KMDIA Fair Competition Code on Transactions of Medical Devices and Detailed Working Guidelines

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KMDIA Fair Competition Code on Transactions of Medical Devices (Nov 10, 2017)	KMDIA Fair Competition Code on Transactions of Medical Devices Detailed Working Guidelines (Nov 10, 2017)	Reference
Chapter 1 General **Article 1 (Purpose)** The purpose of this "Fair Competition Code on Transactions of Medical Devices" (this "Code") is to ensure public order of fair competition in the distribution of Medical Devices and to maintain and improve public health by curbing unfair customer solicitation activities prohibited by Item 3 of Paragraph 1 of Article 23 of the Monopoly Regulation and Fair Trade Law (the "FTL"). **Article 2 (General Principles)** Companies, Distributors, and Lessors shall observe the provisions of this Code according to the following general principles: ① Medical Device marketing activities shall be conducted to the extent that they are accepted as ordinary commercial practices in accordance with relevant laws such as the FTL and socially accepted norms; ② Companies and Distributors shall make efforts to deliver scientific and educational information regarding their products to healthcare professionals and try to maximize the benefits for patients; provided, however, that such efforts by member Companies and Distributors shall not interfere with the independence of healthcare professionals' decision with regard to the selection of Medical Devices to be used for medical practices; ③ Activities under Paragraph 2 of Article 2 should be conducted at		

appropriate venues in accordance with the purpose of such activities; and

④ Financial management including accounting records shall be recorded and managed precisely and transparently based on the facts in accordance with relevant laws and generally accepted accounting principles.

Article 3 (Definitions)

① "Medical Device(s)" shall mean the Medical Devices as designated under Paragraph 1 of Article 2 (Definition of Medical Devices) of the Medical Devices Act (the "MDA");

② "Company(ies)" shall mean entities that are permitted to engage in the business of manufacturing or importing Medical Devices pursuant to Article 6 or Article 15 of the MDA;

③ "Repairer(s)" shall mean entities that engage in the business of repairing Medical Devices after fulfilling the reporting requirements pursuant to Article 16 of the MDA.

④ "Distributor(s), etc." shall mean those entities that are engaged in the business of distributing or leasing Medical Devices after notifying their distribution or lease business pursuant to Article 17 of the MDA.

⑤ "Medical Institution(s)" shall mean those places set forth in Article 3 of the MSA;

⑥ "Healthcare Personnel(s)" ("HCP(s)") shall mean those persons permitted to engage in the provision of health and medical services or licensed or qualified under relevant health and medical services regulations pursuant to Item 3 of Article 3 of the Framework Act on Health and Medical Services. While pharmacists and oriental medical doctors are excluded, pharmacists and oriental medical doctors employed at Medical Institutions are deemed HCPs for the purposes of applying this Code.

⑦ “Foreign Healthcare Personnel(s)” (“FHCP(s)”) shall mean those persons who have had their medical and pharmaceutical knowledge recognized in a country other than Korea but are not recognized as HCPs under the Code. Provided, however, those who belong to a domestic Medical Institution are deemed HCPs for the purposes of application of this Code. ⑧ “Sample(s)” shall mean finished products used for purposes of introducing Medical Devices; ⑨ “Donation” shall mean the provision by Companies of Money or other valuables, free of charge, to Medical Institutions, schools, institutions or organizations which directly conduct academic or scientific research or industry-academic joint projects (“Medical and Medical Device Research Institutions, etc.”), regardless of whether such Money or other valuables are referred to as welcome contribution, sponsorship, endorsement or support monies; ⑩ “Academic Conference(s)” shall mean events held for the purpose of supporting medical research, education, etc. of HCPs by providing scientific and educational information related to medicine to HCPs, regardless of their title or form such as conferences, symposia, seminars or academic events, but excluding events that are in substance hosted by a Company. Among such Academic Conferences, “domestically-held international Academic Conferences” shall mean those domestically-held Academic Conferences of an international scale lasting two or more days, attended by HCPs from five or more countries (HCPs attending as audience, not as presenter, chair or panelist, from five or more countries must come to Korea) or attended by participants of which 150 or more are foreigners, and approved by medical doctors’ associations, dentists’ associations, oriental medical doctors’ associations, or the Korean Medical Devices Industry Association as an international Academic Conference pursuant to Paragraph 1 of Article 28 of the MSA. “International Academy(ies)” shall mean those academies, approved by medical doctors’ associations, dentists associations, oriental medical doctors’ associations, or the Korean Medical Devices Industry Association		

pursuant to Paragraph 1 of Article 28 of the MSA, of which 100 or more regular members are foreigners from five or more countries; ⑪ "Product Presentation(s)" shall mean domestically held events targeting multiple Medical Institutions hosted by a Company for HCPs belonging to such Medical Institutions for the purpose of providing information on its own devices, and the visiting of individual Medical Institutions thereby providing information on its devices to HCPs belonging thereto; ⑫ "Education or Training" shall mean education that communicates information directly relevant to the use of medical technologies that a Company provides to the HCPs and persons engaging in operation and diagnosis in order for such HCP and persons to learn and improve operation and diagnostic skills, or training that relates to safe and effective use of medical technologies; ⑬ "Market Survey" shall mean activities of collecting data by a Company on the market and the size and characteristics of its components, including consumer demand; ⑭ "Post-Marketing Survey" shall mean survey conducted during the reevaluation period by an entity that have obtained product approval for a Medical Device subject to reevaluation under Article 8 of the MDA, such as performance survey, special survey, and clinical study post marketing to collect, review, confirm and verify information relating to such Medical Device's safety and effectiveness and information necessary for proper use of the same. ⑮ "Money or other valuables" shall mean goods, money, or other economic benefits provided by Companies to Medical Institutions, etc. or HCPs including, but not limited to, the following items: 1. Goods, machines, devices, land, buildings, and other constructions (including rights of use); 2. Money, certificates of money deposit, gift certificates, other securities or written promises of payment under various titles;		

3. Entertainment (including food and beverages, invitations or privileged treatment to any performance such as movies or plays, or to various events such as sports, tour, golf, skiing, etc.); 4. Convenience services, such as transportation, lodging and registration for academies; 5. Labor or other services; or 6. Discounts, premiums or sales incentives, etc. (provided, however, that "discounts based on payment terms" and "points accrued from use of credit or debit cards" that are within the permissible scope of economic benefits under the Enforcement Decrees of the MSA or the MDA are excluded). ⑯ "Electronic Documents" shall mean electronic documents as set forth in Article 2, Paragraph 1 of the Framework Act on Electronic Commerce.		
Article 4 (Detailed Working Guidelines) ① The KMDIA may prescribe detailed working guidelines (the "Guidelines") on the detailed rules of this Code that reflect the purpose of this Code. ② The Korea Fair Trade Commission ("KFTC") may recommend to the KMDIA an establishment of or amendment to the Guidelines under Paragraph 1 when necessary to ensure public order of fair competition.	**Article 1 (Purpose)** The purpose of this Detailed Working Guidelines ("Guideline" or "Guidelines") is to set forth detailed regulations pursuant to Article 4 of the Fair Competition Code on Transactions of Medical Devices (the "Code") of the Korean Medical Devices Industry Association (the "KMDIA") in order to facilitate the implementation of the Code.	
Chapter 2 Permissible Scope of Provision of Money or Other Valuables		
Article 5 (Limitation on Provision of Money or Other Valuables)	**Article 2 (Limitation on Provision of Money or Other Valuables)**	

① Companies and Distributors shall neither provide Money or other valuables as defined in Paragraph 13 of Article 3 to Medical Institutions, etc. or HCPs nor respond to demands made by Medical Institutions, etc. or HCPs of Money or other valuables; provided, however, that the foregoing shall not apply to those falling under Articles 6 through 17 that can be recognized as ordinary commercial practices according to social norms. ② Notwithstanding Paragraph 1, in addition to Money or other valuables the provision of which is permitted under the proviso in Paragraph 1, Companies and Distributors may as an exception provide to HCPs Money or other valuables of which the provision has been confirmed to be permissible through an official/formal ruling of Paragraph 2 of Article 23-2 of the MSA and Article 2 of the Enforcement Regulations on Medical Device Distribution and Maintenance of Sales Order decreed by the Ministry of Health and Welfare (the "MoHW"), the competent authority of said provisions. ③ In each of the following cases, a Company shall be deemed to have directly provided Money or other valuables to Medical Institutions, etc. or HCPs: 1. When a Company provides Money or other valuables to the domestic or overseas headquarters or branches, or affiliated companies, distributors, etc. or marketing agencies and demands such Money or other valuables to be provided to Medical Institutions, etc. or HCPs; or 2. When a Company provides Money or other valuables to distributors, etc. or marketing agencies even though it could have known that such Money or other valuables would be delivered to Medical Institution, etc. or HCPs. ④ Providing Money or other valuables to family members, relatives or others with special ties to a HCP, or individuals, companies or other organizations with special ties to a Medical Institution, etc. shall be deemed a provision of the same to the relevant HCP or Medical Institution, etc.	① "Healthcare Personnel(s)" ("HCP(s)") who are restricted from receiving Money or other valuables as set forth in Paragraph 1 of Article 5 of the Code refers to "Healthcare Personnel(s)" set forth in Paragraph 6 of Article 3 of the Code and fall under each of the following Items: 1. HCPs whose qualification/license criteria are set forth under the relevant healthcare laws and regulations. a. The Medical Services Act: doctor, dentist, practitioner of oriental medicine, midwife, nurse b. Law Regarding Medical Technicians, etc.: clinical pathologist, radiology technician, physical therapist, occupational therapist, dental technician and dental hygienist, medical record technician, optician c. Other relevant laws and regulations: hygienist, 1st/2nd class emergency medical technician, prosthesis and brace technician, health education specialist, long-term care worker, nurse assistant, osteopath, acupuncturist, moxibustionist, Medical Institution employed pharmacist and oriental pharmacist d. HCPs as prescribed in the above Sub-Items b. or c. shall be limited to persons operating or providing services at a Medical Institution. 2. A person who is allowed to engage in healthcare services a. Persons operating a Medical Institution (president or director of a legal entity, or other persons engaged to provide services thereat) b. A person providing services at a Medical Institution (excluding those exclusively carrying out general duties unrelated to the healthcare service such as cleaning or security) ② "The provision of money or other valuables to a Medical Institution or HCP by a Company's domestic or overseas headquarters, branch offices or affiliated companies" under Item 1 of Paragraph 3 of Article 5 of the Code shall refer to (i) when the	

