

KPBMA Code of Practice and Working Guideline

Revised on December 20, 2024

KPBMA Code of Practice	Working Guideline
<p>Chapter 1 General Provisions</p> <p>Article 1 (Purpose)</p> <p>The purpose of this Code of Fair Competition in Pharmaceutical Trade (hereinafter referred to as this “Code”) is to ensure fair competition in the distribution of pharmaceuticals among business entities, and to maintain and improve public health by discouraging unfair customer solicitation practices prohibited under Article 45, Paragraph 1, Subparagraph 4 of the Monopoly Regulation and Fair Trade Act (hereinafter referred to as the “Fair Trade Act”).</p>	
<p>Article 2 (General Principles)</p> <p>Business entities shall comply with the provisions of this Code in accordance with the following general principles:</p> <p>① Marketing activities for pharmaceutical products shall be conducted within the scope deemed acceptable under relevant laws, including the Fair Trade Act, and in accordance with commonly accepted commercial practices;</p> <p>② Business entities shall endeavor to provide healthcare professionals with scientific and educational information about their products to maximize patient benefits, provided that such efforts by the business entities shall not interfere with the independence of healthcare professionals in making prescription decisions;</p> <p>③ Activities under Paragraph 2 shall be conducted in appropriate venues in accordance with the purpose of such activities;</p> <p>④ Pursuant to Article 47-2 of the Pharmaceutical Affairs Act (“PAA”), business entities shall prepare an expenditure report detailing economic benefits provided to pharmacists, herbal medicine pharmacists, healthcare workers, healthcare institution founders, or healthcare institution employees within three months after the end of each fiscal year. These reports, along with related records and evidentiary materials, shall be made publicly available as prescribed by the Ministry of Health and Welfare (“MOHW”) and retained for five years; and</p> <p>⑤ Financial management, including accounting records, shall be accurately and transparently</p>	

documented and managed in accordance with the relevant laws and generally accepted accounting principles.

Article 3 (Definitions)

① “Pharmaceuticals” shall refer to the pharmaceutical products as designated under Article 2, Paragraph 4 of the PAA.

② “Business entity(ies)” shall refer to an entity engaged in the business of manufacturing and selling or importing and selling pharmaceuticals, having obtained a manufacturing and/or import license pursuant to Article 31 or 42 of the PAA.

③ “Pharmaceutical wholesaler(s)” or “Wholesaler(s)” shall refer to an entity engaged in the sale of pharmaceuticals, having obtaining a pharmaceutical wholesaler’s license pursuant to Article 45 of the PAA.

④ “Contract Sales Organization(s)” or “CSO(s)” shall refer to an entity or individual contracted by a business entity to carry out pharmaceutical sales promotional activities, including those subcontracted by such entities. In order to offer permissible economic benefits under the PAA and this Code, the relevant terms shall be explicitly stated in the agreement, and all activities shall comply with applicable laws and regulations. In such cases, the term “business entity” in each clause shall be construed as “CSO.”

⑤ “Healthcare institution(s)” shall refer to an institution as designated under Article 42, Paragraph 1 of the National Health Insurance Act.

⑥ “Healthcare professional(s)” or “HCP(s)” shall refer to medical doctors, dentists, doctors of oriental medicine, pharmacists, or herbal pharmacists.

⑦ “Sample(s)” shall refer to finished products of pharmaceuticals produced, for the purpose of introduction, within the scope of Annex 2 of the Enforcement Rules of the PAA.

⑧ “Donation” shall refer to any money or other valuables presented free of charge by business entities to healthcare institutions, schools, institutions or organizations engaged in academic or scientific research, or academia–industry joint projects (hereinafter referred to as “healthcare institutions, etc.”), irrespective of their titles such as welcome contribution, sponsorship, support, donation, etc.

⑨ “Academic conference(s)” shall refer to any event attended by HCPs, conducted with the purpose of providing scientific or educational information related to medical and pharmaceutical fields to support the medical and pharmaceutical research or education of HCPs, irrespective of titles or formats, such as conferences, symposia, seminars, academic events, etc. Events directly hosted by a business entity shall, in practice, be excluded from this definition.

⑩ “Domestically-held international academic conference(s)” shall refer to an academic conference that meets all of the following requirements:

1. Such conference shall be recognized as an international academic conference by the medical doctors’ association, dentists’ association, or oriental medical doctors’ association under Article 28, Paragraph 1 of the Medical Services Act (“MSA”), or by the Korean Pharmaceutical Association or the Association of Korean Oriental Pharmacy under Article 11 or 12 of the PAA, respectively;

2. Such conference shall pass the review conducted in accordance with the review standards for international academic conference established by the medical doctors’ association, dentists’ association, or oriental medical doctors’ association, or the Korean Pharmaceutical Association or the Association of Korean Oriental Pharmacy in compliance with all of the following requirements:

A. Such review standards shall include practical elements such as the number of foreign participants, the level of internationalization of the conference program, the annual application volume, and the quality of the program; and

B. When formulating or amending the review standards, an opportunity to submit opinions shall be provided to the Korea Pharmaceutical and Bio-Pharma Manufacturers Association (hereinafter referred to as the “Association”);

3. Such conference shall be an international-scale academic conference held domestically for two or more days;

4. Such conference shall be attended by HCPs from five or more countries visiting Korea, including presenters, chairs, and panelists; and

5. Such conference shall be attended in person by at least 50 foreign HCPs visiting Korea, including presenters, chairs, and panelists.

Notwithstanding the foregoing, domestically-held international academic conference(s) related to rare diseases that are based on the PAA and relevant regulations from the Ministry of Food and Drug Safety (“MFDS”) shall meet all of the aforementioned requirements 1 to 3 and at least one of requirements 4 or 5.

⑪ “Global academic conference(s)” shall refer to an international-scale academic conference that meets all of the following requirements:

1. Such conference shall be hosted in a different country for each edition;

2. Such conference shall be recognized as a global academic conference by the medical doctors' association, dentists' association, or oriental medical doctors' association under Article 28, Paragraph 1 of the MSA, or by the Korean Pharmaceutical Association or the Association of Korean Oriental Pharmacy under Article 11 or 12 of the PAA, respectively;

3. Such conference shall be conducted for a minimum of two days at an international scale;

4. Such conference shall be attended by foreign HCPs from at least five countries, including presenters, chairs, and panelists; and

5. Such conference shall be attended by at least 50 foreign HCPs, including presenters, chairs, and panelists.

⑫ "International society(ies)" shall refer to an academic society with at least 100 regular members who are foreign nationals from at least five countries, recognized as an international society by the medical doctors' association, dentists' association, or oriental medical doctors' association under Article 28, Paragraph 1 of the MSA, or by the Korean Pharmaceutical Association or the Association of Korean Oriental Pharmacy under Article 11 or 12 of the PAA, respectively.

⑬ "Product presentation(s)" shall refer to an event held in Korea hosted by a business entity targeting multiple healthcare institutions and the HCPs affiliated therewith for the purpose of providing information about its own pharmaceuticals, or the visiting of individual healthcare institutions to provide such information to HCPs affiliated therewith.

⑭ "Market survey" shall refer to activities conducted by a business entity to collect data on the market, including the scale and characteristics of its components, such as consumer needs.

⑮ "Post-marketing surveillance study" or "PMS" shall refer to a study conducted by the marketing authorization holder, including usage surveys, special investigation, and post-marketing clinical trials, etc., in relation to risk management plans, to collect, review, confirm, or verify information on the safety, efficacy, and appropriate use of approved pharmaceuticals subject to risk management plans, pursuant to Article 32-2 and Article 42, Paragraph 5 of the PAA.

⑯ "Money or other valuables," irrespective of the means, shall refer to goods, money, or other economic

benefits provided by a business entity to healthcare institutions, etc., or HCPs, including, but not limited to, any one of the following:

1. Goods, machines, devices, land, buildings, or 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. Business courtesies (food and beverages, invitations or preferential treatment to any performance, including movies or theatrical plays, or various events, including sports, travel, golf, skiing, etc.);

4. Provision of convenience services, including transportation, accommodation, and registration for academic conferences;

5. Provision of labor or other services; and

6. Discounts, premiums or sales incentives, etc. (but excluding “discount according to payment terms” and “accumulated points based on the use of credit cards or debit cards” which fall under permissible economic benefits, etc. pursuant to the Enforcement Rules of the MSA or the Enforcement Rules of the PAA).

⑰ “Electronic document(s)” shall refer to information created in electronic formats using electronic devices with information processing capabilities, such as computers, and transmitted and received, or saved, and which expresses thoughts or ideas through commonly used text or special signs, symbols, etc. that are recognizable by humans (excluding electronic videos and sound).

