc.), clinical activities pre-approved by competent committees of the medical institution concerned shall be included.

2. Clinical activities shall not be carried out for the mere purpose of advertising pharmaceuticals or influencing doctors' prescription of the pharmaceuticals;

3. A member company may make an appropriate amount of payment to medical institution, etc., to which the HCP belongs pursuant to the study agreements for clinical activities and within the scope adequate for HCP's efforts; and

4. A member company shall obtain and attach in handling the related expenses a report on the relevant study from medical institution, etc., with which it entered into the study agreements.

2 A member company may provide the actual expenses incurred by patients' participating in interventional clinical activities

Article 15 (Exhibition and Advertisement)

1 A member company may conduct exhibitions or advertisements targeting HCPs for the purpose of expanding and spreading medical or pharmaceutical knowledge, and for maximizing patients' benefit by disseminating various knowledge

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Article 14 (Clinical Activities other than PMS)

In connection with Article 14 of the Code, member companies shall pay service fees to medical institutions, etc. to which the relevant HCP belongs for the clinical activities performed pursuant to a service agreement and shall not be allowed to pay the contract amount in full unless the service is completed and the report thereof is received.

Article 15 (Exhibition and Advertisement)

1 In the event that a member company pays medical institutions, etc. advertisement fees or booth fees pursuant to Article 15, Paragraph 3 of the Code, the member company shall comply with each of the following items:

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and experiences regarding pharmaceuticals. However, member companies shall report to KRPIA the details of the exhibitions or advertisements every quarter in the form designated by KRPIA.

2 Product information on exhibition must be made ready on the display shelf.

3 When a member company installs 'display shelves' or booths, or advertises at academic conferences held by medical institutions, etc., or advertising media issued by medical institutions, etc., for the purpose of exhibiting, publicizing or advertising its company and its pharmaceuticals, the payment of such fees shall comply with normal business practices.

4 A member company shall not provide compensation for HCPs visiting its exhibition hall. However, souvenirs or promotional materials with minimal value may be provided.

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1. Advertising media for which a member company may pay advertising fees to medical institutions, etc. shall be limited to (i) printed materials or electronic documents equivalent to printed materials prepared by medical institutions, etc. for treatment, prevention, training of diseases, and distributed, displayed to multiple HCPs from multiple institutions, (ii) websites operated by academic societies, etc., and (iii) educational materials (including educational materials in the form of electronic documents) distributed by academic societies, etc. to HCPs and/or the general public. However, the content and format of electronic documents shall be equivalent to the level of printed materials or educational materials in paper document form, and those identical to previous content or prepared through simple revisions shall be excluded.

2. (i) Advertising media produced independently by HCPs or (ii) those produced by medical institutions (institutional journals, research journals, etc.) whose targets of distribution are limited to HCPs belonging to that same medical institution which produced the advertising media and employees/customers of the medical institution concerned or (iii) advertising media prepared by converting non-electronic form documents into electronic form documents shall not be deemed as advertising media for which advertising fees are payable to medical institutions, etc.

3. In the case of advertisement for websites operated by academic societies, etc. under Item 1 (ii), member companies may pay advertising fees of up to KRW1 million per month (excluding taxes) within the limit of KRW10 million per year (excluding taxes); as for other print or electronic advertising media under Item (i) and (iii), member companies shall pay an appropriate amount of advertising fees within the limits stated in the below table after taking into consideration the publisher, circulation size, and advertisement effect, etc. (Unit: KRW 10,000)(excluding taxes); and

Publisher	Table 2	Table 3	Table 1, 4	Inside Page or Electronic Document
Medical Institution	100	70	150	60
Academic Societies, etc	150	100	200	70

4. Member companies shall use one (1) booth per academic conference in principle and shall not use more than two (2) booths. In the case of academic conferences hosted by academic societies, etc., booth fees of up to KRW 3 million (excluding taxes) may be paid for one (1) booth. In the case of academic conferences hosted by medical institutions, booth fees of up to

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KRW 1 million (excluding taxes) may be paid for one (1) booth.

2 Regarding matters to be reported quarterly to KRPIA pursuant to the provisos of Article 15, Paragraph 1 of the Code, member companies shall report to KRPIA details of payments made each quarter determined by the date on which each payment is made by the twentieth (20th) day of the following month (e.g. member companies shall report the details of payments made from January to March by April 20th to KRPIA each year).