	Company provides Money or other valuables to its headquarters, branch office, or other affiliates within and outside Korea ("Affiliates"), and requests that the money or other valuables be provided to Medical Institutions or HCPs, or (ii) when the Company does not, intentionally or through gross negligence, prevent its Affiliates from independently providing money or other valuables to Medical Institutions or HCPs, although the Company was aware or could have been aware of the provision of money or other valuables. ③ Item 2 of Paragraph 3 of Article 5 of the Code refers to instances where Companies, providing money or other valuables to a distributor or marketing agency, knew that the distributor or marketing agency would provide such money or other valuables to Medical Institutions, etc., or HCPs, or could have known but did not know due to gross negligence and provided such money or other valuables to the distributor or marketing agency.	
Article 6 (Provision of Samples) ① Companies and Distributors may provide free of charge to Medical Institutions. Medical Devices in minimum packaging unit marked 'sample' in either Korean or English so as to enable the validation of their features, in which case Companies and Distributors may not provide samples exceeding the minimum amount or minimum period (in the case of re-usable Medical Devices which are expected to be used for a fixed number of times), necessary to validate the features of the Medical Devices concerned; ② Companies and Distributors can provide samples separately for demonstration and evaluation purposes, and shall comply with principles set forth in each of the following: 1. If samples are provided only for demonstration purposes to raise awareness of HCPs and patients with respect to a Medical Device, the samples shall have "Not for Use on the Human Body," or otherwise indicate that the samples cannot be used for patients, on their packaging or documents attached thereto.	**Article 3 (Samples)** ① The "minimum packaging unit or minimum amount, minimum period" in Article 6 of the Code is based on the minimum package unit or minimum amount [minimum unit in terms of amount] or minimum period of the respective Companies. The minimum period refers to the minimum period required to test performance of a Medical Device prior to the purchase; provided, that such period shall not exceed one month. However, in cases where a significant amount of time is required for installation of relevant equipment and software for using the Medical Device or for training on instructions, the one-month-period shall be calculated from the date when a HCP becomes capable of using the Medical Device in practice. ② Companies and Distributors may provide one to two demonstration products or evaluation products pursuant to Paragraph 2 of Article 6 of the Code to Medical Institutions (limited to cases where it is determined that it is necessary to evaluate the sample product being provided depending on each medical department) in their minimum	

2. If samples are provided to enable Medical Institutions to evaluate proper use and functions and to make decisions as to use, order or purchase of the relevant product, the samples shall have "When used on a patient, cost may not be charged to the patient." on their packaging or documents attached thereto, and shall only be provided to Medical Institutions or Medical Institutions after explaining the foregoing for their awareness of the same.	package unit or the minimum amounts needed for evaluation [of such products]. Provided, however, for evaluation products, an additional provision may be made for one time only in any of the following circumstances: 1. There has been a material change to the relevant product such as a change in product approval by the Minister of the Ministry of Food and Drug Safety ("MFDS"). 2. The consumer must try the product before purchase (or use), such as with contact lenses. ③ Evaluation products that can be repeatedly used on multiple occasions ("Multiple Use Products") must be in compliance with Paragraph 1 or 2, provided, however, such evaluation products may only be provided according to the following Items for the minimum period (no more than one month) that is reasonably necessary to appropriately evaluate the products: 1. The evaluation criteria for Multiple Use Products including the evaluation period must be clearly stated in advance in writing, and Companies and Distributors must obtain a receipt from the Medical Institution. 2. Ownership rights of the evaluation products during the evaluation period belong to the Company or the Distributor and the Company or the Distributor must not transfer such ownership rights. 3. Upon expiration of the evaluation period, if the Medical Institution does not purchase or lease the product, such product must immediately be collected.	
Article 7 (Donations) ① Companies may make Donations to Medical and Medical Device Research Institutions, etc. for medical, educational or charitable purposes within the scope generally acknowledged by social norms, based on principles set forth in each of the following:	**Article 4 (Donations)** ① Medical and Medical Device Research Institutions etc., as the recipient of the Donations under Paragraph 1 of Article 7 of the Code, refers to institutions or organizations that fall under Items 1 through 4	

1. Donations that fall under any of the following are prohibited: a. Where there is a promise of profits relating to transactions such as the selection of Medical Devices of the Company making the Donation; b. When a Company accepts a Donation request by Medical and Medical Device Research Institutions, etc., giving consideration to its effect on transactions such as the selection of Medical Devices; c. Donations that are used as funds to make payments, which according to social norms should be borne by Medical and Medical Device Research Institutions, etc. with their own funds, such as funds used for purchasing real estate or fixtures, expanding or remodeling facilities, or preserving funds for management, etc.; and d. When a Company repeatedly and continuously provides Donations to the same Medical and Medical Device Research Institutions, etc., without any justifiable reasons therefor. 2. Companies shall, prior to a Donation, make a request to the KMDIA for the selection of Medical and Medical Device Research Institutions, etc., to which Donations will be made ("Beneficiary") by stating the purpose and size of the Donation, etc. in form designated by the KMDIA, after which Companies shall directly make the Donation to the Beneficiary in accordance with the decision by the KMDIA. 3. Not withstanding Item 2, when Medical and Medical Device Research Institutions, etc. request KMDIA for Donations in order to execute projects such as academic awards, campaigns, etc. (notwithstanding Sub-Item c of Item 1, in the case of International Academies the secretariats of which are domestically-based, support funds for the operation of such secretariat are included), Companies shall donate directly to the Beneficiary in accordance with the procedure set forth in each of the following Sub-Items:	of Paragraph 1 of Article 9 of the Code and satisfy each of the following Items. Provided, however, institutions or organizations that fall under Items 1 through 4 of Paragraph 1 of Article 9 include those that satisfy all of the following Items or those that the Fair Competition Code Deliberation Committee determines should be included even if not all of the following are satisfied : 1. A non-profit organization established for the purpose of medical research such as publishing research findings on medicine. 2. An organization equipped with operating regulations. 3. An organization that collects membership fees on a regular basis. 4. An organization that keeps financial or accounting regulations with respect to spending membership fees, other income and research funds, and maintains separate, independent accounting regulations for individual members and Medical Institutions, etc. to which its members belong. Any income earned must not be used for profit but solely for research activities. 5. An organization that has a management structure such as general member meetings, board of directors, an auditor, etc. 6. An organization that has officers and members such as a president, directors, an auditor, etc. 7. An organization that is engaged in medical research activities through meetings held regularly or non-regularly. 8. An organization shall have a periodical to publish its medical research activities. 9. An organization that is not a subordinate organization of any particular Medical Institution and the Beneficiaries of its public funds are a large number of unspecified people. ② Pursuant to Item 2 of Paragraph 1 of Article 7 of the Code, a Company may request the KMDIA to select a Beneficiary in each of	

a. Medical and Medical Device Research Institutions, etc. request KMDIA for Donations by stating in form designated by the KMDIA the name, outline of the project, requested amount, etc. and attaching annexed documents such as a detailed project proposal, budget plan, etc. b. KMDIA reviews the propriety of the project proposal and, based on the result thereof, solicits by announcement Companies which wish to donate and notify the result of such solicitation to the Academic Conference concerned and the donating companies. c. Companies donate directly to the Beneficiary, i.e., the relevant Medical and Medical Device Research Institutions, etc. following KMDIA's notice. 4. Companies shall not make Donations directly to Medical and Medical Device Research Institutions, etc. or HCPs, other than making Donations in accordance with Items 2 and 3 above. 5. After completing the delivery of Donations to the Beneficiary, Companies shall notify the KMDIA of the date, Beneficiary, purpose, amount of Donations, etc. in form designated by the KMDIA within 10 days of the delivery of such Donations. 6. Companies shall attach evidentiary materials which detail the date, Beneficiary, purpose and amount, etc. of such Donations for accounting purposes. ② With regard to Item 2 of Paragraph 1, the KMDIA, on behalf of Companies, shall select a Beneficiary within the scope consistent with Item 1 of the same Paragraph and notify the Company concerned, while verifying whether such Donation by the Company has been made in an appropriate manner in accordance with KMDIA's decision. When making a decision as to the Beneficiary, the KMDIA shall respect the Company's purpose of making such Donation and, if needed, the KMDIA may have the Company attend a meeting of the Fair Competition Code Deliberation Committee to hear its opinion.	the following cases: 1. A Company shall make a request to the KMDIA during the last month of each quarter (March, June, September and December) through the website of the Fair Competition Code Deliberation Committee of the KMDIA ("Website") for the selection of the Beneficiaries for the Donations that will be given during the quarter that is two quarters subsequent to the quarter in which the request is made. 2. The KMDIA shall select the Beneficiary after making a public announcement on its Website inviting Medical and Medical Device Research Institutions, etc., to be selected for Donations for a minimum period of 15 days. The KMDIA shall then notify the Company of the results within 30 days from the date on which the request for consideration was made. Provided, however, the KMDIA shall notify the Company in advance if it cannot carry out the Company's request within the abovementioned period due to unavoidable circumstances. 3. The KMDIA shall select a Beneficiary by reviewing whether the business of the requesting Medical and Medical Device Research Institutions, etc., are in accordance with the principles set forth in Paragraph 1 of Article 7 of the Code based on materials such as detailed business plans (research proposals), budget statements containing the expenditures, costs and detailed items and other pertinent documents submitted by the Medical Institutions, etc., when the KMDIA makes a public announcement. 4. If a Company objects to the notified decision of the KMDIA with respect to the selection of the Beneficiary, such Company may withdraw their request within five days from the date of the notification. ③ Pursuant to Item 3 of Paragraph 1 of Article 7 of the Code, if Medical and Medical Device Research Institutions make requests for donations to the KMDIA, the institutions shall file for deliberation 3 months prior to the initiation of the project along with detailed business proposals and budget statements.	