<p>Article 4 (Working Guideline)</p> <p>① The Association may establish a Working Guideline (hereinafter referred to as the “Guideline”) reflecting the intent of this Code to provide detailed rules thereof.</p> <p>② The Korean Fair Trade Commission (“KFTC”) may recommend to the Association the establishment of or amendment to the Guideline outlined in Paragraph 1, if deemed necessary to ensure the establishment of fair competition order.</p>	<p>Article 1 (Purpose)</p> <p>This Working Guideline (hereinafter referred to as this “Guideline”) is established pursuant to Article 4 of the Code of Fair Competition in Pharmaceutical Trade (hereinafter referred to as the “Code”) with the purpose of specifying details to facilitate the operation of the Code.</p>
<p>Chapter 2. Permissible Scope Regarding Presenting Money or Other Valuables</p> <p>Article 5 (Limitation on Presenting Money or Other Valuables)</p> <p>① Business entities shall neither provide money or other valuables as defined in Article 3, Paragraph 16 to healthcare institutions, etc., or HCPs, nor comply with requests for money or other valuables from such healthcare institutions, etc., or HCPs. However, an exception applies to those falling under Articles 6 through 16, provided that they are within the scope of commonly accepted commercial practice.</p> <p>② Notwithstanding Paragraph 1, in addition to money and other valuables permitted to be presented under the conditions of the same Paragraph, business entities may provide money and other valuables to HCPs as an exception, provided that such provision has been confirmed as permissible by the authoritative interpretation of the MOHW, the competent authority in relation to Article 23–5, Paragraph 1 of the MSA and Article 47, Paragraphs 2 and 3 of the PAA.</p> <p>③ In each of the following cases, business entities shall be deemed to have directly provided money or other valuables to healthcare institutions, etc., or HCPs:</p> <ol style="list-style-type: none"> 1. When the domestic or overseas headquarters, branches, or affiliated companies of the business entity directly provide money or valuables to healthcare institutions, etc., or HCPs, or when the business entity provides money or other valuables to wholesalers, marketing agencies, or CSOs and requests such wholesalers, marketing agencies, or CSOs to deliver them to healthcare institutions, etc., or HCPs; or 2. When the business entity provides money or valuables to wholesalers, marketing agencies, or CSOs, while knowing or having reasonable grounds to know that such money or valuables would be offered to healthcare institutions, etc., or HCPs. <p>④ Presenting money or other valuables to individuals with special ties to HCPs, such as family members or</p>	<p>Article 2 (Limitation on Presenting Money or Other Valuables)</p> <p>① The term “when the domestic or overseas headquarters, branches, or affiliates of a business entity present money or other valuables to healthcare institutions, etc., or HCPs,” as set forth in Article 5, Paragraph 3, Subparagraph 1 of the Code, refers to cases where the business entity presents money or other valuables to its domestic or overseas headquarters, branches, or affiliates and requires them to deliver such money or valuables to healthcare institutions, schools, academic or research institutions, or institutions and organizations engaged in academia–industry collaboration (hereinafter referred to as “healthcare institutions, etc.”), or HCPs. It also includes cases where the business entity knew or should have known that its domestic or overseas headquarters, branches, or affiliates independently presented money or other valuables to healthcare institutions, etc., or HCPs but failed to prevent such actions through willful or gross negligence.</p> <p>② Article 5, Paragraph 3, Subparagraph 2 of the Code refers to instances where money or other valuables are presented to wholesalers, marketing agencies, or Contract Sales Organizations (“CSOs”), while business entities either knew, or through gross negligence failed to know despite being able to know, that the wholesalers, marketing agencies, or CSOs would offer them to healthcare institutions, etc., or HCPs.</p>

relatives, or to individuals, companies, or organizations with special ties to healthcare institutions, etc., shall be deemed equivalent to providing them directly to the respective HCPs or healthcare institutions, etc.

Article 6 (Presenting Samples)

A business entity may provide, free of charge, to healthcare institutions, etc., or HCPs, pharmaceuticals in their minimum packaging units marked as “sample” in either Korean or English to enable the identification of features, such as dosage form, color, taste, and smell. In such cases, the business entity shall not provide samples exceeding the minimum quantity necessary to confirm the dosage form or other characteristics of the pharmaceuticals in question.

Article 3 (Presenting Samples)

- ① Minimum packaging unit under Article 6 of the Code shall mean the minimum packaging unit of each business entity.
- ② When marking the word “sample” in either Korean or English, the business entity shall ensure it is displayed on the exterior of the packaging container in a manner that is clearly recognizable.

Article 7 (Donations)

① Business entities may make donations to healthcare institutions, etc., for medical, pharmaceutical, educational, or charitable purposes within the scope recognized by social norms, in accordance with the principles set forth in each of the following subparagraphs:

1. Donations that fall under any of the following shall not be permitted:

A. Where a promise has been made for profits in connection with the selection, prescription, and trading of pharmaceuticals of the business entity making the donation;

B. When a business entity complies with donation requests made by healthcare institutions, etc., in consideration of its positive influence on the selection, prescription, or trading of pharmaceuticals;

C. Donations that are used as funds to cover costs and expenses that the healthcare institutions, etc., are expected to bear according to social norms, such as funds used for purchasing real estate or fixtures, expanding or remodeling facilities, or reserving fund for management purposes; or

D. When a business entity repeatedly and continuously provides donations to the same healthcare institutions, etc., without any justifiable reason for doing so;

2. A business entity shall, by stating the purpose, amount, etc., of a donation in the form designated by the Association, request the Association to select the healthcare institutions, etc., to which the donation will be delivered (hereinafter referred to as the “beneficiary”) and shall subsequently donate directly to the beneficiary upon the Association’s decision;

3. Notwithstanding Paragraph 2, when healthcare institutions, etc., request the Association for donations to execute projects such as academic awards, campaigns, etc. (however, in the case of international academies with secretariats based domestically, support funds for the operation of such secretariats are included, notwithstanding Subparagraph 1, Item C), business entities shall donate directly to the beneficiary in accordance with the procedure set forth in each of the following subparagraphs:

A. Healthcare institutions, etc., shall request the Association for donations by completing the form designated by the Association, specifying the name and outline of the project, the requested amount, etc., and attaching annexed documents such as a detailed project proposal, budget plan, etc.;

Article 4 (Donations)

① The healthcare 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 refer to the institutions or organizations specified in Article 9, Paragraph 1, Subparagraphs 1 through 4 of the Code. The institutions or organizations under Article 9, Paragraph 1, Subparagraph 4 of the Code shall refer to those that satisfy all of the following requirements, as well as the institutions or organizations approved by the Code Deliberation Committee (hereinafter referred to as the “CDC”), even if they do not satisfy all of the following requirements:

1. A non-profit organization founded for the purpose of medical research, including activities such as publishing research in medicine or pharmacology, etc.;

2. [The organization] shall have operational regulations in place;

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

4. [The organization] shall have financial or accounting regulations in place for the expenditure of membership dues, other income, and research funds; maintain independent accounting regulations separate from those of healthcare institutions, etc., to which individual members or healthcare institution members are affiliated; and ensure that all income is used exclusively for research activities with no intent to generate profit;

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

6. [The organization] shall have executive officers, including a president, directors and auditors;

7. [The organization] shall engage in medical research activities through regular or special meetings;

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

9. [The organization] shall not be subordinate to any specific healthcare institution, and the beneficiaries of its public funds shall consist of a broad and unspecified public.

② In the case of Article 7, Paragraph 1, Subparagraph 2 of the Code, a business entity shall implement donations in accordance with each of the following subparagraphs:

B. The Association shall review the propriety of the project proposal and, based on the results, solicit business entities wishing to donate through an announcement, and subsequently notify the beneficiary and the donating business entities of the solicitation results; and

C. Business entities shall donate directly to the beneficiary upon receiving notice from the Association;

4. Business entities shall not be permitted to make direct donations to healthcare institutions, etc., or HCPs, except for donations made in accordance with Subparagraphs 2 and 3;

5. Upon completion of the delivery of donated money or valuables, business entities shall notify the Association of the date, beneficiary, purpose, amount, etc., of such donation in the form designated by the Association, within 30 days from the date of delivery; and

6. Business entities shall attach detailed evidentiary materials, including the date, beneficiary, purpose, amount, etc., of donations, for accounting purposes.

② Regarding the provisions of Subparagraph 2 of Paragraph 1, the Association, on behalf of the business entity, shall select a beneficiary within the scope conforming to the provisions of Subparagraph 1 of Paragraph 1 and notify the business entity concerned, while verifying that the donation has been made appropriately in accordance with the Association's decision. The Association shall respect the business entity's purpose for making the donation and, if necessary, may require the business entity to attend the Code Deliberation Committee (hereinafter referred to as the "CDC") to express its opinion.

③ Regarding the provisions of Paragraph 1, Subparagraph 3, in reviewing the propriety of the project proposal submitted by the healthcare institutions, etc., or in selecting the donating business entity, the Association shall evaluate whether such review or selection conforms to the provisions of Subparagraph 1 of Paragraph 1 and verify that the donation by the business entity has been made appropriately in accordance with the Association's notice.

④ Notwithstanding the provisions of Subparagraphs 2 through 4 of Paragraph 1, when a business entity wishes to make a donation to healthcare institutions, etc., for charitable purposes, the business entity may donate directly to the beneficiary by notifying the Association in advance, specifying the beneficiary, purpose, amount, etc., in the form designated by the Association. Even in such cases, business entities

1. Business entities shall request the selection of beneficiaries two quarters in advance through the CDC's Pharmaceutical Fair Competition System of the Association (hereinafter referred to as the "reporting site") during the last month of each quarter (March, June, September, or December);

2. The Association shall select beneficiaries by issuing a public announcement of solicitation to healthcare institutions, etc., for a period of at least two weeks via the reporting site. The Association shall complete the selection of beneficiaries and notify the business entity within 60 days of receiving the business entity's request for deliberation. However, if selection cannot be completed within the designated period due to unavoidable circumstances, the Association shall notify the business entity in advance;

3. When issuing a public announcement of solicitation, the Association shall require healthcare institutions, etc., to submit documentation such as detailed project plans (research proposals) and budget plans specifying expenditure items and costs. The Association shall review the content to ensure the project is in accordance with the principles outlined in Article 7, Paragraph 1 of the Code and evaluate the business entity's purpose for making the donation before selecting the beneficiaries; and

4. If the business entity notified of the selected beneficiaries has an objection to the Association's decision, it may withdraw its request for the selection of beneficiaries within five days of receiving the notification.