3 Pursuant to Paragraph 1 of this Article, in carrying out advertisements for which fees are paid, a member company shall not carry out advertisements in excessive numbers in a single academic journal without justifiable reason.

4 When a single academic society, etc., operates multiple websites, Paragraph 1.3 of this Article shall apply based on the total amount of advertising expenses for these websites.

5 A member company shall not provide economic benefits to institutions or organizations hosting academic conferences other than booth fees prescribed under the provisions of this Article such as providing academic conference registration fees for employees responsible for booth installation.

6 Notwithstanding the provisions in this Article, advertising fees for media registered under the Act on the Promotion of Newspapers, Etc. or the Broadcasting Act and conducting independent media activities shall be calculated in accordance with normal business practices.

5. by a member company;

6. In the case of advertisement for websites operated by academic societies, etc., member companies may pay advertising fees of up to KRW1 million per month within the limit of KRW10 million per year; as for other print advertising media, member

7 Regarding matters to be reported quarterly to KRPIA pursuant to the provisos under Article 15, Paragraph 1 of the Code, member companies shall report to KRPIA details of payments made each quarter determined by the date on which each payment is made by the twentieth (20th) day of the following month (e.g. member companies shall report the details of payments made from January to March by April 20th to KRPIA each year).

8 "Souvenirs of a minimal value" in Article 15, Paragraph 4 of the Code shall mean promotional materials. A member company may provide (i) promotional materials of a minimal value for exhibitions held for over-the-counter drugs of the member company and (ii) a pen and a notepad with the company's name, but not the

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Article 16 (Lectures and Consultations)

1 When member companies engage for lectures or consultations HCPs with professional medical and/or pharmaceutical knowledge and experience, member companies shall comply with the following principles and standards.

1. Requests to an HCP for a lecture or consultation shall be limited to cases where the necessity can be objectively recognized for purposes of obtaining medical and/or pharmaceutical or professional information.

2. When a member company selects a HCP for lectures or consultations, it shall apply reasonable standards established based on the HCP's expertise, knowledge and experience, etc. In particular, a member company shall not, without justification, repeatedly request lectures or consultations of the same or similar content to a specific HCP or make requests to an excessive number of HCPs

3. The lecture fee or consulting fee shall be assessed based on the lecture or consulting activities actually performed in light of the HCP's level of knowledge and level of experience and social norms. The lecture fee or consulting fee shall not be paid in full prior to completion of the lecture or consultation.

4. Separate compensation for time spent by HCPs to prepare for the lecture or consultation, or time spent traveling to the lecture or consulting venue shall not be permitted.

5. When a member company makes a request for lectures or consultations, the member company shall execute in advance a written contract with the relevant HCP expressly providing for the content of the lecture or consultation service and the lecture fees or consulting fees.

6. In account settlements for lecture fees or consulting fees, member companies shall attach and retain for five (5) years specific evidentiary materials including reason for selection of the lecturer or consultant, the date and time of the lecture or consultation, list of attendees and signatures, content of lecture or consultation, use of the content of lecture or consultations, etc.

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product's name, inscribed on them, for product presentations organized for prescription drugs of the member company for the purpose of facilitating transfer of medical information during the event. In any case, the member company shall not provide promotional materials exceeding the minimum quantity and economic value required for permitted use.

Article 16 (Lectures and Consultations)

1 Pursuant to provisions of Article 16 of the Code, a member company may provide lecture fees to HCPs in accordance with each of the following items.

1. Lecture fees shall be an amount within KRW 500,000 per each lecture lasting up to one hour within the scope of KRW 1 million per day. The total amount of lecture fees per year shall not exceed KRW 3 million (including all taxes) per HCP.

2. HCPs classified as public officials pursuant to Paragraph 2 of Article 2 of the Improper Solicitation and Provision/Receipt of Money and Valuables Act ("Anti-Graft Act") shall comply with lecture fees, etc. prescribed in the Enforcement Decree of the Anti-Graft Act (Annex 2) as well as the ceiling lecture fees prescribed in Item 1. When there is a difference between the lecture fee ceiling amount prescribed in Item 1 and that prescribed in the Anti-Graft Act, the lower amount shall be complied with.