③ With regard to Item 3 of Paragraph 1, in reviewing the propriety of the project proposal by the relevant Medical and Medical Device Research Institution, etc., or selecting the donating Company, the KMDIA shall consider whether they are consistent with Item 1 of the same Paragraph, and verify whether the Donation by the Company has been made in an appropriate manner in accordance with the KMDIA's notice. ④ Notwithstanding the provisions of Items 2 through 4 of Paragraph 1, when a Company wishes to donate Medical Devices to Medical Institutions, etc. (Medical and Medical Device Research Institutions) for charitable purposes, such Company may donate directly to the Beneficiary after notifying the KMDIA in advance by stating in form designated by the KMDIA the Beneficiary, purpose, size, etc. of such Donation. Even in such a case, Companies shall comply with the principles set forth in Sub-items a through d of Item 1, and Items 5 and 6 of the same Paragraph, and the KMDIA shall verify whether such Donation by the Company has been made in an appropriate manner.	Upon requests for Donations made by approved Medical and Medical Device Research Institutions, etc., pursuant to Item 3 of Paragraph 1 of Article 7, the KMDIA shall make a public announcement on its Website for a minimum period of 15 days inviting Companies that wish to donate and determine the amount of Donation according to the donor Company's request; provided, however, if the sum of the prospective Donation exceeds the requested amount, it shall be proportionally divided by the amount that each Company wishes to donate. ④ Pursuant to Item 2 and 3 of Paragraph 1 of Article 7 of the Code, a Company that makes a request to donate or participates in [the KMDIA's] request for a Donation, shall pay a deliberation fee or service fee to the KMDIA in accordance with the following Items: 1. If the amount of Donation is KRW 100 million or less, the deliberation fee or service fee (the "Deliberation Fee, Etc.") shall be one and a half percent (1.5%) (the amount of the [Deliberation Fee, Etc.] below KRW 100 will be rounded down) of the amount of the Donation; 2. If the amount of the Donation exceeds KRW 100 million, the Deliberation Fee, Etc. will be KRW 1,500,000; 3. If a Company is not a member of the KMDIA, the Deliberation Fee, Etc. will be a fixed rate of three percent (3%) of the Donation amount; 4. The Deliberation Fee, Etc. will be waived in cases where a Company makes a donation of the Company's Medical Devices or pharmaceutical products to Medical Institutions, etc., for charitable purposes pursuant to Paragraph 4 of Article 7 of the Code; 5. The KMDIA will not return the Deliberation Fee, Etc. in cases falling under one of the following Sub-Items: a. After the deliberation is complete, the Company withdraws its request for the selection of the Beneficiary of the Donation;	

	b. The Donation is not approved in the deliberation process; and c. After participating in a Donation program and being notified of the final Donation amount by the KMDIA pursuant to Item 3, Paragraph 1 of Article 7 of the Code, the Company withdraws. 6. The KMDIA shall issue an electronic tax invoice for the Deliberation Fee ⑤ A Company shall prepare and submit an execution report through the Website along with evidentiary materials such as a Donation receipt, etc., to the KMDIA within 10 days from the date on which the delivery of the Donation is completed in accordance with Item 5 of Paragraph 1 of Article 7 of the Code. ⑥ Pursuant to Paragraph 3 of Article 7 of the Code, the Medical and Medical Device Research Institutions, etc., receiving the Donations must submit a statement of accounts, which includes the total income and records of expenditure for the relevant project, and copies of the receipts, which can verify the expenditures, within 3 months after the conclusion of the relevant project in accordance with the execution report on the Website in order to verify and determine whether the Donations were appropriately utilized. ⑦ A Company [wishing to donate to Medical Institutions, etc.] pursuant to Paragraph 4 of Article 7 of the Code must file a report to the KMDIA through the Website 10 days prior to making the Donations, and the Company shall prepare and submit an execution report through the Website along with evidentiary materials of the Donation such as a Donation receipt, etc., to the KMDIA within 10 days from the date on which the delivery of the Donation is completed.	
Article 8 (Sponsorship for Hosting and Operating Academic Conferences)	**Article 5 (Sponsorship for Hosting and Operating Academic Conferences)**	

① Companies may sponsor Academic Conferences held domestically by any of the following institutions or organizations through various means such as Donation, provision of food and beverage, provision of souvenirs, lease of booths or advertisements: 1. Medical doctors' associations, dentists' associations, oriental medical doctors' associations pursuant to Paragraph 1 of Article 28 of the MSA; Medical Institutions pursuant to Paragraph 1 of Article 52 of the same Act; and academic societies (including foreign academic societies), academic institutions/organizations and research institutions/organizations approved and recognized by any of the preceding associations/institutions; and 2. Academic societies (including foreign academic societies), institutions /organizations or research institutions/organizations recognized by the KMDIA. ② Companies that wish to sponsor domestic Academic Conferences shall comply with procedures set forth in each of the following: 1. Institutions and organizations enumerated in Paragraph 1 shall submit a written request on form provided by the KMDIA, which form shall include the name and the outline of the Academic Conference, amount requested, and attach supplementary documentation detailing the conference plan and budget; 2. The KMDIA shall evaluate the Academic Conference plan, identify Companies that wish to participate by public notice based on the evaluation, and notify the results to the requesting institution or organization as well as the Companies; 3. In accordance with the KMDIA notice, Companies shall provide sponsorship funds to the organizer of the specific Academic Conference; and 4. Within one month following the Academic Conference in question, Companies shall submit a sponsorship report on form designated by the KMDIA, and the KMDIA shall verify that the Companies'	① In the event a host [hosting organization or institution] of an Academic Conference requests the KMDIA for sponsorship of the Academic Conference pursuant to Item 1 of Paragraph 2 of Article 8 of the Code, the host of the Academic Conference shall make such request by preparing and submitting the application on the Website before the last month of the quarter (March, June, September, and December) preceding the date of the Academic Conference by two quarters. ② If a Company wishes to provide support for hosting and operating an Academic Conference in accordance with Paragraph 2 of Article 8 of the Code, the Company shall file an application on the Website and shall pay the Deliberation Fee in accordance with Paragraph 4 of Article 4 of the Guidelines. ③ In accordance with Item 4 of Paragraph 2 of Article 8 and Item 2 of Paragraph 4 of Article 8 of the Code, the Company shall prepare and submit its statement of sponsorship of the Academic Conference on the Website to the KMDIA within one month after the completion of the Academic Conference. ④ Pursuant to Item 1 of Paragraph 2 of Article 8 and Paragraph 3 of Article 8 of the Code, the required budget and the statement of accounts for expenditures that the host of the Academic Conference must submit shall be in accordance with the following Items, and when the host of the Academic Conference submits the statement of accounts for expenditures, copies of receipts verifying the expenditures must also be submitted. 1. Total income includes the Donations (support funds) from the Companies, the registration fees (or admissions fees) for the Academic Conference, independent budgets of the Academic Conference, booth fees, income from print media and Internet advertisements, Donations (support funds) from HCPs and Medical Institutions, and means the aggregate sum of the income relating to hosting and operating Academic Conferences. Total income shall not include registration fees or admissions fees from persons (or legal entities) other than	