③ If the Association approves a donation request from healthcare institutions, etc., pursuant to Article 7, Paragraph 1, Subparagraph 3 of the Code, it shall issue a public announcement to business entities for a period of at least two weeks via the Association's reporting site to solicit business entities wishing to donate and determine the donation amount based on the amounts each business entity wishes to contribute. If the total amount of donations offered by business entities exceeds the requested donation amount, the donation amount shall be apportioned among the donating business entities in proportion to the amounts each has expressed willingness to contribute.

④ When participating in a request for beneficiary selection or solicitation for donations pursuant to Article 7, Paragraph 1, Subparagraphs 2 and 3 of the Code, a business entity shall pay a deliberation fee or commission to the Association as follows:

1. If the donation amount is KRW 100 million or less, the deliberation fee or commission (hereinafter referred to as the "deliberation fee, etc.") shall be 1% of the donation amount (rounded down to the nearest

shall comply with the principles set forth in Items A through C of Subparagraph 1 and Subparagraphs 5 and 6 of Paragraph 1, and the Association shall verify that the donation by the business entity has been made in an appropriate manner.

KRW 100, excluding taxes, hereinafter the same);

2. If the donation amount exceeds KRW 100 million, the deliberation fee, etc., shall be KRW 1,500,000 (excluding taxes);

3. For business entities that are not members of the Association, a fixed rate shall apply, and the deliberation fee, etc., shall be 3% of the donation amount;

4. The Association shall not refund the deliberation fee, etc., in the following cases:

A. In the event that a business entity withdraws its request for beneficiary selection after the deliberation has been completed;

B. In the event that the deliberation results in disapproval or rejection; and

C. In the event that a business entity participates in the solicitation for donation pursuant to Article 7, Paragraph 1, Subparagraph 3 of the Code and subsequently withdraws after being notified of the final donation amount by the Association; and

5. The Association shall issue an electronic tax invoice for the deliberation fee, etc., to the business entity.

⑤ Pursuant to Article 7, Paragraph 1, Subparagraph 5 of the Code, business entities shall submit a post-donation report to the Association via the reporting site within 30 days of completing the donation, attaching evidentiary materials such as donation receipts.

⑥ Pursuant to Article 7, Paragraph 3 of the Code, the Association shall receive a final accounting report from the healthcare institutions, etc., within three months after the project's conclusion, including details of total income and expenditures for the project, along with copies of receipts verifying expenses.

⑦ For circumstances under Article 7, Paragraph 4 of the Code, a business entity shall file a pre-donation report with the Association via the reporting site at least 10 days prior to the donation and submit a post-donation report via the reporting site within 30 days of completing the donation, including evidentiary materials such as receipts or acknowledgment of receipt forms issued by the receiving organization.

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

① Business entities may, in adherence to the principles outlined in this Article and Article 7, Paragraph 1, Subparagraph 1 of this Code, support the hosting and operation of domestic academic conferences, as well as domestically-held international academic conferences and global academic conferences as defined in Article 3, Paragraphs 10 and 11, organized by each of the below institutions or organizations within Korea. However, if a business entity provides such support in accordance with this Article, it shall not offer any additional money or other valuables, including donations, food and beverages, souvenirs, booth rentals, or advertisements, related to the academic conference. The provisions of this Article shall also apply to academic conferences conducted virtually (“virtual academic conferences”), where participants in different physical locations engage in real-time interactive video streaming through the internet or other information and communication networks.

1. The medical doctors’ association, dentists’ association, or oriental medical doctors’ association under Article 28, Paragraph 1 of MSA; the association of healthcare institutions under Article 52, Paragraph 1 of the same Act; the Korean Pharmaceutical Association or the Association of Korean Oriental Pharmacy under Article 11 or 12 of the PAA, respectively; and academic societies (including overseas academic societies), academic institutions or organizations, or research institutions or organizations approved or recognized by the aforementioned associations.

2. Academic societies (including overseas academic societies), academic institutions or organizations, or research institutions or organizations recognized by the Association.

② When a business entity wishes to support a domestic academic conference, it shall follow the procedures in each of the following subparagraphs:

1. The institutions or organizations under Paragraph 1 organizing the academic conference shall submit a request for support to the Association using the form designated by the Association, specifying the name and outline of the conference, the requested amount of support, etc., and attaching annexed documents, such as a detailed conference proposal and budget plan, etc.;

2. The Association shall review the propriety of the conference proposal and, if concerns about potential violations of relevant laws or this Code are identified, may request the institution or organization to provide

Article 5 (Support for the Hosting or Operation of Academic Conferences)

① When the organizer of an academic conference wishes to request support from the Association pursuant to Article 8, Paragraph 2, Subparagraph 1 of the Code, the organizer of the academic conference shall complete and submit the application form to the Association through the reporting site during the last month (March, June, September, or December) of the second quarter preceding academic conference date.

② When a business entity wishes to support the hosting and/or operation of an academic conference pursuant to Article 8, Paragraph 2 of the Code, the business entity shall submit an application for support to the academic conference listed in the recruitment announcement via the reporting site, and pay a deliberation fee to the Association. The amount of the deliberation fee shall be determined in accordance with Article 4, Paragraph 4 of this Guideline.

③ A business entity shall prepare a post-support report on the support details and submit it to the Association via the reporting site within one month of the academic conference date or its conclusion pursuant to Article 8, Paragraph 2, Subparagraph 5; Article 8, Paragraph 3, Subparagraph 2; and Article 8, Paragraph 5 of the Code.

④ The required budget and details of expense settlement, each of which is to be submitted by the organizer of an academic conference pursuant to Article 8, Paragraph 2, Subparagraph 1 and Article 8, Paragraph 4 of the Code shall be in accordance with each of the following subparagraphs, and the organizer of the academic conference shall also submit copies of receipts that can prove the expenses when submitting the details of expense settlement:

1. Total income shall refer to the total sum of economic gains received in relation to the hosting or 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 healthcare 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 related to the hosting or operation of an academic conference, including food and beverages, invitation costs for presenters, chairs, and panelists invited by the host, agency commissions, venue rental fees, short-term hired labor costs, and printing and advertising fees, all in connection with the academic

clarification or make corrections within a reasonable timeline. If the institution or organization fails to provide clarification or make corrections within the specified period without a valid justification, or if the clarification provided is deemed unreasonable, the Association shall discontinue the support process;

3. Based on the results of the propriety review in the preceding subparagraph, the Association shall solicit business entities wishing to provide support through an announcement and notify the result thereof to the institutions or organizations, and the business entities concerned.

4. Business entities shall provide support for the academic conference in question in accordance with the Association's notice; and

5. Within one month of the conclusion of the academic conference in question, business entities shall notify the Association of the details of the support provided, using the form designated by the Association, and the Association shall verify whether the support provided by the business entities was appropriate.

③ When a business entity wishes to support a domestically-held international academic conference, it shall follow the procedures set forth in each of the following items:

1. Such business entity may directly support the academic conference in question by notifying the Association in advance and providing details, such as the name of the academic conference, scope of support, etc., using the form designated by the Association; and

2. Such business entity shall notify the Association of the details of the support provided to the academic conference, using the form designated by the Association, within one month of the conclusion of the academic conference. The Association shall thereafter verify whether such support by the business entity was executed in an appropriate manner.

④ Regarding Paragraphs 2 and 3, the Association shall approve the business entity's support of academic conferences on condition that the organizers of domestic academic conferences or domestically-held international academic conferences fund at least 10% of the total costs of the conference in question (excluding costs required for product presentations held during the academic conference) through registration fees (or participation fees) collected from attendees and membership fees from the members of the organizing institutions or organizations.

⑤ When a business entity wishes to support a global

conference; and

3. Administrative costs, such as salaries for secretariat staff of the academic conference organizing institution or organization, expenses for purchasing office supplies, and other operational costs of the secretariat that are not directly related to the academic conference, as well as expenses associated with non-academic content that do not fall under the definition of an academic conference as specified in Article 3, Paragraphs 9 through 12 of the Code, shall not be included in the expenditure.

⑤ The income items included in self-funding under Article 8, Paragraph 4 of the Code shall refer to registration fees (or participation fees) and the academic society's own budget which are unrelated to economic benefits provided by business entities or medical device companies (e.g., membership fees) and are intended to support the academic conference. This shall not include registration fees or participation fees received from individuals (or entities) other than HCPs or officers and employees of healthcare institutions, etc., nor economic benefits provided by pharmaceutical companies, medical device companies, pharmaceutical (or medical device) wholesalers, or CSOs.

⑥ A business entity that wishes to support a domestically-held international academic conference or a global academic conference pursuant to Article 8, Paragraph 3 or 5 of the Code, respectively, shall check the list of domestically-held international conferences on the Association's reporting site, submit an application for support at least 30 days prior to the conference date, and provide support directly to the academic conference in question.

⑦ Provisions under Article 8, Paragraph 8 of the Code shall not apply to product presentations (e.g., Satellite Symposium, Luncheon Symposium) held during academic conferences.

⑧ Support funds (including those for product presentations held during an academic conference) provided by a business entity shall be paid directly to the organizer of the academic conference pursuant to Article 8, Paragraph 2, Subparagraph 4 of the Code. However, among the support details completed through the procedures specified in Article 8, Paragraph 2, Subparagraphs 1 through 3, costs, such as travel expenses and speaker fees, etc., associated with overseas speakers (who are not considered HCPs under the Code, employed overseas at the time of the conference, and are recognized for their medical and scientific knowledge and expertise in countries outside Korea) invited by the business entity to product presentations held during the academic conference

academic conference under Article 3, Paragraph 11, it shall follow the procedures specified in Paragraph 3 of this Article. However, the self-funding requirement outlined in Paragraph 4 of this Article shall not apply to the support of global academic conferences.