3. Notwithstanding Item 1 and Item 2, up to KRW 5 million per year can be recognized as the annual ceiling amount when there is a justifiable need such as when new products or new indications are the lecture topics or where there is a limited number of HCPs equipped with the expertise required for lectures.

4. Lectures must be attended by 10 or more audience members (excluding lecturer).

2 Pursuant to provisions of Article 16 of the Code, a member company may provide consulting fees to HCPs in accordance with each of the following items.

1. Consulting fees shall be an amount within KRW 500,000 per each consulting session within the scope of KRW 1 million per day. The total amount of lecture fees per year shall not exceed KRW 3 million (including all taxes) per HCP.

2. Consultation fees shall take into consideration the level and degree of the consultation, expertise, knowledge and experience

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2 Member companies shall report quarterly to the KRPIA the date and time of the lecture or consultation and the payment details of the lecture fees or consulting fees, etc. in accordance with the form designated by the KRPIA.

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of the consultation, etc. but shall be calculated based on actual time and effort exerted in providing the consultation. In calculating the consulting fee and payment process, a member company shall not without justifiable grounds apply to HCPs preferential standards different from those applied to lecturers.

3. When a member company directly pays consulting fees to HCPs and even in cases of indirect payments made through medical institutions, the relevant consulting fees will be added to the annual total amount calculation above if the member company could have been aware that the consulting fees were paid to the relevant HCPs. However, for consultation related to the pharmaco-economic analysis of pharmaceutical products, consultation related to R&D/clinical studies, etc. where services provided in excess of the foregoing ceiling amount can be objectively recognized, then the above consulting fee ceiling amount shall not be applied.

3 With regard to items to be reported on a quarterly basis pursuant to Paragraph 2 of Article 16 of the Code, a member company shall report on a quarterly basis to the KRPIA by the 20th of the following month of the date of payment (e.g., payments made from January to March of each year shall be reported by the 20th of April).

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CHAPTER 3. APPLICATION OF THE CODE

Article 17 (Code Deliberation Committee)

1 KRPIA shall establish and operate CDC to deliberate or resolve each of the following Items:

1. Matters related to the investigation and evaluation on whether a violation of the Code has been made and the remedy thereof
2. Authoritative interpretation on inquiries from member companies regarding the possibility that a certain act may constitute a violation of the Code

3. Matters which fall under each of the following Sub-Items:

A. Selection of beneficiaries under the provisions of Paragraph 2 of Article 7; the propriety of business proposals by medical institutions requesting donations under Paragraph 3 of the same Article; the selection of donating member companies; and the propriety of donations under Paragraphs 2 through 4 of the same Article;

B. Propriety of domestic academic conference proposals under Paragraph 2 of Article 8; whether to support member companies that wish to sponsor academic conferences; the conformity to conditions of sponsoring academic conferences under Paragraph 3 of the same Article; and the propriety of sponsoring academic conferences under Paragraph 4 of the same Article; and

C. Approval of product presentations and the propriety of product presentations under the provisions of Paragraph 2 of Article 10;

4. Matters related to enactment or revision of the Working Guideline; and

5. Other matters requested by KRPIA in relation to the Code.

2 CDC shall consist of 10 persons including one (1) chairperson, five (5) persons of whom that fall under the following Items shall be included as commissioners. As a commissioner, the standing officer of KRPIA shall be the secretary of CDC.

1. Two (2) persons recommended by Korea Consumer Agency (including one (1) legal professional);

2. One (1) person recommended by National Health Insurance Corporation; and

3. Two (2) persons recommended by Korean Medical Association.

3 Resolutions in CDC shall be made by the affirmative votes of majority of the attending commissioners at a meeting attended by two thirds or more of total commissioners.

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Article 17 (Composition of the CDC)

1 Five (5) of the CDC commissioners shall be appointed through resolution of the Board of Directors of KRPIA (hereinafter "BOD").

2 The chairman of KRPIA (hereinafter "KRPIA Chairman") may request the BOD or the institutions under each Items of Paragraph 2 of Article 17 of the Code two (2) months before the day the CDC is required to be organized or the day the term of a commissioner expires, or within one (1) week from the day there is vacancy caused by resignation, etc., of a commissioner that they appoint or recommend commissioners within thirty (30) days from the day of the request.

