ARTED

The Association of Research Based Medical Technologies Manufacturers

PRINCIPLES OF COMMUNICATION WITH HEALTHCARE PROFESSIONALS, ETHICAL RULES AND CODES OF BUSINESS PRACTICE

This Code is drafted to define the ethical responsibilities of our members, in strict compliance with the applicable laws and regulations. To this end, due account has particularly been taken to ensure the compliance of ARTED's *Principles of Communication with Healthcare Professionals, Ethical Rules and Codes of Business Practice ("Code of Ethics")* with the applicable laws and regulations. However, if and to the extent the provisions of the Code of Ethics conflict with or become in contradiction with the laws and regulations, the relevant laws and regulations shall prevail. Inclusion of more restrictive and inhibitive provisions in the members' internal regulations and procedures, providing that they are in conformity with this Code of Ethics, does by no means contradict the principles of our association.

THE PRINCIPLES OF COMMUNICATION WITH HEALTHCARE PROFESSIONALS, ETHICAL RULES AND CODES OF BUSINESS PRACTICE

ARTED – The Association of Research Based Medical Technologies Manufacturers

1. INTRODUCTION

The Association of Research Based Medical Technologies Manufacturers (ARTED) represents its member organizations (to be hereinafter shortly referred to collectively as "members" and individually as a "member") which develop, produce and offer for sale medical products, technologies and relevant services and treatments (Medical Technologies) used for diagnosis, treatment, monitoring, management, diminishing and healing of healthcare problems and diseases in order to ensure that patients lead a long and healthy life.

ARTED has dedicated its entire means to contributing to the progress of medical science, improvement of patient care services, and particularly, development of high quality and innovative medical technologies for achievement of said objectives. ARTED has assumed the responsibility of ensuring the application of ethical rules in the course of interactions between its members and healthcare professionals (doctors, dentists, pharmacists, nurses, midwives, and other professionals listed in the Law on Methods of Performance of Medicine and Medical Sciences no. 1219), other health-related professionals in fields of healthcare fields that have no direct application on humans as listed in the Regulation on Job and Duty Definitions of Healthcare Professionals and Other Professionals Assigned in Healthcare Services, other health sector employees such as technicians working in and for healthcare institutions and organisations, and employees of hospital purchasing and reimbursement departments, etc., institutions providing healthcare services, and governmental bodies and authorities. There are many types of relationships between members and healthcare professionals ("HCP") that develop and move medical science forward and improve patient care services. Included among these relationships are the following:

- **Development of Medical Technologies**: Development of innovative medical devices and improvement of existing products require cooperation between members and healthcare professionals.
- **Secure and Effective Use of Medical Technologies**: Secure and effective use of medical technologies requires provision of the required and appropriate usage instructions, training, education, services and technical support by members to healthcare professionals.
- **Research and Training**: Support provided by members to clinical studies, training activities and activities aimed at developing professional skills contributes to patient security and increases access to new technologies.

- **Support of Charitable and Donation Activities**: Members may make monetary or in kind donations or grants to activities organized for the public interest. These activities will increase access to otherwise inaccessible patient populations, and at the same time will increase the quality of healthcare services and treatment services provided.
- **Good Promotional Practices for Medical Devices**: For the sake of development of patient health and security, medical devices should be promoted within the frame of ethical rules, fairly and in accordance with competition principles, and by using evidence-based and scientific data which help healthcare professionals and technicians working in the field of medical devices in healthcare institutions and organisations independently form their own opinions.

2. OBJECTIVES OF ARTED CODE OF ETHICS

Members are aware of the fact that working in line with ethical standards and in full compliance with the applicable laws, particularly the Regulation on Sales, Advertisement and Promotion of Medical Devices and the Guidelines of said Regulation is very important for effective maintenance of the cooperation between medical technologies and medical devices industry and healthcare professionals. In their relationships with healthcare professionals, members must support the application of ethical business practices and industrial practices based on social responsibility. Members must continue to show respect to the obligation of healthcare professionals to take their treatment-related decisions independently.

ARTED recognizes that the most important duty of healthcare professionals is to act in such manner as to provide the best services in favour and for the good of patients. Members offer the best services in favour and for the good of patients by cooperating with healthcare professionals. Said cooperation should comply with ethical rules at the highest level, and by establishing adequate transparency, should be carried out in accordance with the applicable laws and regulations. ARTED assumes the responsibility of ensuring application of ethical rules between its members and healthcare professionals in order to ensure that medical decisions are always taken by paying regard to the highest interests and benefits of patients.