⑥ To verify whether a domestic academic conference under Paragraph 2 of this Article was held appropriately according to the conference plan, the Association shall notify the organizers of the academic conference in advance to submit detailed expense settlements and other evidentiary materials within three months of the conference's conclusion. If the organizers do not agree to this requirement, the Association may terminate the support process for the academic conference. Additionally, if the organizers fail to submit expense settlement details and other evidentiary materials, or if they deviate from the conference plan reviewed by the Association without a valid justification, the Association may reject future requests for support from the organizers of the academic conference in question.

⑦ To ensure that the medical doctors' association, dentists' association, or oriental medical doctors' association under Article 28, Paragraph 1 of the MSA, or the Korean Pharmaceutical Association or the Association of Korean Oriental Pharmacy under Article 11 or 12 of the PAA, respectively (hereinafter referred to as the "medical doctors' association, etc."), can verify that the domestically-held international academic conferences or global academic conferences under Paragraph 3 or 5 of this Article, respectively, were appropriately conducted according to the conference plan, the Association shall notify the organizers of the academic conference in advance to submit the expense settlement details and other relevant evidentiary materials within three months of the conclusion of the conference. If the organizers do not agree to this requirement, the medical doctors' association, etc., may terminate the support process for the academic conference. Additionally, if the organizers fail to submit the expense settlement details and other evidentiary materials, or implement the conference in a manner that deviates from the plan reviewed by the medical doctors' association, etc., without a valid justification, the medical doctors' association, etc., may reject future requests for support from the organizers of the academic conference in question.

⑧ If a surplus arises from the expense settlement review of domestic academic conferences, domestically-held international academic conferences, or global academic conferences under Paragraphs 2, 3, or 5 of this Article, respectively, the Association shall permit the concerned academic conference organizer to use the surplus exclusively for the hosting or operation of domestic academic

may be paid directly by the business entity to the overseas speakers.

conferences, domestically-held international academic conferences, or global academic conferences for which support is requested pursuant to Paragraph 2, 3, or 5 of this Article, respectively, and the Association shall take appropriate measures to prevent duplicate support during the review of support requests from the concerned organizer. If the concerned academic conference organizer uses the surplus for purposes (operational expenses of the academic society, etc.) unrelated to the hosting or operation of domestic academic conferences, domestically-held international academic conferences, or global academic conferences, the Association may reject future support for academic conferences requested by the concerned academic conference organizer.

⑨ In relation to Paragraphs 2, 3, and 5, a business entity shall not be involved in determining the agenda, format, participants, or related materials of an academic conference it supports, and shall attach specific evidentiary materials detailing the support when accounting for the expenses related to the hosting or operation of the academic conference.

⑩ In relation to the support for hosting and operating academic conferences, the provisions of this Article shall take precedence over Article 7 (Donations). Business entities that do not provide support for domestic academic conferences, domestically-held international academic conferences, or global academic conferences in accordance with this Article may instead support such academic conferences through booths and advertisements, as prescribed in Article 15 (Exhibitions and Advertisements).

⑪ If it is confirmed through a court ruling (including first-instance decisions, regardless of whether they are finalized), administrative actions, or investigations by the Association that a business entity has supported the hosting or operation of an academic conference for improper purposes, the Association shall not approve the business entity's support for hosting or operating academic conferences for a period of two years from the date such violation is discovered.

Article 9 (Sponsorship for Participation in Academic Conferences)

① A business entity may sponsor HCPs participating in domestic or overseas academic conferences hosted by an institution or an organization as specified in each of the following subparagraphs:

1. A non-profit legal entity established for the purpose of medical or pharmaceutical research;

2. The medical doctors' association, dentists' association, or oriental medical doctors' association under Article 28, Paragraph 1 of the MSA, the association of healthcare institutions under Article 52, Paragraph 1, or the Korean Pharmaceutical Association or the Association of Korean Oriental Pharmacy under Article 11 or 12 of the PAA, respectively, and academic societies (including overseas academic societies), academic institutions or organizations, or research institutions or organizations approved or recognized by the aforementioned associations;

3. Universities under Paragraph 2, Subparagraph 1 of the Higher Education Act, or industry-academia cooperation foundations under Article 25, Paragraph 1 of the Promotion of Industrial Education and Industry-Academic Cooperation Act; or

4. Academic societies (including overseas academic societies), academic institutions or organizations, or research institutions or organizations recognized by the Association.

② A business entity that wishes to provide sponsorship shall adhere to the principles set forth in each of the following subparagraphs:

1. Domestic and overseas academic conferences under Paragraph 1 shall be limited to those held at appropriate venues with manner and content consistent with academic or educational purposes;

2. Support for HCPs shall be limited to transportation costs, registration fees, meal allowances, and accommodation costs equivalent to the actual expenses provided by the host of the academic conference to the presenters, chairs, and panelists. However, if the HCP receives partial or full financial support for such expenses, irrespective of the title or form, such as travel or meeting expenses, from healthcare institutions, etc., the business entity shall not provide duplicate support for the same expenses;

3. A business entity shall support HCPs by depositing the fund with the Association for the designated academic conference that it intends to support. Any support directly made to institutions or organizations

Article 6 (Sponsorship for Participating in Academic Conferences)

① Presenters (including poster presenters and e-poster presenters with designated presentation times), session chairs, and panelists under Article 9, Paragraph 2, Subparagraph 2 of the Code, refer to the HCPs selected by the host of an academic conference. However, support for presenters is limited to the primary author and one co-author (for e-poster presenters, support is limited to one individual).

② In the event that the HCPs under Paragraph 1 receive partial or full financial support for academic conference participation from sources other than a business entity, the Association shall endeavor to ensure that support provided by the business entity under this Article does not result in duplicate support.

③ In relation to Article 9, Paragraph 2, Subparagraph 3 of the Code, business entities shall submit an application through the reporting site at least 60 days prior to the academic conference date. The Association shall then publish the application and accept support requests from the academic conference hosts to facilitate participant support through the hosts.

④ The hosts of the academic conference shall, within 30 days of its conclusion, submit evidentiary materials verifying the eligibility and attendance of participants under Article 9, Paragraph 2, Subparagraph 2, along with receipts for actual expenses and sponsorship application details, to the Association. The Association shall review the submission, notify the business entity of the confirmed sponsorship amount, and complete and deliver the same to the host of the academic conference.

⑤ Transportation costs, registration fees, meals, and accommodation expenses equivalent to the actual expenses under Article 9, Paragraph 2, Subparagraph 2 of the Code shall be governed by each of the following subparagraphs:

1. Transportation costs for participation in academic conferences held abroad refer to the round-trip economy class international airfare for the shortest route to the destination, based on the confirmed fare for the return date. For domestic academic conferences, transportation costs refer to the economy class fare for domestic airlines, KTX, express buses, or equivalent public transportation to the destination, substantiated at the time of expense settlement with a statement of itinerary, receipts, and boarding passes;

2. Registration fees shall, in principle, be prepaid, and

organizing the academic conference or related persons thereto, or individuals participating in the academic conference, other than support through the Association, shall not be allowed:

4. Support to participate in the academic conference shall not be combined with entertainment or business courtesies, such as tour, sightseeing, and leisure activities. The support for HCP's companion shall not be allowed; and

5. A business entity shall attach the evidentiary materials detailing 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.

③ The Association shall carry out each of the following undertakings regarding the support for academic conference participation:

1. The Association shall provide funding to the academic conference designated by the business entity in lieu of the business entity. However, the Association shall designate only the purpose and use under Subparagraphs 1 and 2 of Paragraph 2 and shall not designate individuals participating in the academic conference:

2. After the conclusion of the academic conference, the Association shall receive the required evidentiary materials 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.; and

3. The Association shall, in good faith, manage all materials regarding expense payment and ensure that the supporting business entity can always peruse and copy the relevant materials upon request.

the applicable amount in Korean Won shall be calculated based on the exchange rate on the payment date or as indicated on the credit card statement:

3. Meal expenses shall be supported based on the number of days attended during the academic conference period, in accordance with each of the following items:

A. For domestic academic conferences, support is provided for up to three meals per day, with a maximum of KRW 50,000 per invoice per meal paid for with one's personal credit card or in cash in the area where the academic conference is being held; and

B. For overseas academic conferences, support is provided as a flat rate per day based on the classification of the country and city in Annex 4, "Overseas Travel Expense Table," of the Overseas Travel Expense Regulations for Public Officials. The rates are KRW 100,000 for Grade A, KRW 80,000 for Grade B, KRW 60,000 for Grade C, and KRW 50,000 for Grade D. For countries or cities not included in the classification, the classification of the nearest capital city shall apply;

4. Accommodation expenses shall be supported up to KRW 200,000 per night for domestic conferences and up to KRW 350,000 per night for overseas conferences, and when necessary, support may be provided from one day before the day on which the academic conference begins to the day on which it ends. However, incidental expenses such as minibar, movies, laundry, or phone charges are excluded from accommodation expenses;

5. When participating in academic conferences held overseas, local transportation costs shall mean a flat rate of KRW 100,000 per academic conference; and

6. At the time of expense settlement, the exchange rate applied shall be the first announced cash-buying exchange rate from the Korea Exchange Bank on the day before the conference begins (or the last business day if the preceding day is a holiday).

⑥ Business entities shall pay a processing fee to the Association for participant support services in accordance with Article 4, Paragraph 4 of this Guideline.

