KMDIA Fair Competition Code on Transactions of Medical Devices

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.

CHAPTER 2 PERMISSIBLE SCOPE OF PROVISION OF MONEY OR OTHER VALUABLES

Article 5 (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.

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.

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.

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:

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:

   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.

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.

Article 8 (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' 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 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 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

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.

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 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.

Article 11 (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 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 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 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.

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.

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;

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.

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 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.

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 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 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)

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

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.