3 If it becomes difficult to operate the CDC due to absence of appointment or recommendation of commissioners in part within the period designated above, the remaining commissioners shall be appointed through resolution of the appointed or recommended commissioners. The commissioner appointed according to this Paragraph shall be deemed as the commissioner appointed or recommended pursuant to Article 17, Paragraph 2 of the Code.

4 The chairperson shall preside over the meeting as the chair of the CDC.

5 The detailed rules under Article 17, Paragraph 5 of the Code shall be established and amended through resolution of the CDC (hereinafter "Operation Rules").

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- 4 CDC may establish or operate illegal drug distribution report centers, working committees, etc., to supervise, investigate and take measures against unfair business practices.
- 5 Matters necessary for the operation, investigation, measures of the CDC shall be determined in the operation rules.

Article 18 (Investigation of Code Violation)

- 1 When a complaint is reported to KRPIA or CDC acknowledges a violation of the Code, CDC shall conduct necessary investigation to deal with those matters.
- 2 Member companies shall cooperate with CDC's investigation regarding the provision of Paragraph 1.
- 3 CDC may impose a monetary penalty of up to KRW 5million and refer the case to the KFTC for required measures in connection with a member company which does not cooperate with investigation set forth in Paragraph 1. In this case, CDC shall prepare a written document describing the contents of violation and measures ("decision letter") and notify it in writing to the relevant member company (including reporters, in case of a report). If a member company subject to the penalty fails to raise an objection under Paragraph 1 of Article 21, the relevant member company shall pay the penalty within fifteen (15) days from the date of imposition.

Article 19 (Actions against Code Violation)

Actions against any violation of the Code shall be determined as follows:

- 1 When CDC acknowledges a code violation upon its deliberation, CDC shall prepare a decision letter and notify in writing the relevant member companies (including reporters, in case of a report).
- 2 A member company which receives the decision letter under Paragraph 1 shall submit a written document of corrective actions already taken or a plan for corrective actions to CDC within 15 days. If any advertisement or promotional materials using printing, Internet or any other similar methods are determined by the CDC as a code violation, the relevant member company, upon receipt of the decision letter, shall immediately cease to use or distribute the relevant violated materials, and in case of any

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Article 18 (Term of Office)

- 1 The term of office for the commissioners shall be one (1) year, and the term of the succeeding commissioner shall be the remaining term of his/her predecessor in case of resignation during the term.
- 2 In case of resignation by a commissioner during his/her term, KRPIA Chairman shall request for appointment or recommendation of a new commissioner according to the preceding Article to the institution which appointed or recommended the resigning commissioner, and select the succeeding commissioner according to the preceding Article.

Article 19 (Convocation of CDC Meeting)

- 1 The CDC meeting shall be held at the time and place set forth under the Operation Rules, or at the time and place indicated in the notice dispatched by the chairperson to each commissioner one (1) week in advance.
- 2 Notwithstanding the above, the CDC meeting may be convened whenever there is consent of two thirds (2/3) of the commissioners.

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broadcasting advertisement, the relevant member company shall cease to use it within 7 days.

3 If a member company fails to accept the corrective actions pursuant to the decision letter set forth in Paragraph 1, CDC may notify the member company's code violation and CDC's measures to KFTC and MOHW. Separately from the above measures, CDC may take any of the following measures:

1. Imposition of monetary penalty of up to KRW 100 million for each violation (the member company subject to the monetary penalty shall pay the penalty within 15 days from the date of imposition);
2. Termination of KRPIA membership; and/or
3. Notice to the top management of headquarters of the member company.

4 Any failure to submit a plan for corrective actions to the chairman of KRPIA under Paragraph 2, to complete the corrective actions within the corrective period, or to pay the penalty determined by CDC under Paragraph 3 by a member company shall be deemed to be another code violation.

Article 20 (Cooperation Obligation by Member Company)

Member companies shall actively cooperate with CDC's operations to implement this Code in a smooth manner.

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Article 20 (Method of Deliberation and Resolution)

1 Commissioners may participate in the deliberation and resolution of the CDC through communication means which simultaneously transmits and receives audio and video files. In such a case, the pertinent commissioner shall be deemed to have attended the meeting.