⑦ The host of the academic conference under Paragraph 3 of this Article shall include domestic academic societies that have been delegated with the responsibilities under this Article in written form by the international academic society hosting the relevant academic conference.

⑧ The Association may establish standards related to sponsoring participants and the settlement of accounts expense reconciliation for academic conferences, and these standards shall take effect upon approval by the CDC. The CDC may amend the relevant standards as necessary.

Article 10 (Product Presentations)

① Notwithstanding Article 5, Paragraph 2 of the Code, a business entity hosting product presentations for multiple healthcare institutions may not provide any money or valuables but may only provide actual expenses equivalent to travel, accommodation, and food and beverages to participating HCPs, within the scope allowed by social norms, and shall comply with each of the below subparagraphs. However, product presentations held during academic conferences are regarded as a part of the academic conference in question, and accordingly, support for such presentations shall be governed by Articles 8 and 9.

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

2. When holding product presentations, a business entity shall take caution to ensure that the venue, content, and format of the event are not misperceived as unfair practices.

② In the case where accommodation is prearranged to be provided to HCPs participating in a product presentation under Paragraph 1 prior to its opening, the business entity shall file an application for the Association's approval 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 the Association, obtain the Association's prior approval, and report to the Association the details of expense settlement within one month of the conclusion of the product presentation in question. The Association shall verify whether the business entity operated the product presentation in an appropriate manner. For other product presentations under Paragraph 1, business entities shall notify the Association according to the form designated by the Association one week prior to the opening of such product presentations.

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

④ Notwithstanding Article 5, Paragraph 2 of the Code, when a business entity presents its pharmaceuticals by visiting individual healthcare institutions, the business entity may not provide any money or valuables, other than food and beverages.

⑤ A business entity shall not hold product

Article 7 (Product Presentations)

① In accordance with Article 10, Paragraph 1 of the Code, business entities may provide HCPs attending product presentations with reimbursement for actual travel and accommodation expenses, as well as food and beverages of up to KRW 100,000 per meal (excluding taxes and service charges, but including light refreshments; hereinafter the same applies to all food and beverage provisions under this Guideline).

② For product presentations covered under the first sentence of Article 10, Paragraph 2, business entities shall apply for approval to hold the product presentation via the reporting site no later than two months prior to the product presentation date and submit to the Association via the reporting site an expense settlement report, including evidentiary materials, within one month of the conclusion of the product presentation.

③ When applying for approval to hold a product presentation pursuant to Paragraph 2, business entities shall pay a deliberation fee of KRW 100,000 (excluding taxes) to the Association.

④ For product presentations covered under the second sentence of Article 10, Paragraph 2, business entities shall report to the Association via the reporting site at least one week prior to the product presentation date.

⑤ In accordance with Article 10, Paragraph 4 of the Code, the value of food and beverages that a business entity may provide to each HCP is limited to a maximum of four times per month, and no more than KRW 100,000 per day (excluding taxes and service charges, but including light refreshments).

presentations for the purpose of providing food and beverages needed at meetings of HCPs.

Article 11 (Provision of Pharmaceuticals for Clinical Trials)

A business entity may provide HCPs or healthcare institutions with pharmaceuticals for clinical trials free of charge in quantities necessary for conducting clinical trials whose clinical trial protocols have been approved by the Minister of MFDS pursuant to Article 34, Paragraphs 1 to 7 of the PAA (or clinical trials whose clinical trial protocols have been approved by the Institutional Review Board, in cases falling under Article 24, Paragraph 8 of the Regulations on the Safety of Medicinal Products, etc.), in which case nonclinical trials (animal testing, laboratory testing, etc.) pre-approved by the relevant committees of the healthcare institution concerned shall be included.

Article 12 (Market Survey)

① A business entity shall report to the Association the results of the market survey in a form designated by the Association on a quarterly basis, and may provide money and other valuables as consideration for market surveys within the scope commonly accepted by social norms. However, if a business entity directly conducts a market survey of HCPs, no money or other valuables may be provided as remuneration.

② A business entity shall conduct a market survey primarily for the purpose of collecting market data, and shall not utilize or disguise it as a sales promotional activity or a means of providing compensation to HCPs.

③ A business entity shall conduct a market survey as an activity to collect valuable information aimed at promoting the use of quality pharmaceuticals and enhancing patient benefit.

④ A business entity shall clearly disclose to the participating HCPs from the initial stage of engagement that the purpose of the activity is a market survey.

Article 8 (Market Survey)

① When a business entity contracts a market survey agency to conduct market survey, each of the following subparagraphs shall be complied with:

1. The market survey agency shall not disclose to the participating HCPs the business entity commissioning the research, nor disclose the participating HCPs to the business entity;

2. The selection of HCPs participating in the market survey shall be made independently by the market survey agency;

3. HCPs participating in the market survey may be provided with food and beverages (excluding taxes and service charges, but including light refreshments) or a token of appreciation (including taxes) worth up to KRW 100,000; and

4. For market survey requiring 30 minutes or more of response time, an appropriate honorarium of up to KRW 100,000 (including taxes) may be provided per HCP.

② In relation to the proviso in Article 12, Paragraph 1 of the Code, business entities shall report the quarterly payment details to the Association via the reporting site by the 20th day of January, April, July, or October, based on the business completion date (e.g., payment details from January to March shall be reported by April 20 of the same year).

Article 13 (Post-Marketing Surveillance Study)

① A business entity shall conduct a PMS pursuant to the protocols and implementation guidelines approved by the MFDS, and shall comply with each of the following principles:

1. A PMS shall be conducted within the scope recognized as having medical or pharmaceutical necessity based on the PAA and relevant MFDS regulations, and the number of cases surveyed shall be appropriate to the objectives and content of the study, supported by objective and reasonable evidence for calculating the number of cases;

2. A business entity shall not request a PMS from healthcare institutions which have not adopted or purchased the target pharmaceuticals;

3. A business entity shall not request a PMS on the condition of adopting, continuously purchasing, or increasing the amount of purchase of the target pharmaceuticals;

4. Compensation to HCPs participating in the PMS shall be paid when survey of matters deemed necessary, considering the purpose of the surveillance, is fully conducted, and the results thereof are reported to the business entity;

5. A business entity shall not pay the full compensation to the HCPs before receiving the reports set forth in Subparagraph 4, and the compensation shall be reasonable within the bounds of social norms; and

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

② A business entity shall not provide any economic benefit to patients participating in a PMS.

Article 9 (Post-Marketing Surveillance Study)

① Pursuant to Article 13 of the Code, business entities may compensate HCPs up to KRW 50,000 per case report (including taxes) for PMS services. However, if additional surveys are deemed necessary based on the PAA and relevant MFDS regulations, such as rare diseases, long-term follow-up studies, or frequent reports of serious adverse events, a reasonable amount of up to KRW 300,000 (including taxes) may be provided.

② In relation to Article 13, Paragraph 1, Subparagraph 5 of the Code, business entities shall pay HCPs for PMS services in accordance with the terms of the service agreement (including a detailed statement of expense calculation).

Article 14 (Clinical Activities other than PMS)

① A business entity may plan clinical activities for the purpose of obtaining medically or pharmaceutically important information on the clinical characteristics of pharmaceuticals, diseases, or other healthcare fields of significant interest to it, pursuant to the PAA and relevant MFDS regulations, and shall comply with each of the following principles and standards:

1. Only those cases whose clinical trial protocols have been approved by the Minister of MFDS pursuant to Article 34, Paragraphs 1 and 7 of PAA (or, in the case of Article 34, Paragraph 2, those whose clinical trial protocols have been approved by the Institutional Review Board) shall be permitted. However, in the case of nonclinical studies (animal testing, laboratory testing, etc.), clinical activities pre-approved by competent committees established at the healthcare institution in question shall be included;

2. Clinical activities shall not be conducted solely for the purpose of promoting pharmaceuticals or influencing physicians' prescription practices of pharmaceuticals;

3. A business entity may make an appropriate amount of payment to healthcare institutions, etc., with which the HCP is affiliated, pursuant to the study agreements for clinical activities and within a scope reasonable for the HCP's efforts; and

4. A business entity shall obtain a result report on the relevant study from healthcare institutions, etc., with which they have entered into a study agreement, and attach it as part of the accounting process for related expenses.

② A business entity may, based on an agreement, provide reimbursement for actual expenses incurred by patients participating in interventional clinical activities.

③ In accordance with the principles and standards described in Paragraph 1, a business entity may provide funding for clinical trials initiated by investigators without external requests, on pharmaceuticals whose safety or efficacy has not been verified or those that are already marketed following approval or notification.

Article 10 (Clinical Activities other than PMS)

In relation to Article 14, Paragraphs 1 and 3 of the Code, business entities shall pay the costs associated with the clinical activities to the healthcare institutions, etc., with which the relevant HCP is affiliated, pursuant to a contract agreement, and shall not be allowed to pay the contract amount in full unless the contract terms are fulfilled and the result report is received.

Article 15 (Exhibition and Advertisement)

① A business entity may conduct exhibitions or advertisements targeting HCPs for the purpose of disseminating knowledge and experiences related to pharmaceuticals, with the goal of expanding and promoting medical or pharmaceutical knowledge and maximizing patient benefits. However, the business entity shall report the details of such exhibitions or advertisements to the Association on a quarterly basis, using the form designated by the Association.

② Information about products on display shall be made readily available at the exhibition booth.

③ If a business entity sets up display shelves or booths, or advertises at academic conferences organized by healthcare institutions, etc., or in advertising media published by such healthcare institutions, etc., for the purpose of exhibiting, promoting, or advertising its company or its pharmaceuticals, the payment of such fees shall comply with normal business practices.