sponsorship of the Academic Conference was carried out in an appropriate manner. ③ With regard to Paragraph 2, the KMDIA shall approve of sponsorships by Companies under the condition that at least 30% of the total amount (excluding any costs related to Product Presentations taking place during the Academic Conference) necessary to hold the Academic Conference is self-funded through collection of registration fees from conference participants and membership fees of academic institution or organization hosting the conference. For the KMDIA to confirm that this condition is met, the host of the Academic Conference shall notify the KMDIA with an expense report within 3 months following the end of the Academic Conference. If the host fails to comply with this requirement or if the KMDIA fails to receive such expense report, the KMDIA may refuse all support for Academic Conferences hosted by such host in the future. ④ Companies that sponsor domestically-held international Academic Conferences shall comply with the following: 1. Companies can provide direct sponsorship for the Academic Conference by notifying the KMDIA in advance in form designated by the KMDIA, which form shall include the name of the Academic Conference, overview, amount to be provided and sponsorship details; and 2. Within one month following the Academic Conference, Companies shall submit a sponsorship report on form specified by the KMDIA and the KMDIA shall verify that the Companies' sponsorship of the Academic Conference was carried out in an appropriate manner. ⑤ With regard to Paragraph 4, the KMDIA may request the host of the Academic Conference to submit the list of participants per each country, details of Company(ies)'s sponsorship details, cost settlement history, and other necessary materials if there is a need to confirm whether the approval conditions for a domestically-held international Academic Conference have been satisfied. If the host of the Academic Conference refuses to comply with such request, the	HCPs or employees of medical care institutions, economic benefits received from Medical Device companies or Distributors of Medical Devices (or pharmaceutical products). 2. Total expenditure includes fees paid for food and beverages, cost to invite presenters, chairpersons and panelists that have been invited by the host of the Academic Conference, lecture fees, service fees for agencies, fees to rent the venue, fees for short term employment, printing and advertisement fees, and means the aggregate sum of all expenditures relating to hosting and operating Academic Conferences. 3. The total expenditure shall not include administrative expenses without direct relevance to Academic Conferences such as personnel expenses of offices of the hosting institution or organization of the Academic Conference, office fixture purchasing costs and other office operational expenses. The total expenditure shall not include expenditures for non-academic content and that does not fall under the definition of an Academic Conferences under Paragraph 8 of Article 3 of the Code. ⑤ "Self-funded" income in Paragraph 3 of Article 8 of the Code refers to registration fees (or admission fees) and independent budgets of the organizer of the Academic Conference which does not constitute economic benefits provided by the Company or any other Medical Devices Company (e.g., membership dues) and set aside for the Academic Conference. ⑥ Pursuant to Paragraph 6 of Article 8 of the Code, refunds shall be given in accordance with the below. 1. As for Academic Conferences held in Korea pursuant to Paragraph 3 of Article 8 of the Code, the host of the Academic Conference shall return the remaining amount to the KMDIA calculated in accordance with Paragraph 6 of Article 8 of the Code. The KMDIA shall give refunds in proportion to each Company's share of support funds for the relevant Academic Conference.	

KMDIA may refuse such host's sponsorship requests for all future Academic Conferences, or request Companies to refuse sponsorships and Companies must comply with such request. ⑥ With regard to Paragraph 3, if there are funds remaining after the conclusion of an Academic Conference, the host of the Academic Conference shall return the remaining funds to the KMDIA within 3 months so that they are returned to Companies that made the donation. However, with regard to Paragraph 5, if there are funds remaining after the conclusion of an Academic Conference, they shall be returned to Companies that made the donations within 3 months after conclusion of the Academic Conference . ⑦ With regard to Paragraphs 2 through 4, Companies may not participate in deciding the agenda, proceedings, participants or related materials of the Academic Conference they sponsor, and shall attach documents substantiating the sponsorship details for their accounting records. ⑧ With respect to sponsorships described in Paragraph 1, there is no cap limiting a Company's voluntary support through lease of booths or advertisements. In case of conflict among Articles 8 (Sponsorship for Hosting and Operating Academic Conferences), 7 (Donations) and 17 (Exhibitions and Advertisements), Article 8 shall govern. **Article 9 (Sponsoring for HCP Participation in Academic Conferences)** ① Companies may sponsor HCPs participating in domestic or overseas Academic Conferences hosted by any of the following institutions or organizations: 1. Non-profit organization established for the purpose of academic research related to medicine/Medical Devices; 2. Medical doctors' associations, dentists' associations, oriental medicine doctors' associations pursuant to Paragraph 1 of Article 28	2. As for domestically-held international Academic Conferences pursuant to Paragraph 4 of Article 8 of the Code, the host of the Academic Conference shall, pursuant to Paragraph 6 of Article 8, give refunds of the remaining amounts in proportion to each Company's share of support funds for the relevant Academic Conference. ⑦ In the event a Company wishes to sponsor an international Academic Conference that is hosted in Korea pursuant to Paragraph 4 of Article 8 of the Code, the Company shall submit a report on the Website and evidentiary materials demonstrating that the relevant Academic Conference is in fact an international Academic Conference 30 days before the start date of the Academic Conference. Provided, however, if the Company wishes to sponsor an Academic Conference that is on the list of international Academic Conferences provided by the Korea Medical Association, etc., and posted by the KMDIA on its website, the requirement pursuant to this Paragraph to attach evidentiary materials demonstrating that the Academic Conference is in fact an international Academic Conference does not apply. ⑧ Paragraph 7 of Article 8 of the Code does not apply to Company Product Presentations held during Academic Conferences (Satellite symposium, Luncheon symposium, etc.). **Article 6 (Sponsorship for HCP Participation in Academic Conferences)** ① The presenters (including poster and e-poster presenters), chairpersons and panelists set forth in Item 2 of Paragraph 2 of Article 9 of the Code refer to HCPs designated by the organizations hosting the Academic Conference. Sponsorship of these HCPs will be based on the actual expenses, provided, however, for presenters, only the primary author and one other co-author may be sponsored. As for poster presenters (including e-poster presenters), only one participating presenter who is either a primary author or a co-author of the abstract, may be sponsored.	

of the MSA; Medical Institutions pursuant to Paragraph 1 of Article 52 of the same Act; and academic societies (including foreign academic societies), academic institutions/organizations and research institutions/organizations approved and recognized by any of the preceding associations/institutions; 3. Universities pursuant to Paragraph 1 of Article 2 of the Higher Education Act or industry-academic cooperation foundations pursuant to Paragraph 1 of Article 25 of the Law Regarding Promotion of Industrial Education and Industry-Academic Cooperation; and 4. Academic societies (including foreign academic societies), academic institutions/organizations or research institutions/organizations recognized by the KMDIA. ② Companies that wish to provide sponsorship shall following the principles set forth in each of the following: 1. Domestic and overseas Academic Conferences permitted under Paragraph 1 of Article 9 shall be limited to those held at an appropriate venue and in compliance with the academic or educational purposes; 2. Sponsorship of HCPs shall be limited to actual expenses of transportation costs, registration fees, meal costs, and lodging expenses that the presenters, chairs and panelists receive from the host of the Academic Conference; 3. A Company shall sponsor HCPs by designating the Academic Conference that it intends to support and entrusting with the KMDIA the funds therefor. Any support, other than through the KMDIA, directly provided to institutions or organizations hosting the Academic Conference or persons related thereto, or to individual participants are prohibited; 4. Sponsorship of participation in an Academic Conference may not be combined with entertainment or treatment, such as tour, sightseeing and leisure activities, and may not be provided to persons accompanying HCPs; and	② With respect to the participation of HCPs in Academic Conferences pursuant to Paragraph 1, when HCPs are sponsored, in full or in part, by parties other than the Company, the KMDIA shall use its best efforts to prevent repeated sponsorship as the Company has already provided sponsorship in accordance with this Article. ③ With respect to Item 3 of Paragraph 2 of Article 9 of the Code, the host of an Academic Conference shall submit a request on the Website 90 days prior to the start date of the Academic Conference, and the Company shall submit an application on the Website 60 days prior to the start date of the Academic Conference. The KMDIA shall sponsor the participants through the host of the Academic Conference. ④ The KMDIA shall review evidentiary materials regarding the actual expenses for the cost of transportation, registration fees, cost of meals, and the cost of lodging along with the statement of accounts for actual expenses provided by the host of the Academic Conference pursuant to Item 2 of Paragraph 2 of Article 9 of the Code after the completion of the Academic Conference. The KMDIA shall notify the results [of the review] to the Company, and request the Company to make the support payment to the KMDIA, so that the payment can be delivered to the host of the Academic Conference. ⑤ The amount equivalent to actual expenses for the cost of transportation, registrations fees, cost of meals and lodging under Item 1 of Paragraph 2 of Article 9 of the Code is set forth in the Items below, and the amounts shall include the VAT (the same shall apply hereinafter). 1. For an overseas Academic Conference, the cost of transportation shall be the price based on a round-trip fare of an economy class flight of the shortest route to the destination with a confirmed return date. For a domestic Academic Conference, the cost of transportation shall be based on the fares of an economy class flight of a domestic airline, KTX seats, express buses, or other forms of mass transportation to the destination, which may be evidenced by a statement containing the itinerary, receipts, or boarding passes.	

5. In accounting for expenses relating to the sponsorship of participation in Academic Conferences, Companies shall attach documentation substantiating the details regarding the host, agenda, participants and supporting amounts, etc. of the relevant Academic Conference. ③ With regard to the sponsorship for participation Academic Conferences, the KMDIA shall perform the following services: 1. On behalf of Companies, the KMDIA shall provide funding to the Academic Conference designated by such Companies; provided, however, that the KMDIA shall designate only the purpose and use under Item 2 of Paragraph 2, and may not designate individuals participants of the Academic Conference; 2. Following the completion of the Academic Conference, the KMDIA shall collect necessary documentation from the host of Academic Conference or HCPs who participated in the Academic Conference, and disclose on its website the host, agenda, sponsorship amounts and use; and 3. The KMDIA shall in good faith manage all materials relating to expense payments, and shall make available for inspection and duplication at any time upon request by the supporting Company.	2. Registration fees shall be based on pre-registration, and the Korean Won amount calculated using the exchange rate on the date the funds were remitted, or the amount stated on a credit card statement shall be applied. 3. With respect to the cost of meals, three meals per day [consumed at] local restaurants during meal hours and paid with a personal credit card or cash shall be provided for the length of stay during the Academic Conference. [Such support] shall be limited to a maximum of KRW 100,000 per meal receipt, and KRW 150,000 per day. Provided, however, if payment is made with cash, an explanatory statement and receipts must be submitted. 4. With respect to the cost of lodging, an amount up to KRW 200,000 per night if in Korea and up to KRW 350,000 per night for overseas stays will be provided. If deemed necessary, lodging expenses may be provided for a duration of one night prior to the start date of the Academic Conference up to the last day of the Academic Conference. Provided, however, lodging expenses shall not include incidental costs such as charges for the mini bar, movies, laundry service, phone calls, etc. 5. In case of overseas Academic Conferences, the round-trip transportation expenses between the airport and the hotel, and the round-trip transportation expenses between the hotel and the conference venue (limited to one round trip per day) shall be provided. A maximum of KRW 150,000 may be provided per person during the conference period. Only transportation receipts specifying the time, departure point and destination [shall be reimbursed]. 6. The applicable exchange rate shall be the first exchange rate announced by the Korea Exchange Bank for cash purchase on the day before the start date of the Academic Conference (if such day falls on a holiday, then the first exchange rate announced on the immediately preceding business day). ⑥ With regard to Item 2 of Paragraph 3 of Article 9 of the Code, the KMDIA shall post the details of sponsorship of participants in	