2 Commissioners may exercise deliberation and voting rights in writing. Chairperson shall dispatch the documents and reference materials needed for the commissioners to exercise the rights as set forth above one (1) week before the date of the meeting. In such a case, the pertinent commissioner shall be deemed to have attended the meeting.

3 In the event of absence of any legal experts among the commissioners, the CDC may invite an outside legal expert with ample experience and knowledge on healthcare and fair trade to attend the meeting and to state his/her opinion on the legal issues related to the agenda.

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Article 21 (Record Management by KRPIA)

- 1** KRPIA shall preserve the following materials for 5 years:
 1. Materials reported, submitted, notified by, member companies, materials managed by KRPIA, and materials subject to deliberation and decision by CDC pursuant to Articles 7, 8, 9, 10, 12, and 15; and
 2. Information on CDC's investigations and actions pursuant to Articles 17 and 18.
- 2** KRPIA shall faithfully respond to requests to submit the materials under Paragraph 1 made by the KFTC or MOHW.

Article 22 (Appeal, etc.)

- 1** If a member company has an objection to the contents of deliberation and resolution of the CDC, it may appeal in writing to the CDC within 15 days from the date of notice of the contents of deliberation and resolution of the CDC.
- 2** CDC shall re-deliberate and resolve the appeal set forth in Paragraph 1 within 30 days, and notify the results to the relevant member company.
- 3** CDC shall promptly take actions pursuant to its decision letter, absent any appeal under Paragraph 1.

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Article 21 (Installation of Working Committee and Sub-Committee)

- 1** The CDC may set up and operate sub-committees for effective deliberation and resolution of matters set forth under Article 17, Paragraph 1 of the Code.
- 2** A sub-committee shall be composed of three (3) commissioners including one (1) outside commissioner, and the chair of the sub-committee shall be designated by the chairperson.
- 3** The authorities and operation of the working committees under Article 17, Paragraph 4 of the Code and the sub-committees hereunder shall be as set forth in the Operation Rules.

Article 22 (Meeting Minutes)

- 1** Minutes shall be prepared with regard to the proceedings of a meeting of the CDC.
- 2** Recorded in the minutes shall be the agenda, the proceedings of the meeting, the results thereof, dissenters and reason for their objection, and the commissioners present at the meeting shall write their names and affix seals or sign thereon. The meeting minutes may be replaced with audio or video recordings of each meeting.

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CHAPTER 4 SUPPLEMENT

Article 23 (Amendment to or Repeal of the Code)

Any amendment to this Code shall be subject to KFTC's prior review.

Addendum

- 1 (Effective Date) The Code shall become effective as of the date of the decision notified by the KFTC
- 2 [Interim measure for filing reports regarding lectures and consultations] The amended provisions of Article 16 of the Code apply to lectures and consultations held from 1st January of 2018.

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Article 23 (Conflict of Interest)

Commissioners who have conflict of interest in connection with the agenda subject to deliberation and resolution shall be excluded from the deliberation and resolution for the pertinent agenda at the request of the party concerned or the commissioner himself/herself, or ex officio by the chair. The commissioner thus excluded shall be excluded from the number of total commissioners participating in the resolution concerned.

Article 24 (Discovering and Reporting of Violations)

- 1 Any person who discovers a violation of the provisions of this Code by member companies may report the occurrence of such to the CDC within five (5) years from the date of the completion of such acts.
- 2 If it acknowledges that a violation of the provisions of this Code has been committed, the CDC may conduct the necessary investigation ex officio in connection with reports made by any person other than member companies.
- 3 The CDC may take the following measures if deemed necessary for the investigation of this case:
 1. Summon the parties concerned, interested parties, or witnesses to a hearing and hear their testimonies;
 2. Designate and invite expert witnesses;
 3. Issue an order to a member company or its officer or employee to present necessary information or materials, or to maintain custody of the presented materials or information; and/or
 4. Examine the materials submitted to KRPIA by the reported members companies.
- 4 In the event a member company reported false information intentionally or due to gross negligence, the CDC may impose a penalty on the reporting member company.
- 5 The method and procedure of reporting shall be as determined in the Operation Rules.