④ A business entity shall not provide any compensation to HCPs for visiting its exhibition booth. However, to facilitate the smooth dissemination of medical and pharmaceutical information on site, the business entity may provide pens and notepads displaying the company name but shall not include product names.

Article 11 (Exhibition and Advertisement)

① If a business entity pays advertising fees or booth fees to healthcare institutions, etc., pursuant to Article 15, Paragraph 3 of the Code, the business entity shall comply with each of the following subparagraphs:

1. Advertising media for which a business entity may pay advertising fees to healthcare institutions, etc., shall be limited to (i) printed materials or equivalent electronic documents created by healthcare institutions, etc., for the purpose of treatment, prevention, or education of diseases, which are distributed or displayed to a wide audience of HCPs across multiple healthcare institutions, (ii) websites operated by organizations established for academic purposes in medical or pharmaceutical fields (hereinafter referred to as the “academic societies, etc.”), and (iii) educational materials (including educational materials in electronic document form) 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 independently created by HCPs, (ii) advertising media created by healthcare institutions (institutional newsletters, research journals, etc.), where the distribution target is limited to HCPs affiliated with the healthcare institution that created the advertising media, as well as the employees and visitors of the said healthcare institution, and (iii) advertising media created by converting non-electronic documents into electronic form (digitalized documents) shall not be considered as advertising media for which advertising fees are payable to healthcare institutions, etc., by the business entity;

3. For advertisements on websites operated by academic societies, etc., under Subparagraph 1 (ii), business entities may pay advertising fees of up to KRW 1 million per month (excluding taxes) within the limit of KRW 10 million per year (excluding taxes). As for other printed or electronic advertising media specified in Subparagraphs 1 (i) and (iii), business entities shall pay an appropriate amount of advertising fees within the limits set in the table below, considering the publisher, circulation volume, and advertising effect, etc. However, in the case of printed or electronic advertising media, business entities shall, in principle, be limited to one advertisement per academic conference, and may not exceed a maximum of two advertisements per academic conference;

(Unit: KRW 10,000) (excluding taxes)

Publisher	Table 2	Table 3	Tables 1 & 4	<u>Flyers or Electronic Documents</u>
Other academic societies and healthcare institutions	100	70	150	60
Academic societies	150	100	200	70

Table 1: Front cover, Table 2: Back of the front cover, Table 3: Back of the back cover, Table 4: Back cover

4. Business entities shall, in principle, use one booth per academic conference, and may not exceed a maximum of two booths;

5. For academic conferences eligible for booth fee payments under this Article, medical and pharmaceutical academic topics shall last for three hours or more. Booth fee payments shall not be permitted for academic conferences with agendas entirely unrelated to academic matters. This also applies to situations where participants in different locations attend academic conferences through real-time, interactive video streaming via the internet or other communication networks, as defined in Article 3, Paragraphs 9 through 12 of the Code (hereinafter referred to as "virtual academic conferences" in this Article); and

6. For academic conferences eligible for booth fee payments under this Article (including virtual academic conferences), there shall be at least 50 participants (registrants) from academic societies and individual healthcare institutions. However, for rare disease societies, the requirement is at least 25 participants (registrants).

② The booth fees under the preceding paragraph may be paid in accordance with the following criteria based on the host and format of the academic conference:

1. For virtual academic conferences hosted by the medical doctors' association, dentists' association, or oriental medical doctors' association under Article 28, Paragraph 1 of the MSA, or the association of healthcare institutions under Article 52, Paragraph 1 of the same Act, or by the Korean Pharmaceutical Association or the Association of Korean Oriental Pharmacy under Article 11 or 12 of the PAA, respectively, where at least 5,000 participants are expected for the concerned edition of the conference, the booth fees shall be no more than KRW 3 million per case (up to 2 cases totaling KRW 6 million). However, for an academic conference held in-person or in a

hybrid format (a combination of virtual and in-person conference where at least 20% of total participants, including speakers, attend in-person. Hereinafter referring to the same in this Paragraph), the booth fees shall be no more than KRW 5 million per case (up to 2 cases totaling KRW 10 million);

2. For academic conferences, symposia, resident training, or training lectures hosted by academic societies approved or recognized by the medical doctors' association, dentists' association, or oriental medical doctors' association under Article 28, Paragraph 1 of the MSA, the association of healthcare institutions under Article 52, Paragraph 1 of the same Act, or the Korean Pharmaceutical Association or the Association of Korean Oriental Pharmacy, or their regional branches under Article 11 or 12 of the PAA, respectively, the booth fees shall range from KRW 2 million to 3 million per case. However, the booth fees may only be paid if the event is held in an in-person or hybrid format; no booth fees shall be paid for events held exclusively virtually;

3. For academic conferences, standalone symposia, resident training, or training lectures hosted by affiliated organizations, local chapters, branches of individual academic societies, or individual healthcare institutions, the booth fees shall range from KRW 500,000 to 1 million per case. However, booth fees may only be paid if the event is held in an in-person or hybrid format. No booth fees shall be paid for events held exclusively virtually; and

4. For academic conferences, symposia, resident training, or training lectures, held in a co-hosted or co-organized format, the maximum amount payable shall be determined based on the applicable payment standards with the lowest upper limit.

③ In relation to the proviso under Article 15, Paragraph 1 of the Code, business entities shall report the quarterly payment details for advertisements and booth fees to the Association via the reporting site by the 20th day of January, April, July, or October, based on the conclusion date of the advertisement or booth (e.g., details for activities conducted from January to March shall be reported by April 20). In doing so, business entities shall obtain and retain the following evidentiary materials from healthcare institutions, etc., or academic societies, etc., in relation to the reported payment details:

1. Documentation on the academic conference proposal (including venue, time, format [virtual, in-person, hybrid, etc.], topics, and estimated number of participants);

2. For academic conferences with a history of previous editions, documentation on previous editions

(including venue, time, topics, format, and participant numbers). For first-time academic conferences with no history of previous editions, documentation demonstrating the absence of previous sessions (relevant official letters, etc.); and

3. Documentation on the outcomes of the academic conference (including evidence of participant numbers, the number of advertisements, and the location of advertisements).

④ When a single academic society, etc., operates multiple websites, the provisions of Paragraph 1, Subparagraph 3 of this Article shall apply based on the total advertising expenses for all such websites.

⑤ Notwithstanding the provisions of this Article, advertising fees for media registered under the Act on the Promotion of Newspapers, etc., or the Broadcasting Act, which conduct independent media activities, shall comply with the standard business practices generally conducted by the respective media outlet.

⑥ The provisions of this Article shall apply equally to CSOs. In such cases, the term “business entity” in each clause shall be construed as “CSO.”

Article 16 (Lectures and Consultations)

① When a business entity engages HCPs with professional medical or pharmaceutical knowledge and experience for lectures or consultations, the business entity shall comply with the principles and standards described in each of the following subparagraphs:

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 acquiring medical, pharmaceutical, or professional information;

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

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

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

5. When a business entity makes a request for lectures or consultations, the business entity shall execute a written contract in advance with the relevant HCP, expressly providing for the content of the lecture or consultation services and the lecture fees or consultation fees; and

6. In account settlements for lecture fees or consulting fees, business entities shall attach and retain for five years specific evidentiary materials, including the rationale for selecting the lecturer or consultant, the date and time of the lecture or consultation, the list of participants with signatures, the content of the lecture or consultation, the use of the content of the lecture or consultation, etc.

② After the payment of lecture or consultation fees, business entities shall report the payment details, including the date and time of the lecture or consultation, and the payment details, etc., on a quarterly basis to the Association, in accordance with the reporting form designated by the Association, by the 20th day of January, April, July, or October, based on the date of lecture or consultation completion.

Article 12 (Lectures and Consultations)

① Pursuant to the provisions of Article 16 of the Code, a business entity may pay lecture fees to HCPs in accordance with each of the following subparagraphs:

1. Lecture fees shall be an amount calculated based on the activities actually performed, taking into consideration the level of knowledge and experience, etc., of the HCP and shall comply with each of the following items:

A. Lecture fees shall be limited to KRW 500,000 per hour of lecture, within the scope of KRW 1 million per day and KRW 3 million per year (all amounts include taxes);

B. For HCPs classified as public officials pursuant to Article 2, Paragraph 2 of the Improper Solicitation and Graft Act (hereinafter referred to as the "Anti-Graft Act"), when there is a difference between the lecture fee ceiling amount prescribed in Item A and that prescribed in the Anti-Graft Act, the lower amount shall be complied with; and

C. Notwithstanding Items A and B, up to KRW 5 million may 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; and

2. Lectures shall be attended by 10 or more attendees (excluding lecturer).

② Pursuant to provisions of Article 16 of the Code, a business entity may pay consultation fees to HCPs in accordance with each of the following subparagraphs:

1. Consultation fees shall be calculated taking into consideration the level and degree of the consultation, the expertise, knowledge, and experience of the consultant, etc., and shall be paid in accordance with each of the following items:

A. Consultation fees shall be based on the effort and time actually expended in providing the consultation, and shall be an amount within KRW 500,000 per consultation session within the scope of KRW 1 million per day, with an annual total limit of KRW 3 million (all amounts including taxes); and

B. Notwithstanding Item A, the foregoing annual ceiling amount shall not apply if the consultation is objectively recognized as providing services or deliverables exceeding the foregoing ceiling amount, such as consultations related to pharmaco-economics evaluations or research and development, or clinical

matters;

2. When a business entity directly pays consulting fees to HCPs, and even in cases of indirect payment of consultation fee made through healthcare institutions, etc., the relevant consulting fees shall be added to the annual total amount calculation above if the business entity could have been aware that the consulting fees were paid to the relevant HCPs; and

3. In the process of consulting fee calculation and payment, a business entity shall not, without justifiable grounds, apply to HCPs preferential standards different from those applied to lecturers.