	Academic Conferences for the preceding quarter on its website in January, April, July and October ([including] the name of the Academic Conference, host of the Academic Conference, sponsoring Company, total sponsorship amount, number of participants sponsored, name of Medical Institutions to which the sponsored participants are affiliated, etc.). ⑦ The Company shall pay a transaction fee that covers administrative costs associated with sponsorship to the KMDIA pursuant to Paragraph 4 of Article 4 of the Guidelines.	
Article 10(Product Presentation) ① Based on principles set forth in each Item below, a Company may provide actual travel expenses, actual lodging, food and beverage, and souvenirs within the scope allowed by social norms to HCPs who participate in such Company's Product Presentations targeting multiple Medical Institutions. Provided, however, Product Presentations taking place during an Academic Conference shall be deemed a part of such conference and any support therefor shall thus be governed by Articles 8 and 9: 1. Travel expenses, lodging, food and beverage, and souvenirs may be provided only to HCPs directly related to the Product Presentation, and may not be provided to persons accompanying HCPs; and 2. When holding a Product Presentation, Companies should ensure that the event venue, event contents and the manner in which the Product Presentation is held are not misunderstood as unfair practices. ② In case where the provision of lodging to HCPs participating in the Product Presentation of Paragraph 1 prior to its opening is prearranged, Companies shall obtain prior approval from the KMDIA by submitting their plans in form designated by the KMDIA. The	**Article 7 (Product Presentation)** ① Pursuant to Item 1 of Paragraph 1 of Article 10 of the Code, Companies may provide travel expenses, lodging, food and beverages and souvenirs based on actual expenses to HCPs participating in the Product Presentations in accordance with the following Items: 1. Lodging expenses up to KRW 200,000 per night may be provided to a HCP participating in a Product Presentation. 2. With respect to the cost of transportation, round-trip fare to and from the destination where the Product Presentation is held shall apply. The cost of transportation shall be based on the fares of an economy class flight of a domestic airline, KTX seats, express buses, or other forms of mass transportation to the destination, which may be evidenced by a statement containing the itinerary, receipts, or boarding passes. 3. If food and beverages are necessary, up to three meals per day, up to KRW 100,000 per meal (one receipt), or up to KRW 150,000 per day may be provided. 4. Souvenirs valued at up to KRW 50,000 may be provided.	

plan shall be submitted for review at least 40 days prior to the Product Presentation and shall include supplementary documentation such as the specific proposal and budget. Within one month following the Product Presentation, Companies shall submit an expense report (the KMDIA shall verify that the Product Presentation was managed in an appropriate manner). In the case of all other Product Presentations described in Paragraph 1, Companies shall report to the KMDIA their plans in form designated by the KMDIA at least a week prior to the Product Presentation. ③ In accounting for Product Presentation expenses, Companies shall attach detailed evidentiary materials on the date and time, venue, agenda, list of participants, expenses disbursed, etc. of the relevant Product Presentation. ④ In case of Product Presentations where a Company presents on its Medical Devices by visiting individual Medical Institutions, the Company may provide to HCPs food and beverage and promotional items of a small value carrying the name of the Company or its product. ⑤ Product Presentations shall not be held for the purpose of providing food and beverage to a meeting of HCPs.	② In case lodging expenses are anticipated to be provided for a HCP participating in a Product Presentation pursuant to the first part [first sentence] of Paragraph 2 of Article 10 of the Code, the Company shall apply for the KMDIA's approval to hold the Product Presentation by attaching supporting documents through the Website along with evidentiary materials including event program, draft budget, etc. 40 days before the Product Presentation date, and submit a statement on the settlement of expenses with evidentiary materials including event program, list of participants and a statement of accounts, etc. on the Website within one month after the end of the Product Presentation. ③ When a Company applies for the KMDIA's approval to hold a Product Presentation pursuant to Paragraph 2, the Company must pay a Deliberation Fee of KRW 200,000 (VAT not included) to the KMDIA. Provided, however, the Deliberation Fee along with the notification of changes will be waived if [the Company] is merely reporting a simple change (change of date, venue etc.) to the program of the Product Presentation for which the KMDIA has deliberated. ④ In cases of Product Presentations pursuant to the latter part [last sentence] of Paragraph 2 of Article 10 of the Code, the Company must report to the on the Website attaching evidentiary materials including event programs, draft budget, etc. one week before the Product Presentation date. ⑤ Pursuant to Paragraph 4 of Article 10 of the Code, a Company may provide each HCP food and beverages valued at up to KRW 100,000 per day (not to exceed four times per month), and promotional items valued at less than KRW 10,000 bearing the name [or logo] of the Company or its product. Provided, however, [the provision of] food and beverages may not exceed four times per month to a single HCP including those provided for Education or Training pursuant to Article 11.	
Article 11(Education or Training)	**Article 8 (Education or Training)**	

① Companies can hold domestic or overseas Education or Training to HCPs and persons engaging in operation and diagnosis belonging to Medical Institutions for them to obtain and improve operation or diagnostic skills. ② Based on principles set forth in each of the following Items, a Company may provide actual travel expenses, lodging, food and beverage, and souvenirs within the scope allowed by social norms to HCPs and persons engaging in operation and diagnosis belonging to Medical Institutions who participate in such Company's domestic Education or Training held for multiple Medical Institutions, or oversea Education or Training held for the Company's Medical Device which is not imported into the domestic market to obtain and improve operation and diagnostic skills with respect to such Medical Device. Provided, however, Education or Training taking place during an Academic Conference shall be deemed a part of such Academic Conference and any support therefor shall thus be governed by Articles 8 and 9: 1. Travel expenses, lodging, food and beverage, and souvenirs may be provided only to HCPs and persons engaging in operation and diagnosis directly related to the Education or Training, and may not be provided to persons accompanying HCPs or persons engaging in operation and diagnosis; and 2. When holding an Education or Training, Companies shall ensure that the event venue, event contents and the manner in which the Education or Training is held are not misunderstood as unfair practices. ③ In case of overseas Education or Training held by an importer of Medical Devices relating to Medical Devices which have been imported after obtaining import approval (notification), such importer may not provide support set forth in ② above to HCPs and persons engaging in operation and diagnosis who participate in such Education or Training, and shall ensure that the place and content of the event, and the manner in which the event is to be held, are not misunderstood	① Expenses for travel, lodging, food and beverage, and souvenirs equivalent to the actual expense incurred for HCPs participating Education or Training pursuant to Paragraph 2 of Article 11 of the Code shall be each of the following Items: 1. With respect to lodging, in case of a domestic [Education or Training], an amount up to KRW 200,000 will be provided. In case of an overseas [Education or Training], an amount up to KRW 350,000 will be provided. 2. With respect to the cost of transportation, round-trip fare to and from the destination where the Education or Training is held shall apply. The cost of transportation shall be based on the fares of an economy class flight of a domestic airline, KTX seats, express buses, or other forms of mass transportation to the destination, which may be evidenced by a statement containing the itinerary, receipts, or boarding passes. 3. If food and beverages are necessary, up to three meals per day, up to KRW 100,000 per meal (one receipt), or up to KRW 150,000 per day may be provided. 4. Souvenirs valued at up to KRW 50,000 may be provided. ② Pursuant to Paragraph 2 of Article 11 of the Code, overseas Education or Training by an importer shall not be repeated unless there are changes in the use, etc., of the Medical Device, such as changes in approval, etc., by the Minister of the MFDS. ③ Pursuant to Paragraph 2 of Article 11 of the Code, the "Medical Devices of a Company, which have not been imported to Korea" refers to those Medical Devices that have not been imported after obtaining import approval (notification). ④ Pursuant to Paragraph 4 of Article 11 of the Code, in case where a Company provides lodging in holding Education or Training for HCPs, the Company must submit an application for preliminary	