3. MAIN PRINCIPLES

This Code of Ethics is based on the following main principles:

- **The Principle of Separation:** The relationship between the medical technologies and medical devices industry and healthcare professionals cannot be misused for the purpose of providing undue or improper advantages or benefits, or to affect purchasing decisions. This relationship cannot be associated with purchasing decisions or conditioned upon conditions such as the recommendation of members' products.

- **The Principle of Transparency:** Interaction between medical technologies and medical devices industry and healthcare professionals should be transparent, and in conformity with the applicable laws and regulations and professional codes of conduct.
- **The Principle of Equivalence:** In situations where the engagement of healthcare professionals to provide a service for or on behalf of a member is permissible under the applicable laws and regulations, the remuneration paid by the member should be or proportional or equivalent to the fair market value of the services performed by the healthcare professional.
- **The Principle of Documentation:** For interactions between a member and a healthcare professional, where the services are performed by the healthcare professional for or on behalf of the member pursuant to the applicable laws and regulations, there should be a mutually signed written agreement, setting out the purpose of the interaction, the services to be performed by the healthcare professionals, and the details of remuneration and expenses to be paid by the member. Activities envisaged by the agreement must be substantiated and proven by activity reports and other similar documents. The agreement and the relevant reports, invoices and similar other appropriate and required documentation must be kept by the member for the period required by the applicable laws to support both the acceptability of the remuneration paid and the need for the services.
- **The Principle of Image and Perception:** In all their interactions with healthcare professionals and healthcare institutions and organisations, members should take into consideration the image of the medical technologies industry to be projected to public, and the perception to be formed therein.

4. COMPLIANCE WITH ARTED CODE OF ETHICS

Members must require their advisors, consultants, distributors, sub-distributors and all other third parties authorized to carry out the interaction with healthcare professionals with respect to sales, promotion, etc. of their products and other activities to comply with standards equivalent to ARTED principles. Accordingly, the agreement to be signed when entering into such interactions should impose obligations on third parties to comply with this and equivalent documents. This Code of Ethics determines the standards applicable to various interactions with healthcare professionals.

5. PRINCIPLES OF COMMUNICATION WITH HEALTHCARE PROFESSIONALS, ETHICAL RULES AND CODES OF BUSINESS PRACTICE

5.1. Meetings Organized by Members

5.1.a Scientific Meetings and Training Activities Organized by Members:

Where permitted by the applicable laws and regulations, members may organize scientific meetings in order to transfer the existing know-how or to develop new knowledge for healthcare

professionals, as well as training activities featuring device promotions and trainings in order to assist with the secure and effective use of medical technologies. These scientific meetings and training activities should be held at appropriate places that meet the technical requirements, by taking into consideration the applicable laws and regulations and the qualification of participants, in such manner as to not leave the scientific and training purposes of the meeting as a secondary concern.

Scientific meetings and training activities to be organized by members must especially comply with the following rules.

- Scientific and training activities aimed at promotion of medical devices should not be used for any purpose other than transferring the existing know-how and/or developing new knowledge.
- Events organized by the members for the promotion of medical devices will be considered to be training activities.
- For member-organized scientific meetings, members may only pay for participants' transportation and accommodation expenses if they provide support for participation to the extent permitted by the applicable laws and duly notify such support to the Ministry of Health. In this case, the support provided to the participants should be limited to the registration fee, reasonable accommodation and transportation costs and meal expenses. The period and costs of transportation and accommodation should also be kept at a reasonable level.
- Programs and activities should be organized in reasonable places fit for the purpose of the meeting, such as offices, premises and training centres of member companies and clinics and laboratories, including hotels or commercial meeting premises allowing active and effective exchange of information. Geographical location and venue of the event must be in compliance with the applicable laws and regulations, and not be the main attraction of the event.
- Training personnel should have adequate competence and proficiency to be able to provide said training.
- Members should not allow for the covering of the expenses of spouses or guests of healthcare professionals, or any other attendants who do not have any professional interest in the information shared at the event.
- Social activities for entertainment purposes should not be organized in member-organized scientific meetings and training activities. Entertainment includes, dance and music activities, sight-seeing trips, theatre excursions, sporting events or other similar leisure arrangements.
- In their scientific meetings and training activities, members may provide hospitality to the extent permitted by the applicable laws. Due care should be taken to ensure that third parties having no direct connection with the program of scientific meeting or training activities do not have access to such hospitality.