③ When a business entity has paid lecture fees or consultation fees pursuant to Article 16, Paragraph 2 of the Code, the business entity shall submit the payment details on a quarterly basis via the reporting site by the 20th day of January, April, July, or October, based on the date of lecture or consultation completion (e.g., payment details from January to March of each year shall be reported by April 20).

④ The provisions of this Article shall equally apply to CSOs. In such instance, “business entity” in each Paragraph shall be construed as “CSO.”

Article 17 (Obligations for Management and Oversight of Contract Sales Organizations)

① When contracting out promotional activities for pharmaceuticals to a CSO, a business entity shall do so by executing a written contract in advance. The contract shall include the CSO's name and representative, business office location, registration number, details of the contracted promotional activities (names of the contracted pharmaceutical products, commission rates per product, scope of activities, etc.), contract term, and the contract acceptor's obligations and compliance requirements, as stipulated under the PAA. The business entity shall thereafter be responsible for the management and oversight of the contracted activities. In such cases, the business entity shall retain the written contract and related evidentiary materials for five years.

② A business entity shall not contract out promotional activities for pharmaceutical products to another business entity or any individual or entity that has not registered under Article 46-2, Paragraph 1 of the PAA.

③ Before entering into a contract with a CSO, business entities shall establish and implement a due diligence program to verify whether the CSO is appropriate from a fair competition perspective.

④ Business entities shall require the CSO (including any subcontracted CSO to whom the original CSO further delegates promotional activities) to complete training on fair competition in pharmaceutical distribution, etc., as stipulated by the PAA, at an educational institution designated by the MOHW. The business entity shall also, on a regular basis, verify that the relevant CSO has completed the training on fair competition in pharmaceutical distribution, etc.

⑤ To ensure the maintenance of fair competition in the distribution and sales of pharmaceuticals, business entities shall continuously monitor the activities performed by the CSO during the term of the contract. If a business entity becomes aware that the CSO has violated the business entity's policies or contractual compliance requirements, it shall request corrective action from the CSO. If the issue is not rectified within the specified timeline, the business entity shall terminate the contract.

⑥ The commission paid by a business entity to the CSO shall be within the scope of a reasonable level in light of social norms and fair business practices.

⑦ If the CSO further contracts out the promotional activities for the contracted pharmaceutical products to another CSO (including cases where the subcontract is modified), the business entity shall require the CSO to notify it in writing (e.g., a

Article 13 (Obligations for Management and Oversight of Contract Sales Organizations)

① Written contracts executed pursuant to Article 17, Paragraph 1 of the Code shall include the following information:

1. The name of the CSO and its representative;
2. The location of the CSO's business office and its registration number;
3. Details of the promotional activities being contracted out, including the names of the contracted pharmaceutical products and the commission rate for each product;
4. The term of the contract agreement;
5. The obligations and compliance requirements of the contract acceptor (including training of CSOs in accordance with the PAA);
6. Recording and reporting of expenditures related to the provision of economic benefits (including preparation of expenditure reports on economic benefits provided by the CSO and verification of such reports);
7. Matters related to monitoring and audits;
8. Requirements for corrective action and contract termination in the event of violations of contractual compliance requirements; and
9. Other compliance-related policies of the business entity.

② The due diligence program under Article 17, Paragraph 3 of the Code shall be conducted prior to entering into the initial contract. However, if additional due diligence is required due to contract term extension, etc., it may also be conducted during the contract term.

③ A business entity shall not contract out promotional activities for pharmaceuticals to a CSO that has a special relationship with a healthcare institution or pharmacy, where such relationship falls under any of the following subparagraphs:

1. A healthcare institution or pharmacy founded by an individual or entity who has a special relationship with the CSO (hereinafter referred to as "special relations party"), where the relationship falls under any of the following items:

A. If the CSO is an individual, any relative within the second degree of kinship (relative as defined by Article 767 of the Civil Code);

subcontract notification form and a copy of the subcontract agreement) within 30 days of executing the subcontract. In such instances, the business entity shall also ensure that the CSO executes a written subcontract agreement with the second CSO and retains the subcontract agreement and evidentiary materials for five years from the date of such execution.

B. If the CSO is a corporation, any officer of the relevant corporation or their relatives within the second degree of kinship;

C. If the CSO is a corporation, a person who effectively controls the relevant corporation (referring to individuals who contribute or own more than 50% of the relevant corporation's total contributions, total issued shares, or total equity shares, as well as individuals who exert dominant influence over the composition of the relevant corporation's board of directors or its business operations; hereinafter the same in this Paragraph);

D. If the special relations party under Item C is a corporation, any officer of the relevant corporation or individual who effectively controls the relevant corporation;

E. If the special relations party under Item C or D is an individual, their relatives within the second degree of kinship;

F. Any corporation that effectively controls the CSO;

G. Any corporation effectively controlled by the special relations party under this Subparagraph; and

H. Any employee of the CSO or its special relations party under this Subparagraph (in the case of a corporation, this includes officers; in the case of an individual, this includes commercial agents or employees under an employment contract. Hereinafter the same applies in this Paragraph); and

2. A healthcare institution or pharmacy if the CSO is a special relations party with the founder of the healthcare institution or pharmacy falling under any of the following:

A. If the founder of the healthcare institution or pharmacy is an individual, any relative within the second degree of kinship;

B. If the founder of the healthcare institution is a corporation, any officer of the relevant corporation or their relatives within the second degree of kinship;

C. If the founder of the healthcare institution is a corporation, any individual who effectively controls the relevant corporation;

D. If the special relations party under Item C is a corporation, any officer of the relevant corporation or individual who effectively controls the relevant corporation;

E. If the special relations party under Item C or D is an individual, their relatives within the second degree of

kinship;

F. Any corporation that effectively controls a corporate healthcare institution;

G. Any corporation effectively controlled by the special relations party under this Subparagraph; and

H. Any employee of the founder of a healthcare institution or pharmacy, or their special relations party under this Subparagraph.

④ Training under Article 17, Paragraph 4 of the Code shall be conducted at least once per year, and the business entity shall retain documentation to evidence the training. This requirement may be substituted by training conducted at a contract training institution designated by the MOHW.

⑤ Monitoring and regular audits under Article 17, Paragraph 5 of the Code shall be conducted at least once per year. However, if additional audits related to the CSO's contracted activities are deemed necessary, they may be conducted as needed.

⑥ If a business entity becomes aware that the CSO has violated the business entity's compliance policies or contractual compliance requirements, the business entity shall request corrective action within 10 days of becoming aware of the violation. If corrective action cannot be taken within this period due to additional fact-finding requirements, the business entity shall request the CSO to verify the facts of the violation within 10 days, and once the necessary facts are confirmed, corrective action shall be taken immediately.

⑦ Business entities shall retain the documentation related to Paragraphs 1 through 5 for a period of five years.

CHAPTER 3. Application of the Code

Article 18 (Code Deliberation Committee)

① The Association shall establish and operate a CDC to deliberate or decide on each of the following matters:

1. Matters related to consultation, guidance, and grievance handling regarding this Code;

2. Matters pertaining to each of the following items:

A. Selection of donation beneficiaries pursuant to Paragraph 2 of Article 7; assessment of the propriety of business proposals for donations requested by healthcare institutions, etc., under Paragraph 3 of the same Article; selection of donation beneficiaries; and evaluation of the propriety of donation activities under Paragraphs 2 through 4 of the same Article;

B. Assessment of the propriety of domestic academic conference proposals under Paragraph 2 of Article 8; approval of support by business entities seeking to sponsor academic conferences under the same Paragraph; compliance with the conditions for sponsoring academic conferences under Paragraph 3 of the same Article; and evaluation of the propriety of sponsoring academic conference under Paragraph 4 of the same Article; and

C. Approval for hosting product presentations and evaluation of their propriety pursuant to Paragraph 2 of Article 10;

3. Investigation and actions related to business entities that have violated or are likely to violate this Code;

4. Matters related to the establishment and amendment of the Guideline; and

5. Other matters related to this Code as requested by the Association.

② The CDC shall consist of 10 individuals, including one Chairperson, and five individuals that fall under each of the below subparagraphs shall be included as commissioners. The Association's standing officers shall attend the CDC as officers, and the Association's Secretariat shall serve as the CDC's administrative

Article 14 (Composition and Operation of the CDC)

① The commissioners of the CDC under Article 18 of the Code, including those recommended pursuant to Paragraph 2 of the same Article of the Code, shall be appointed by the President of the Association.

② The term of office for commissioners shall be one year and may be renewed. However, the term of a commissioner filling a vacancy shall be limited to the remaining term of their predecessor.

③ The Chairperson of the CDC under Article 18, Paragraph 2 of the Code shall be elected by a vote of the commissioners and shall preside over the CDC's affairs.

④ The CDC shall, in principle, hold regular meetings at least once a month. However, the Chairperson shall convene additional meetings in each of the following circumstances:

1. When requested by at least two-thirds of the affiliated commissioners;

2. When the Chairperson deems it necessary;

3. When the Board of Directors of the Association deems it necessary; or

4. When requested by the President of the Association.

Article 15 (Working Committee)

① Pursuant to Article 18, Paragraph 4 of the Code, the CDC may operate a working committee to support the tasks of the CDC described in Article 18, Paragraph 1 of the Code.

② A working committee shall be composed of the commissioners of the Association's Compliance Expert Committee.