as unfair trade practices. ④ In case where the provision of lodging to HCPs and persons engaging in operation and diagnosis participating in domestic Education or Training is prearranged or in case of overseas Education or Training, Companies shall obtain prior approval from the KMDIA by submitting their plans in form designated by the KMDIA. The plan shall be submitted for review at least 40 days prior to the Education or Training and shall include supplementary documentation such as the specific proposal and budget. Within one month following the Education or Training, Companies shall submit an expense report to the KMDIA (the KMDIA shall verify that the Education or Training was managed in an appropriate manner). In case of domestic Education or Training provided to multiple Medical Institutions without providing lodging to participants, Companies shall report to the KMDIA their plans in form designated by the KMDIA at least a week prior to the Education or Training. ⑤ In case where a Company provides Education or Training to HCPs and persons engaging in operation and diagnosis in a Medical Institution by visiting such Medical Institution, Companies may provide to participants food and beverage and promotional items of a small value carrying the name of the Company or its product. Provided, however, food and beverage provided to the same HCP or person engaging in operation and diagnosis may not exceed four times per month, which includes the case of Product Presentations under Paragraph 4 of Article 10. ⑥ In accounting for domestic or overseas Education or Training expenses, Companies shall attach detailed evidentiary materials on the date and time, venue, agenda, list of participants, expenses disbursed, etc. of the relevant Education or Training. ⑦ Education or Training may not be held for the purpose of providing food and beverage to a meeting of HCPs and persons engaging in operation and diagnosis. ⑧ For HCPs participating as lecturers at Product Presentations held	deliberation on the Website 40 days prior to the Education or Training date attaching evidentiary materials including event program, draft budget, etc. The Company must submit a statement on the settlement of expenses on the Website with evidentiary materials attached including event programs list of participants and a statement of accounts within one month after such Education or Training. ⑤ When a Company applies for the KMDIA's approval to conduct an Education or Training pursuant to Paragraph 4, the Company must pay a Deliberation Fee of KRW 200,000 (VAT not included). Provided, however, the Deliberation Fee along with the notification of changes will be waived if [the Company] is merely reporting a simple change (change of date, venue etc.) to the program of the Education or Training for which the KMDIA has deliberated ⑥ In case where a Company conducts a Education or Training to multiple Medical Institutions without providing lodging, the Company must report to the KMDIA through the Website with evidentiary materials including event program, draft budget, etc. 7 days before the Education or Training date. ⑦ Pursuant to Paragraph 5 of Article 11 of the Code, a Company may provide each HCP food and beverages valued at up to KRW 100,000 per day (not to exceed four times per month), and promotional items valued at less than KRW 10,000 bearing the name [or logo] of the Company or its product. Provided, however, [the provision of] food and beverages may not exceed four times per month to a single HCP including those provided for Product Presentations pursuant to Article 10 of the Code. ⑧ With regard to Paragraph 8 of Article 11 of the Code, a Company may provide to lecturers for overseas Product Presentations for Medical Devices or for events held for acquiring/improving surgical and diagnostic skills, economic benefits equivalent to actual expenses such as travel expenses, lodging, food and beverages and souvenirs within the scope prescribed by Article 9 through Article 11 of the Code.	

for HCPS from multiple foreign Medical Institutions to convey information about its Medical Devices or at Education or Training conducted for the purpose of acquiring and improving surgical and diagnostic skills that are held overseas and hosted by Medical Device Manufacturer(s), actual expenses for travel, lodging, food and beverage and souvenirs can be provided within the scope allowed by social norms.		
Article 12(Lectures and Consultations) ① Companies shall not solicit lectures or consultations or provide honoraria or consultation fees for the purpose of promotion of sales to HCPs, and when soliciting HCPs with expertise and experience in medicine or Medical Devices for lectures or consultations based on a need for such HCP's expertise and experience in medicine or Medical Devices, Companies shall comply with principles and standards set forth in each of the following: 1. Requests to an HCP for a lecture or consultation shall be limited to cases where the necessity can be objectively recognized for purposes of obtaining medical or professional information such as Product Presentation under Article 10, Education or Training under Article 11, and consultation and training or education for officers and employees of Companies; 2. The honorarium or consulting fee shall be assessed based on the lecture or consulting activities actually performed in light of the HCP's level of knowledge and level of experience and social norms. The honorarium and consulting fee shall not be paid in full prior to completion of the lecture or consultation. 3. When handling accounting affairs with respect to honoraria or consulting fees, Companies shall preserve evidentiary materials detailing the reason for selection of such lecturer or engagement of such consultant, the date and time of the lecture or consultation, the contents of the lecture or consultation, and the usage thereof, etc. 4. When Companies request lectures or consultations from HCPs, they must execute a written contract stipulating the services to be	**Article 9 (Lectures and Consultations)** ① Pursuant to Article 12 of the Code, honorarium that a Company may pay to a HCP shall be up to KRW 500,000 per each lecture lasting up to one hour within the scope of KRW 1 million per day or KRW 2 million per month. The aggregate amount of lecture fees shall not exceed KRW 3 million per HCP for a given year. However, up to KRW 5 million per year can be recognized as the annual ceiling amount when there is increase in demand for lectures due to a new product launch, when there is a limited number of HCPs that can conduct lectures, when there is lack of there is a lack of Education or Training facilities or other justifiable need. In addition, lecture fees for HCPs classified as public officials pursuant to Paragraph 2 of Article 2 of the Improper Solicitation and Provision/Receipt of Money and Valuables Act ("Anti-Graft Act") shall also be in compliance with external lecture fees, etc. prescribed in the Anti-Graft Act and Enforcement Decree thereof. ② A Company shall not, without justification, repeatedly request lectures or consultations of the same or similar content to a specific HCP or excessively make requests to many HCPs. ③ When a Company requests HCPs to provide consultation, the Company shall execute in advance a written contract specifying the consultation services and consulting fee with the HCP providing such services. The consulting fee may not exceed KRW 500,000 per HCP per consultation or KRW 3 million per HCP per annum. Provided, however, simple written consultations taking place by visiting Medical Institutions are not permitted, and are subject to Article 14 (Market	

provided and the value of the compensation before the services are provided. 5. When settling accounting affairs with respect to honoraria or consulting fees, Companies shall retain evidentiary materials detailing the reason for selection of such lecturer or engagement of such consultant, the date and time of the lecture or consultation, the contents of the lecture or consultation, the list of participants and their signatures, and the usage of the contents of the lecture or consultation, etc. for a period of 5 years. ② Companies shall report to the KMDIA the date and time of the lecture or consultation and the payment details of the honorarium or consulting fee, etc. within 20 days from the date when the honorarium or consulting fee has been fully paid, in form designated by the KMDIA. **Article 13(Provision and Lease of Medical Devices for Clinical Trials)** Companies may provide or lease Medical Devices to HCPs or Medical Institutions free of charge in quantity necessary for the clinical trials that have been approved by the Minister of the Ministry of Food and Drug Safety ("MFDS") pursuant to Paragraph 1 of Article 10 of the MDA or by the Institutional Review Board (IRB). This includes non-clinical trials (animal testing or experimental testing, etc.) that have been pre-approved by the relevant committee within the Medical Institution concerned. **Article 14(Market Survey)** ① Companies may provide Money and other valuables as compensation for Market Surveys within the scope allowed by social norms, provided that the Company reports the details of the Market Surveys to the KMDIA each quarter in form designated by the KMDIA.	Surveys) of the Code and Paragraph 1 of Article 10 of the Guidelines. ④ Lectures must be attended by 10 or more audience members and the lecturer must deliver medical or professional information for at least 40 minutes. Provided, however, there shall be no restriction on the number of audience members with respect to Education or Training under Article 11 of the Code due to the need for a direct transfer of skills [technique, etc.]. ⑤ After a Company has paid honoraria or consulting fees to a HCP in accordance with Paragraph 2 of Article 12 of the Code, the Company shall report the same to the KMDIA through the Website along with evidentiary materials within 20 days from the date of payment of the honorarium or consulting fee. **Article 10(Market Survey)** ① In the event that a Company conducts a Market Survey by way of a request to a market survey agency, the following Items shall be complied with: 1. The market survey agency shall not disclose the identity of the Company to the participating HCPs or the identity of the participating	

② Companies shall conduct Market Surveys for the primary purpose of collecting market data, and may not utilize or disguise Market Surveys as promotional activities to or a means to compensate HCPs and if Companies directly conduct Markey Surveys without utilizing market survey agencies, they shall not provide Money or other valuables to HCPs. ③ Companies shall ensure that Market Surveys are performed in order to collect useful information to promote the use of good-quality Medical Devices and advance patients' interest. ④ Companies shall clearly disclose from the initial stage of recruitment that it is a Market Survey. **Article 15(Post-Marketing Survey)** ① Companies shall conduct Post-Marketing Surveys in accordance with the Post-Marketing Survey plan and implementation standards approved by the MFDS, and shall comply with principles set forth in each of the following: 1. The Post-Marketing Survey shall be conducted within the scope acknowledged as medically necessary based on Medical Device laws and relevant regulations of the MFDS, with an appropriate sample size in light of the purpose and content of the survey. 2. Companies may not solicit Post-Marketing Survey at Medical Institutions that have not selected or purchased the Medical Device concerned. 3. Companies may not solicit Post-Marketing Survey on condition of continued selection or purchase or increase in the amount of purchase of the Medical Device concerned.	HCPs to the Company; 2. The market survey agency shall independently select the HCPs who will participate in the Market Survey; 3. Food and beverages or "compensatory" gifts of up to KRW 100,000 may be provided to HCPs participating in the Market Survey; and 4. An appropriate amount of compensation not exceeding KRW 100,000 may be provided only to those HCPs participating in a market survey that requires 30 minutes or more to complete. ② With respect to the proviso in Paragraph 1 of Article 14 of the Code, the Company shall report to the KMDIA through the Website the details of [the payments made] each quarter based on the date on which each payment was made by the fifteenth day of January, April, July, and October. **Article 11(Post-Marketing Survey)** ① As compensation for services concerning Post-Marketing Surveys pursuant to Article 15 of the Code, a Company may pay up to KRW 50,000 per case report to a HCP [participating in a Post-Marketing Survey]. Provided, however, an appropriate amount of compensation of up to KRW 300,000 may be paid in the event it is recognized that additional surveys are necessary including those for rare diseases, long-term follow-up surveys or reports for frequent and significant adverse effects provided under the Medical Device Act and its Enforcement Decree and the relevant regulations of the MFDS. ② In accordance with Item 5, Paragraph 1 of Article 15 of the Code, a Company shall pay HCPs compensation for the Post-Marketing Survey according to a service agreement (including a statement on the calculation of expenses).	