- Inviting a healthcare professional to a meeting or supporting their participation to a scientific meeting must not be contingent upon a promise to prescribe, use or recommend the member firms' devices or to reach a certain amount of sales of the relevant devices. Invitation and/or support for participation should not be linked to the past services of a healthcare professional within their capacity as the prescribing person.
- Before supporting a healthcare professional's participation to a meeting, members should notify the manager of related healthcare professional, management of the official authority or other authorized official authority regarding the support in written. The notifications regarding scientific meetings and training activities made to the Ministry of Health or sign of contracts, in which the official authority of the healthcare professional takes place as a party, corresponds to necessity of written notification.

5.1.b Other Meetings Organized by Members

Members shall organize meetings contains discussions of commercial conditions and do not contains any promotional item or content regarding sales of a product which is not in the scope of Public Procurement Act. These meetings should be organized in accordance with the following rules.

- These meetings should, as a rule, take place in the workplace or in a place close to workplace of the official authority and organization management invited to the meeting.
- Support of accommodation or transportation for healthcare professionals should not be provided for such meetings.

5.2. Support of Third Party Organized Scientific Meetings

Third party organized scientific meetings help in transfer and sharing of scientific knowledge, the support of medical developments, and the provision of efficient healthcare services. To this end, members may support such activities organized for said purposes and objectives, providing that they are in compliance with the applicable laws and regulations and the rules determined by professional organizations. Members should ensure that the activities that are a part of these meetings do not move the scientific purpose of meeting into the background.

Members should ensure that the third-party scientific meetings they support have Conference Vetting System approval, in case supported third-party scientific meetings are covered by the CVS administered by the MedTech Europe Compliance Panel.Members may support such activities, examples of which have been provided below, by providing scientific, technical, organizational and/or logistical help.

5.2.a. Support of Healthcare Professionals

To the extent permitted by the applicable laws and regulations and the professional practices and codes of conducts, members may provide financial support to cover the participation costs of healthcare professionals attending scientific meetings. Pursuant to MedTech Europe Code of Ethical Business Practice, the financial support provided to the HCP for third party organized scientific meetings should not be provided directly, but shall be provided through indirect sponsorship method.

Indirect sponsorship is the type of sponsorship when the HCPs who will be sponsored to participate in third party organized scientific meetings are selected by healthcare institutions and organizations, not by the Members. Upon the notification to the Member Company of the HCPs who are selected by healthcare institutions and organizations, the support shall be provided to the HCPs when the required controls and notifications in accordance with the Turkish legislation in force are completed.

The relationship between the Member who provides indirect sponsorship and healthcare institution and organization which selects the HCP who will participate in scientific meeting should be regulated by an agreement.

As well as Member companies are subjected to notifications of scientific meetings in accordance with local legislation, they are not obliged to provide indirect sponsorship to the HCPs who will participate in third party organized medical device trainings. Similarly, Member companies are not obliged to provide indirect sponsorship to the HCPs who will participate in satellite symposium as a speaker.

Said financial support should be limited to the registration fee and reasonable travel, meal and accommodation expenses of healthcare professionals. Registration fee to be paid under sponsorship must only be related to the scientific element of the scientific meeting, and should not include the costs of social activities such as opening cocktail and gala dinner. Supported transportation and accommodation should be kept at a reasonable level in terms of both time period and value.

Members must fully comply with the laws and regulations pertaining to disclosures or approval requirements for this sponsorship and, along with the notification required to be provided to official authorities pursuant to the applicable laws and regulations, must maintain transparency by making a written notification containing a detailed statement about sponsorship to the manager and/or management of the healthcare professional. The notifications regarding scientific meetings and training activities made to the Ministry of Health or sign of contracts, in which the official authority of the HCP takes place as a party, corresponds to necessity of written notification. Participation and/or support costs must not be paid directly to the healthcare professional.

5.2.b. Promotional Channels and Stands

Members may engage in promotional activities by leasing various different channels or stand areas.

5.2.c. Support of Scientific Meetings (Sponsorship)

Members may sponsor the organizing party of a meeting in order to reduce the general expenses and costs of participation in the meeting. The meeting organizer must make a written demand to the member, and the sponsorship fee must be paid directly to the meeting organizer or training institution. The meeting organizer is solely responsible for the program content and for the selection of staff members to be assigned therein. Members should not make any intervention to the content of program, other than suggesting a speaker or expressing opinions about the program if asked by the organizer.