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Article 25 (Recommendation of Correction against Breaches)

- 1 If a violation of the Code has been committed, the CDC may establish the corrective measures and recommend the member company concerned to comply with those measures.
- 2 Any person receiving such recommendation as above shall notify the CDC within ten (10) days of receiving the notice of recommendation for correction as to whether or not he/she will accept such recommendation.
- 3 If the person receiving the recommendation for correction as above accepts it, corrective action shall be considered to have been taken under this Code.

Article 26 (Opportunity to State Opinion)

- 1 Before issuing corrective actions or imposing penalties in response to violations of this Code, the CDC shall give the parties concerned (both the reporting party and reported member company; hereinafter the same) and interested parties opportunity to state their opinions.
- 2 The parties concerned or interested parties may be summoned to attend a hearing of the CDC to state their opinions or present relevant materials.

Article 27 (Temporary Order)

In the event an act of a member company is likely to incur irreparable damage upon other member companies, the chairperson may issue, at the request of the reporting party by or ex officio, an order of commission or omission in connection with the act concerned until deliberation or resolution by the CDC.

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Article 28 (Suspension of Execution of Corrective Order)

1 In the event the person who has received a corrective order files an appeal, and if it is deemed necessary for prevention of irreparable damage which may arise from execution of the order or continuation of the procedure, the decision to suspend the execution of the order or continuation of the procedure (hereinafter "Suspension of Execution") may be made at the request of the party concerned.

2 The CDC may cancel the Suspension of Execution at the request of the party concerned or ex officio in the event the cause for the Suspension of Execution ceases to exist following the decision of the Suspension of Execution.

Article 29 (Performance Guarantee)

1 The CDC may order the member company, which was found to have repeatedly violated the Code three (3) times or more within a year, to be audited by an outside legal expert, and to report the result thereof to the CDC.

2 In the event the member company, which has received the corrective order or was ordered to pay penalty, fails to comply with the same, the CDC may notify imposition of order to relevant HCPs or medical institutions, etc.

Article 30 (Indemnification)

Member companies shall not raise any legal claims against the commissioners, KRPIA, or officers and employees of KRPIA in connection with their performance of duties under the Code and this Guideline.

Article 31 (Training Sales Personnel)

1 Member companies shall regularly and continuously educate all sales personnel interacting with HCPs to ensure compliance with the Code and this Guideline.

2 Member companies shall evaluate the performance of duties by sales personnel regularly and continuously, and take appropriate measures if they are found to have violated the Code and the Guideline.

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Article 32 (Education of Member Companies)

- 1 KRPIA may set up an ethical business practice committee for effective implementation of the Code.
- 2 The ethical business practice committee shall perform the following duties and report the result thereof to the CDC
 1. Review and reply to inquiries of member companies concerning interpretation of the Code;
 2. Set up and implement plans to educate member companies regularly about the Code
 3. Support the education on the Code by member companies;
 4. Prepare and distribute Q&A booklet in connection with the Code; and
 5. Prepare and distribute a manual on ethical business practices to member companies.

Article 33 (Record Management by KRPIA)

- 1 Unless otherwise stipulated in this Guideline, KRPIA shall ensure that only the officers, employees, commissioners of KRPIA, or the relevant member companies have access to the materials submitted by the member companies under Article 21, Paragraph 1, Item 1 of the Code.
- 2 The management and submission of materials under Article 20 of the Code may be carried out electronically.

Article 34 (Appeal)

In the event the resolution cannot be made within the period set forth under Article 22, Paragraph 2 of the Code due to unavoidable circumstances, the CDC may decide to extend the period up to 30 days.

Article 35 (Calculation of Periods)

Article 156 (Starting Point of Computing Period) or Article 161 (Holiday and Maturity Point of Period) of the Korean Civil Code shall apply in calculating the periods under the Code and this Guideline.

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Article 36 (Calculation of Amounts)

The price of goods under this Guideline shall be determined at the fair market value of the goods concerned or similar goods, and the price of goods without any market value shall be determined at the cost incurred by the member company providing them.

Article 37 (Service of Documents)

The provisions under Articles 14 through 16 of the Administrative Procedures Act shall apply to the service of documents hereunder.

Article 38 (Confidentiality)

Any commissioners, and officers and employees of KRPIA, who are working or have worked in connection with the duties under the Code, shall not disclose or exploit for purposes other than implementation of the Code the confidential information of member companies acquired while in office.

Addendum

1 This Guideline shall become effective on the date of approval by the CDC.