4. Compensation for HCPs who participate in the Post-Marketing Survey shall be paid when the survey on the items necessary for the purposes of the survey has been fully completed and the results thereof have been reported to the Company. 5. Full payment of compensation may not be made to the HCPs before receiving the report set forth in Item 4, which amount shall be reasonable in light of social norms. The number of case reports for which compensation can be made shall be the minimum number of case reports required to be filed pursuant to Article 10 of the Enforcement Regulations of the MDA; provided, if a need arises for the case reports for a particular product for the purposes of research, obtaining license overseas or registration, the number of case reports may be increased as decreed by the Minister of the MFDS. ② Companies may not provide any economic benefit to the patients participating in the Post-Marketing Survey.		
Article 16(Clinical Activities other than Post-Marketing Survey) ① Companies may plan clinical activities for the purpose of obtaining medically important information on clinical characteristics of Medical Devices, diseases or other healthcare areas of significant interest to such Companies pursuant to the MDA and relevant MFDS regulations, and shall comply with each of the following principles and rules: 1. Only clinical activities that have been approved by the Minister of the MFDS pursuant to Paragraph 1 of Article 10 of the MDA or by the Institutional Review Board (IRB) shall be allowed. Provided, however, in cases of non-clinical trials (animal testing or experimental testing, etc.), clinical activities that have been pre-approved by the relevant committee within the Medical Institution concerned are included; 2. Clinical activities shall not be carried out for the mere purpose of advertising Medical Devices or to influence the selection of Medical Devices by doctors;	**Article 12(Clinical Activities other than Post-Marketing Survey)** In connection with Article 16 of the Code, a Company shall pay service fees for the clinical activities performed pursuant to a service agreement to Medical Institutions, etc., to which the relevant HCP is affiliated, and shall not pay the contract amount in full before the service is completed and the report on the results thereof is received.	

3. Companies may make payments, within the scope corresponding to the HCP's efforts, to the Medical Institutions, etc. to which the HCPs belong, pursuant to the research contract for such clinical activities; and 4. Companies shall obtain a report on the results of the research from the Medical Institution, etc. with which it entered into a research contract, and shall attach such report when accounting for relevant expenses. ② Companies may provide actual expenses incurred by the participation of patients in interventional clinical activities, pursuant to the contract.		
Article 17(Exhibitions and Advertisements) ① Companies may conduct exhibitions or advertisements targeting HCPs for the purpose of expanding and disseminating medical information and maximizing patients' interest by widely disseminating various knowledge and experience relating to Medical Devices. Provided, however, Companies shall make quarterly reports to the KMDIA of the details of the exhibitions or advertisements conducted, in form designated by the KMDIA. ② Information on the products on exhibit must be available at the display stand. ③ When a Company installs display stands or booths or advertises at an Academic Conference hosted or in advertising media issued by Medical Institutions, etc. for the purpose of exhibiting, publicizing or advertising the Company and its Medical Devices, payment of fees thereof shall comply with ordinary business practices. ④ Companies may not compensate HCPs for visiting their exhibition pavilion. Provided, however, souvenirs or promotional materials of a small value may be provided.	**Article 13(Exhibitions and Advertisements)** ① In the event that a Company pays Medical Institutions etc., advertisement fees or booth fees pursuant to Paragraph 3 of Article 17 of the Code, the Company shall comply with each of the following Items: 1. Advertising media for which a Company may pay advertising fees to Medical Institutions, etc., shall be limited to (i) print materials, or electronic documents equivalent to such, prepared by Medical Institutions, etc., for treatment, prevention, education of diseases, which are distributed and displayed to multiple HCPs from multiple Medical Institutions, (ii) websites operated by organizations related to [the practice of] medicine established for academic purposes ("Academic Societies, Etc."), and (iii) educational materials(including electronic documents) distributed by Academic Societies, Etc., to HCPs and (or) the general public. 2. Advertising media produced independently by HCPs or those produced by Medical Institutions (institutional journals, research journals, etc.) whose target of distribution is limited to HCPs affiliated with that same Medical Institution which produced the advertising media and employees or customers of the Medical Institution concerned shall not be deemed as advertising media for which	

advertising fees are payable to Medical Institutions, etc., by a Company;

3. In the case of advertising on websites operated by Academic Societies, Etc., under (ii) of Item 1, a Company may pay advertising fees of up to KRW 1 million per month and up to KRW 10 million per year. With respect to print or electronic advertisements prescribed by (i), (iii) of Item 1, a Company must pay an appropriate amount of advertising fees within the limits stated in the table below after taking into consideration the publisher, circulation, and advertising effect, etc. Provided, that the content and format of electronic documents shall be equivalent to those of print materials or training materials. Those with the same contents or minimal modification as before are not entitled to advertisement fees for electronic documents. In case of advertising both on print and on electronic documents, advertisement fees only for those on print may be provided.

(Unit: KRW 10,000)

Publisher	**Table 2**	**Table 3**	**Table 1,4**	**Pages or Electronic Documents**
Medical Institution	100	70	150	60
Academic Societies, Etc.	150	100	200	70

4. A Company shall as a general rule use one booth per Academic Conference (excluding Academic Conferences that have applied for sponsorship for hosting and operating an academic conference in accordance with Article 8 of the Code), but shall not use more than two booths.

5. In the case of Academic Conferences hosted by academic societies, or academic institutions or organizations or research institutions related to [the practice of] medicine, standard booth fees are KRW 2 million per booth, and a Company may pay up to KRW 3 million as a usage fee for one booth based on the nature, size, number of participants, etc., of the Academic Conference. In the case of a Academic Conference hosted by a Medical Institution, standard booth

	fees are KRW 500,000 per booth, and a Company may pay up to KRW 1 million for one booth based on the nature, size, number of participants, etc., of the Academic Conference. ② With respect to the proviso in Paragraph 1 of Article 17 of the Code, the Company shall report to the KMDIA through the Website the details of the payments made each quarter based on the date on which each payment was made by the fifteenth day of January, April, July, and October. ③ "Souvenirs or promotional materials of a small value" under the latter part [last sentence] Paragraph 4 of Article 17 of the Code refer to souvenirs or promotional items valued at up to KRW 10,000.	
Chapter 3 Application of the Code **Article 18(Fair Competition Code Deliberation Committee)** ① The KMDIA shall establish and operate a Fair Competition Code Deliberation Committee (the "Committee") to deliberate and resolve each of the following Items: 1. Matters relating to the consultation, guidance and resolution of problems regarding the Code; 2. Matters which fall under each of the following Sub-items; a. Selection of Beneficiaries under Paragraph 2 of Article 7; the propriety of business proposals by Medical Institutions requesting Donations and the selection of donating Companies under Paragraph 3 of the same Article; and the propriety of Donations under Paragraphs 2 through 4 of the same Article; b. Propriety of domestic Academic Conference proposals and whether to support Companies that wish to sponsor Academic Conferences under Paragraph 2 of Article 8; compliance with conditions of sponsoring Academic Conferences under Paragraph 3 of the same Article; and the propriety of sponsoring Academic Conferences under Paragraph 4 of the	**Article 14(Composition and Operation of the Fair Competition Code Deliberation Committee)** ① Members of the Fair Competition Code Deliberation Committee (the "Committee") stipulated in Article 18 of the Code shall be appointed by the Chairperson of the KMDIA (the "Chairperson"), including those members that have been recommended pursuant to Paragraph 2 of the same Article of the Code. ② The term of office of a member shall be one year, with a possibility of serving consecutive terms. Provided, however, a member who replaces another during a term shall serve the remaining term of his or her predecessor. ③ The Chairperson of the Committee ("Committee Chair") under Paragraph 2 of Article 18 of the Code shall be elected by a vote of the members, and shall oversee the affairs of the Committee. ④ As a general rule, the Committee shall convene a regular meeting once or more per month. In case of any of the following, the Committee Chair may convene additional meetings apart from its regular meetings or may defer a regular meeting:	

same Article; and c. Appropriateness of approval for and implementation of Product Presentations under Paragraph 2 of Article 10 and Education or Training under Article 11. 3. Matters related to the investigation of and measures against Companies which violated the Code or are at risk of violating the Code; 4. Establishment of and amendments to the Guidelines; and 5. Other matters related to the Code as requested by the KMDIA ② The Committee shall consist of 10 persons including a chairperson, and shall include five persons as specified below. The secretary shall be appointed by the standing president of the KMDIA. 1. Twp persons recommended by the Korea Consumer Agency (including one legal expert); 2. One person recommended by the Health Insurance Review & Assessment Service; and 3. Two persons recommended by the Korean Medical Association. ③ Resolutions of the Committee shall be made by the affirmative vote of the majority of the attending Committee members at a meeting attended by two-thirds or more of total members. ④ The Committee may establish and operate a report center for illegal distribution of Medical Devices and a working committee, etc. to supervise, investigate and take measures against unfair business practices ⑤ Other matters necessary for the operation, investigation, measures of the Committee shall be prescribed in separate rules of operation.	1. At the request of more than one-third (1/3) of the members; 2. When the Committee Chair deems it necessary; 3. When the Board of Directors of the KMDIA deems it necessary; or 4. At the request of the Chairperson of the KMDIA to convene a meeting. **Article 15(Establishment of Task Assistance Committee)** ① Pursuant to Paragraph 4 of Article 18 of the Code, the Committee may establish and operate a Task Assistance Committee (the "TAC") to assist the Committee's proceedings specified in Paragraph 1 of Article 18 of the Code. ② The TAC shall be composed of approximately 20 persons appointed by the Chairperson of the KMDIA from the officers and employees of the member companies. ③ The term of a TAC member shall be one year, with a possibility of serving consecutive terms. Provided, however, a member who replaces another during a term shall serve the remaining term of his or her predecessor. ④ The Chairperson of the TAC (the "TAC Chair") shall be elected by a vote of the members, and shall oversee the affairs of the TAC. ⑤ The TAC shall convene in the following instances: 1. When the TAC Chair deems it necessary; 2. When the Committee deems it necessary; 3. When the Board of Directors of the KMDIA deems it necessary; or	

