## Rules of AMDD for Compliance with Competition Law

Article 1 "Purpose"

The purpose of these rules is as follows.

(1) To ensure that officers and employees of American Medical Devices and Diagnostics Manufacturers' Association (hereinafter referred to as "AMDD"), and officers and employees of Member Companies who participate in Assembly or activities of AMDD shall duly respect and comply with the competition laws of each country and area (hereinafter referred to as the "Competition Law") including the Act on Prohibition of Private Monopolization and Maintenance of Fair Trade (hereinafter referred to as the "Antimonopoly Act") in their activities conducted for or by AMDD, such as management of all AMDD's Assembly, information exchange at or by AMDD, etc.

(2) To ensure that AMDD shall respect and comply with the Antimonopoly Act and Competition Law in its activities as a trade association of the industry.

Article 2 "Definitions"

- 1 As used in these rules, "Assembly" shall mean all assemblies, regardless of their manner or form, such as Executive Committees, committee meetings, subcommittee meetings, meetings of working groups, study sessions, Social Gathering, etc. that are considered as a part of AMDD activities.
- 2 As used in these rules, "Meeting" shall mean all and any Assembly other than Social Gathering.
- 3 As used in these rules, "Social Gathering" shall mean Assembly for the purpose of cultivating mutual friendship such as a New Year's Celebration Party, etc.
- 4 As used in these rules, "Member Companies" shall mean companies who have acceded to AMDD.
- 5 As used in these rules, "Officers and Employees of AMDD" shall mean the chairman, vice-chairman, directors, auditors, advisors, committee chairman, and staff members of the secretariat of AMDD.

Article 3 "Scope of Application"

These rules shall apply to all activities of AMDD and the following personnel:

(1) Officers and Employees of AMDD;

(2) Officers and employees of Member Companies who participate in Assembly or activities of AMDD.

Article 4 "Duties of Directors, etc."

- 1 The chairman, vice-chairman, directors, and auditors (hereinafter referred to as "Directors, etc.") shall promptly report to Executive Committee if they come to know that any question has arisen or may arise about the contents or operation of these rules.
- 2 The Staff Director shall assist Directors, etc. in performing their duties in accordance with these rules.

Article 5. "Conduct of Assembly"

1 Attendees of an Assembly shall not speak about any of the following matters before and after as well as during the Assembly, except for matters which are already publicly available.

(1) Prices, price changes, price structures, pricing strategies, price reductions, bidding conditions, quantities, inventories, costs, etc. of the goods or services which Member Companies will supply or will be supplied with.

(2) Capital investment; scrapping of facility; volume of production and supply; capacity of production and supply; plan for development, production, procurement, and sales; customers; sales area; model of product to be supplied; market share; demand forecast; demand trend; etc. of Member Companies.

(3) Other matters that specifically relate to major competitive measures for business activities of Member Companies.

- 2 The chairman of the Meeting as well as Officers and Employees of AMDD attending the Meeting shall check and confirm beforehand that agendas, meeting materials, etc. of the Meeting do not include any contents which may cause problems from the perspective of or under the Competition Law.
- 3 All discussions during the Meeting shall, in principle, be made in line with the agendas and meeting materials which have been checked and confirmed beforehand.
- 4 Before the start of the Meeting, the chairman of the Meeting shall present, distribute, or read the following rules which are a summary of the provisions of paragraph 1 of this Article (hereinafter referred to as "Compliance Rules") to ensure the attendees are aware of such rules.

"Compliance Rules"

The attendees of this assembly shall not speak about any of the following matters before and after as well as during the assembly, except for matters which are already publicly available.

i) Any matters regarding the price or quantity of goods and services

ii) Any matters regarding a bid

iii) Any matters regarding the capacity, plan, or policy for development, production, and sales

iv) Others which may specifically relate to major competitive measures

If it is uncertain whether any matter corresponds to any of the above or not, such a matter shall not be brought up for discussion.

- 5 The chairman of the Meeting shall have someone take minutes of the Meeting for the purpose of recording the fact that proper actions are taken at the Meeting. The chairman shall keep the original or a copy of the minutes of the Meeting.
- 6 If, during the Meeting, anyone makes a statement which may cause problems from the perspective of or under the Competition Law, the chairman of the Meeting shall take actions such as alerting the speaker, etc. If the speaker does not stop speaking about the matter despite such actions, the chairman shall end the said Meeting and then shall specify the reasons for ending the Meeting in the minutes of the Meeting, and shall make a report in writing about the circumstances to the Chairman of AMDD without delay.

If Officers and Employees of AMDD attending a Meeting consider that any statement made by an attendee may cause problems from the perspective of or under the Competition Law, they shall assist in the progress of the Meeting in view of compliance with the Competition Law by means such as suggesting that the chairman of the Meeting give an alert to such attendee.

7 Before the start of a Social Gathering, Officers and Employees of AMDD attending the Social Gathering shall ensure the attendees are aware of the Compliance Rules by presenting, distributing, or reading such rules.

If anyone makes a statement which may cause problems from the perspective of or under the Competition Law, Officers and Employees of AMDD attending the Social Gathering shall take actions such as alerting the speaker, etc. If the speaker does not stop speaking about the matter despite such actions, such Officers and Employees shall end the said Social Gathering, and shall make a report in writing about the circumstances to the Chairman of AMDD without delay.

Article 6 "Collection, Control, and Provision of Statistical Information"

1 Collection, control, and provision of statistical information (hereinafter referred to as "Statistical Service") shall be performed by a third party that does not have any conflict of interests with Officers and Employees of AMDD or Member Companies. The Statistical Service shall be performed subject to prior approval of the Directors, etc.

- 2 The Officers and Employees of AMDD engaged in a Statistical Service shall exercise strict control on information collected from Member Companies to prevent disclosure of such information to anyone other than such Officers and Employees of AMDD.
- 3 To prevent any problem from the perspective of or under the Competition Law, when statistical information is provided to any third party or Member Companies, only collective information which is recapitulative and which has been aggregated to the extent that any specific information on each individual company will not be identified or extracted, may be provided.

Article 7 "Training and Thorough Understanding by Member Companies"

- 1 To enhance the knowledge of each individual, if needed, Directors, etc. shall conduct training courses for Officers and Employees of AMDD and Member Companies about compliance with the Competition Law.
- 2 AMDD shall make efforts to ensure Member Companies have a thorough understanding of these rules.

Article 8 "Investigation"

- 1 In the event of any violation or possibility of violation of these rules, the Officers and Employees of AMDD nominated by the Chairman of AMDD, with cooperation of the secretariat, shall investigate and analyze the cause of such violation, and shall report the result to Executive Committee. The said Officers and Employees may outsource the investigation and analysis to an appropriate third party, if necessary.
- 2 Executive Committee shall take appropriate actions in response to the result of the investigation of the preceding paragraph.

Article 9 "Revision or Abolition of Rules"

Any revision or abolition of these rules shall be based on the resolution of Executive Committee.

Supplementary provision

These rules shall be implemented from the 4<sup>th</sup> day of January, 2016.