③ A working committee shall be formed upon a resolution passed by the attendance of at least one-half of the total commissioners of the CDC and affirmative votes of the majority of the attending commissioners.

<p>secretary.</p> <p>1. Two individuals recommended by the Korea Consumer Agency (including one legal expert).</p> <p>2. One individual recommended by the National Health Insurance Service.</p> <p>3. Two individuals recommended by the Korean Medical Association.</p> <p>③ Resolutions of the CDC shall be made by the affirmative votes of the majority of the attending commissioners at a meeting attended by at least two-thirds of all commissioners.</p> <p>④ The CDC may establish and operate illegal drug distribution report centers, working committees, etc., to monitor, investigate, and take measures against unfair business practices.</p> <p>⑤ Other necessary matters concerning the operation, investigation, and measures of the CDC shall be determined by the Guideline.</p>	<p>Article 16 (Resolution, etc.)</p> <p>① In relation to Article 18, Paragraph 3 of the Code, the CDC may exercise its deliberation and voting rights in writing. When exercising voting rights in writing, the Chairperson shall send the documents and reference materials needed for the commissioners to exercise the rights as set forth above at least one week prior to the date of the meeting. In such cases, the pertinent commissioner shall be deemed to have attended the meeting in person.</p> <p>② When addressing an agenda item related to a member company affiliated with either the CDC or the working committee, the concerned commissioner or working committee member shall not participate in the deliberation, resolution, or investigation of the agenda item in question. In such cases, the total membership of the CDC shall be recalculated by excluding the number of related commissioners pursuant to this Paragraph.</p> <p>③ A commissioner shall not delegate another person to attend the CDC meeting on their behalf.</p> <p>④ The CDC and the working committee shall not use matters related to their duties for purposes outside the scope of their work or disclose such matters externally without the CDC's decision.</p> <p>⑤ Commissioners attending the CDC meeting may receive allowances and other necessary expenses within the budget.</p>
<p>Article 19 (Investigation of Code Violation)</p> <p>① The CDC shall conduct any necessary investigations if a violation of this Code is recognized, or if it deems it necessary to address matters reported to the Association.</p> <p>② Business entities shall cooperate with the CDC's investigation related to the matters described in Paragraph 1.</p> <p>③ The CDC may impose a monetary penalty of up to KRW 5 million on business entities that fail to cooperate with the investigation described in Paragraph 1 and may request the KFTC to take necessary actions.</p>	<p>Article 17 (Receipt of Reports)</p> <p>① The Association shall receive reports of violations of the Code submitted through methods such as in-person delivery, postal mail, email, or facsimile.</p> <p>② If the content of a report is unclear or additional materials are required, the Association may request supplemental materials within a reasonable period.</p> <p>③ If the reporter fails to provide the requested supplemental materials within the period specified under Paragraph 2, the Association may grant an additional period of up to seven days for supplementation, limited to a single request. If the reporter still fails to provide the necessary supplemental materials within this period, the report may be closed pursuant to Article 19.</p>

Article 18 (Investigation Procedures)

① Pursuant to Article 19, Paragraph 1 of the Code, the Association shall, within 10 days of becoming aware of a violation or receiving a report of a violation, request the relevant business entity (hereinafter referred to as the “respondent”) to verify the facts related to the alleged violation or report.

② The respondent shall, within 10 days of receiving the fact-checking request form, submit a written response, such as a written explanation or a corrective action plan, to the Association.

③ Upon receiving the respondent’s written response, the Association shall, within seven days, present the matter to the working committee, which shall review the fact-checking request form, and either conduct additional investigations or submit its findings and review opinions to the CDC.

④ If necessary for the investigation and verification, the CDC or the working committee may require the respondent’s officers or employees to attend meetings.

⑤ If a non-member company is reported or found to have violated this Code, the CDC may notify the KFTC or MOHW of such violation.

Article 19 (Closure of reports)

① If a report of a violation of the Code falls under any of the following subparagraphs, the investigation under Article 17 of this Guideline does not have to be conducted or may be discontinued:

1. The content of the report is clearly false;
2. The report lacks sufficient information about the reporter, such as their name or contact information, making it impracticable to take corrective measures, such as requesting supplementation;
3. The reporter fails to supplement the content of the report or the evidentiary materials despite receiving two or more requests for supplementation within the designated period;
4. The reporter submits a new report without justifiable reason regarding a matter for which they have already been notified of the results of the prior report;
5. An investigation into the reported matter has been initiated or already concluded in accordance with applicable laws;
6. The content of the report is unrelated to a violation of this Code; or

7. There is no evidence to substantiate the reported violation of the Code.

② If a report of a violation of the Code is not investigated or is closed pursuant to Paragraph 1, the reporter shall be notified, where the notification shall include the specific reasons for such action.

Article 20 (Actions against Code Violation)

① When the CDC determines that there has been a violation of this Code, it may take each of the following measures to ensure that the business entity responsible for the violation undertakes the necessary actions to rectify the violation, refrains from engaging in the same or similar violations, and complies with other related requirements:

1. Issue a warning;

2. Take a minor disciplinary action in cases where the violation of the Code is clear and poses a risk of damaging the reputation of the pharmaceutical industry; and

3. Take a severe disciplinary action in cases where the violation is evident, serious, or constitutes an unlawful act that could result in legal sanctions.

② The CDC may impose a monetary penalty of up to KRW 10 million as a minor disciplinary action.

③ The CDC may impose each of the following subparagraphs as severe disciplinary actions, which may be applied cumulatively:

1. A monetary penalty of up to KRW 100 million;

2. Referral to the relevant authorities for prosecution; and

3. A request for termination of the Association membership.

④ If the CDC determines that a business entity subject to actions such as a warning etc., under Paragraph 1 has failed to comply with such measures, it may request the KFTC and MOHW to take appropriate actions.

Article 20 (Actions)

① A warning under Article 20, Paragraph 1, Subparagraph 1 of the Code is issued in cases where the violation of the Code is isolated and minor, where a violation has not yet occurred but there is a significant likelihood of its occurrence in the future, or where a violation occurred but was ceased during the investigation period with no risk of recurrence.

② A minor disciplinary action under Article 20, Paragraph 1, Subparagraph 2 of the Code is imposed in cases where the violation is systematic, intentional, or repetitive and continuous, but does not reach a serious level of content or severity, or where no improvements are made despite receiving a warning.

③ A severe disciplinary action under Article 20, Paragraph 1, Subparagraph 3 of the Code is imposed in cases where the violation is systematic, intentional, or repetitive and continuous, and the nature and severity of the violation are clear and serious, where the violation constitutes an unlawful act subject to legal sanctions, or where no improvements are made despite receiving minor disciplinary action.

<p>Article 21 (Obligation of Cooperation by Business Entities)</p> <p>Business entities shall actively cooperate with CDC’s operations to ensure smooth implementation of this Code.</p>	<p>Article 21 (Indemnification)</p> <p>Business entities shall not file any legal claims against the commissioners, working committee members, the Association, and the officers and employees of the Association in connection with their performance of duties under the Code and this Guideline.</p>
<p>Article 22 (Record Management by the Association)</p> <p>① The Association shall retain the following materials for five years:</p> <ol style="list-style-type: none"> 1. Materials reported, submitted, and notified by business entities, materials managed by the Association, and materials subject to deliberation and decision by the CDC pursuant to Articles 7, 8, 9, 10, 12, and 15; 2. Materials related to or in connection with the investigations and actions of the CDC pursuant to Articles 18 and 19; and 3. Materials related to or in connection with the investigations and actions of the CDC pursuant to Articles 19 and 20. <p>② The Association shall, in good faith, respond to requests to submit materials under Paragraph 1 made by the KFTC or MOHW.</p>	<p>Article 22 (Record Management by the Association)</p> <p>① Unless otherwise stipulated in this Guideline, the Association shall ensure that only the officers and employees, commissioners, and working committee members of the Association, or the relevant business entities have access to the materials submitted by the business entities under Article 22, Paragraph 1, Subparagraph 1 of the Code.</p> <p>② The management and submission of materials under Article 22 of the Code may be carried out electronically.</p>
<p>Article 23 (Appeal, etc.)</p> <p>① Prior to taking actions under Paragraph 3 of Article 19 and Paragraphs 1 to 3 of Article 20, the CDC shall prepare in writing the details of its intended actions (hereinafter referred to as the “decision letter”) and notify the relevant business entity accordingly.</p> <p>② The business entity under Paragraph 1 may appeal in writing to the CDC within 10 days from the date of the decision letter.</p> <p>③ If an appeal is filed under Paragraph 2, the CDC shall provide the business entity with an opportunity to present additional arguments and evidence, and, based on the submitted materials, conduct a review within 30 days and decide on appropriate actions accordingly.</p> <p>④ The CDC shall promptly take actions pursuant to its decision letter absent any appeal under Paragraph 2.</p>	<p>Article 23 (Decision Letter)</p> <p>① Pursuant to Article 23, Paragraph 1 of the Code, the CDC shall notify the relevant business entity the details of the intended actions (hereinafter referred to as the “decision letter”) within 10 days of the date of the related decision.</p> <p>② A business entity notified of the decision letter under Paragraph 1 shall either appeal or communicate its intention to accept the details of the action to the CDC within 10 days of receiving the decision letter.</p> <p>③ A business entity subject to penalties shall pay such penalties within 30 days of receiving the decision letter. However, if the business entity files an appeal, such penalties shall be paid within 30 days of receiving the final decision letter following re-deliberation.</p>
<p>Chapter 4 Supplement</p> <p>Article 24 (Amendment of the Code)</p> <p>Any amendment to this Code shall be subject to prior</p>	

review by KFTC.