	4. At the request of the Chairperson of the KMDIA. ⑥ Resolution of the TAC shall be made by the affirmative votes of the majority of the attending members at a meeting attended by at least one-half of enrolled members of the Committee. **Article 16(Resolutions, Etc.)** ① With respect to Paragraph 3 of Article 18, the Committee may deliberate and exercise its voting rights in writing. The Chairperson shall dispatch the document and reference materials needed for the Committee members to exercise the rights as set forth above one week before the date of the Committee meeting. In such a case, the relevant Committee members shall be deemed to have personally attended the meeting. ② In the event that the deliberation is made over a matter that involves a member company that is represented in either the Committee or the TAC, any member belonging to said Company may not participate in the deliberation and resolution, investigation, etc., as to such matter. In such a case, the total number of members enrolled in the Committee shall be the total number after excluding the number of members whose participation is prohibited pursuant hereto. ③ A member may not elect a third-person as proxy to be present at a Committee meeting. ④ The Committee and the TAC shall not use matters of the Committee or the TAC for a purpose other than that of the Committee or the TAC, and shall not disclose any such matter to others outside without prior authorization by the Committee. ⑤ Members who attend the Committee may be provided with an allowance and other necessary expenses within the budget.	

Article 19(Investigation of Code Violations) ① When a violation of the Code is known to have occurred or is reported to the KMDIA, the Committee shall initiate necessary investigation to address such matters. ② Companies shall cooperate with the Committee's investigation on matters related to Paragraph 1. ③ With regard to a Company which does not cooperate with the investigation under Paragraph 1, the Committee may impose a monetary penalty of up to KRW five million and may refer to the KFTC to take necessary measures.	**Article 17(Investigation Procedures)** ① The Committee may establish and operate a "Fair Competition Code Reporting Center" pursuant to Paragraph 4 of Article 18 and Paragraph 1 of Article 19 of the Code. In the event a violation of the Code is confirmed to have occurred or is reported, [the KMDIA] shall, within 10 days of the date on which the violation was recognized, make a request to the relevant Company (the "Reported Company") to verify the facts in order to determine the details of the violation or report. ② The Reported Company shall submit a response such as an explanation or plan for corrective actions to the KMDIA within 10 days from the date of the receipt of the KMDIA's request for verification of the facts. ③ Within seven days of the date of receipt of an answer, the KMDIA shall introduce the same as an agenda item in the TAC and the TAC shall, upon reviewing the answer, conduct further investigation or present its opinion to the Committee. ④ The TAC or the Committee may, when an investigation or verification is necessary, request the presence of officers or employees of the Reported Company at its meeting. ⑤ In the event where a violation of the Code by a non-member Company is known to have occurred or is reported, the Committee may notify the same to the Korea Fair Trade Commission or Ministry of Health and Welfare.	
Article 20(Measures against Code Violations) ① In the event the Committee finds a Code violation, it may take any one of the following measures against the Company that committed the violation in order to have such Company undertake measures to correct the violation, refrain from engaging in any activity identical or	**Article 18(Measures)** ① A warning as set forth in Item 1 of Paragraph 1 of Article 20 of the Code shall be imposed in such cases where the violation of the Code is an isolated or minor event, or no violation has yet occurred but there is substantial risk that a violation will occur, or the relevant conduct has	

similar to said violation and implement other matters related to the above: 1. Warning 2. Light Penalty: If there is a clear violation of the Code and as a result there is a risk of damage to the reputation of the Medical Devices industry 3. Heavy Penalty: If there has been a clear and serious violation of the Code or if the violation may result in a legal disposition ② The Committee may impose a monetary penalty of up to KRW 10 million as a Light Penalty. ③ The Committee may cumulatively take the following measures as a Heavy Penalty: 1. Monetary penalty of up to KRW 100 million; 2. Filing of a complaint to the relevant government agency; and 3. Request for the Company's expulsion of the KMDIA membership ④ In the event the Committee finds that a Company which has been subject to a warning, etc. pursuant to Paragraph 1 above is not complying with the measure, the Committee may refer to the KFTC or the MoHW to take necessary measures. **Article 21(Duty to Cooperate by Companies)** Companies shall actively cooperate with the Committee's operations to ensure the smooth implementation of the Code. **Article 22(Management of Record by the KMDIA)**	ceased during the investigation and there is no risk of repeated violation. ② A "light penalty" as set forth in Item 2 of Paragraph 1 of Article 20 of the Code shall be imposed in such cases where despite the violation being systematic or intentional, or repetitive and continuous, the substance and degree of the violation does not rise to a level of being serious, or in cases where the violation is not corrected even after a warning is issued. ③ A "heavy penalty" as set forth in Item 3 of Paragraph 1 of Article 20 of the Code shall be imposed in such cases where the violation is committed in a manner that is systematic or intentional, or repetitive and continuous and the substance and degree of the violation is clear and serious, the violating act may be subject to penalties under law, or in cases where the violation is not corrected even after a light penalty is imposed. **Article 19(Immunity)** A Company may not raise any legal claims against the members of the Committee, members of the TAC, the KMDIA or its officers and employees in connection with their performance of duties under the Code and the Guidelines. **Article 20(Record Management by KMDIA)**	

① The KMDIA shall preserve the following materials for five years: 1. Reports, submitted materials and notices from Companies, materials managed by the KMDIA, and materials relating to the Committee deliberations and resolutions pursuant to Articles 7, 8, 9, 10, 11, 12 , 14 and 17; and 2. Materials relating to investigations and measures taken by the Committee pursuant to Articles 19 and 20. ② The KMDIA shall respond in good faith to submission requests by the KFTC or the MoHW of the materials under Paragraph 1. **Article 23(Filing of Objections, etc.)** ① In the event the Committee intends to take measures pursuant to Paragraph 3 of Article 19 or Paragraphs 1 through 3 of Article 20, the Committee shall prepare the measures to be taken ("Proposed Decision") and give notice thereof to the Company in question. ② The Company notified pursuant to Paragraph 1 above may file an objection with the Committee in writing within 10 days from the date of receipt of the Proposed Decision. ③ In the event an objection is filed pursuant to Paragraph 2 above, the Committee shall provide the Company with an opportunity to make additional arguments and submit additional evidence, undertake within 30 days a second review based on such materials, and thereafter shall decide on a measure according to the results of such review. ④ The Committee shall promptly take measures pursuant to its Proposed Decision if there is no objection pursuant to Paragraph 2. **Chapter 4 Supplementary Provisions**	① Unless otherwise prescribed in this Guideline, the KMDIA shall ensure that only the officer and employees or the KMDIA, members of the Committee or the TAC, or the relevant Company has access to peruse the materials under Item 1 of Paragraph 1 of Article 22 of the Code. ② The management and submission of materials under Article 22 of the Code may be carried out electronically. **Article 21(Draft Decisions)** ① In accordance with Paragraph 1 of Article 23 of the Code, the Committee shall give notice to the Company regarding measures to be taken (the "Draft Decision") within 10 days from the date on which the Committee issued its resolution. ② Upon notification of the Draft Decision pursuant to Paragraph 1, the recipient Company must file an objection or notify the Committee as to whether or not it will accept the Draft Decision within 10 days from the date of receipt of the Draft Decision. ③ A Company that has been imposed a monetary penalty shall pay such penalty within 30 days from the date of receipt the Draft Decision. Provided, however, in the event a Company files an objection, the Company shall pay the monetary penalty within 30 days from the date of receipt of a final decision following a redeliberation.	

Article 24(Amendment to the Code) Any amendment to this Code following the approval thereof by the KFTC shall be subject to the KFTC's prior review. **Addendum** ① [Effective Date] The effective date of this code shall be the date of approval by the KFTC.	**Article 22(Standard for Application of Taxes and Levies)** Whether the various costs and expenses provided for under these Working Guidelines are inclusive of taxes and other levies shall be determined as follows: 1. VAT excluded: Deliberation fee or service fee under Article 4 Paragraph 4, Article 5 Paragraph 2, Article 6 Paragraph 7, Article 7 Paragraph 3, and Article 8 Paragraph 5 of the Working Guidelines; and exhibition and advertising fees under Article 13 Paragraph 1 Items 3 and 6 of the Working Guidelines; 2. VAT and service charge excluded, refreshment expenses included: Expenses for food and beverages for product presentations and educational and training sessions under Article 7 Paragraph 1 Item 3 and Article 8 Paragraph 1 Item 3 of the Working Guidelines; 3. Taxes, etc. included: Lectures and consultation fees under Article 9 Paragraphs 1 and 3 of the Working Guidelines; compensation under Article 10 Paragraph 1 Item 4 of the Working Guidelines 4. VAT included: Costs other than as provided for in Items 1 through 3 hereof Addendum ① [Effective Date] This Guideline shall become effective from February 11, 2011. Addendum ① [Effective Date] This Guideline shall become effective from April 11, 2011. Addendum ① [Effective Date] This Guideline shall become effective from June	

	10, 2011. Addendum ① [Effective Date] This Guideline shall become effective from January 13, 2012. Addendum ① [Effective Date] This Guideline shall become effective from July 1, 2012. Addendum ① [Effective Date] This Guideline shall become effective from Month/Date, 2017.	