Due care should be taken to ensure that the meetings to be supported by the members are in compliance with the applicable laws and regulations. Members must particularly make sure that the meeting venue is compliant with the appropriate time interval set forth under the applicable laws, and that the meeting does not include social, sports and leisure activities.

5.2.d. Satellite Symposium

Members may sponsor satellite symposium in scientific meetings, and may make presentations on issues consistent with the general scope of meeting, providing that all information are selected fairly, carefully and in a balanced manner in scientific terms. Members may determine the content of these activities and may be responsible for the selection of trainers. Organization must be documented in a written agreement, and members' support should be stated on all materials relating to satellite activity.

5.3. Consulting Services Provided by Healthcare Professionals

To the extent permitted by the laws applicable to healthcare professionals, healthcare professionals may provide consulting services through services such as market research and studies, participation in advisory boards and consultative committees, product development, training activities sponsored by members, or presentations in scientific meetings.

Where permitted by the applicable laws and the professional principles and code of conducts required to be complied with by healthcare professionals, a written consulting service agreement must be signed by and between members and healthcare professionals and all other relevant parties in accordance with the following practical rules and principles:

- Members must clearly determine their needs and requirements for the said services and consultancy before establishing contact with and demanding service from the potential Healthcare Professional consultant. In selection of consultants, the attributes and expertise of the consultant for the intended purposes should be taken into consideration.

- The number of the healthcare professional consultants to be served should not exceed the number of reasonable consultants required for the counselling requirement mentioned above.
- The selection of the HCP for consulting services could not be linked to the past, current or future product purchase, lease, recommendation, prescription, usage or supply of the HCP.
- Services to be provided by the consultant must be described in detail.
- Remunerations to Healthcare Professionals should not be made in return for or on the basis of an explicit or implicit mutual agreement or contract promising to use, purchase, lease, provide, apply, order, prescribe or recommend the members' products, or to include them into codex, or to provide them with another privileged or qualified status.
- The remuneration to be paid in consideration for the services to be provided by the consultant should be clearly specified. If this service is in the form of a speech or a written or oral declaration, this remuneration may be determined as an honorarium. In consideration for said services of healthcare professionals, a remuneration determined over fair market value thereof should be paid only to a bank account in accordance with the applicable laws and regulations. If a healthcare professional does not demand any remuneration for their services, this must be clearly stated in the agreement. All payments should be made in compliance with the current tax laws and other applicable regulations.
- If the consultant is employed by a public administration or a public university, the remuneration should be paid directly to the administration of the institution or to the revolving funds of the relevant institution. Due care should be taken to ensure that the relevant institution is aware of the services to be provided by the relevant healthcare professional under the said agreement, and/or the approval of the relevant institution should be obtained.
- If the healthcare professional is not employed by a public administration or a public university, and is authorized to issue a self-employment invoice, the remuneration for the consulting services may be paid directly to the healthcare professional in exchange for a self-employment invoice.
- Members may further cover the reasonable travel, meal and accommodation expenses incurred by consultants in the course of performance of services subject to their engagement.
- Members must adhere to the disclosure and approval requirements relating to engagement of healthcare professionals as consultants in accordance with the applicable laws and regulations.
- Members should give written notice explaining the purpose and scope of the consultancy relationship to the manager and/or management of official authority of the healthcare professional appointed as consultant. The sign of the contract, in which the official authority of the HCP takes place as a party, corresponds to necessity of written notification.

- Venue and conditions of meetings held with consultants should be suitable to the subject matter of consultancy services. Meetings should be organized in reasonable venues that are fit for the purpose of the meeting, such as offices, premises and training centres of member companies and clinics and laboratories, including hotels or commercial meeting premises allowing active and effective exchange of information.
- Hospitality offered during consultant meetings should be reasonable in terms of value, in accordance with the program of the meeting in terms of time and be connected to the purpose of meeting.
- Where permitted by the laws and regulations applicable to healthcare professionals, when members agree with healthcare professionals for development of a work subject to intellectual property rights, they should enter into a written contract pledging to make a payment amounting to the fair market value thereof. However, members should not in any case and by no means provide any material or financial benefit or advantage to healthcare professionals in connection to medical devices that may be purchased in the future, including any medical device prescribed by the healthcare professional in the past or medical technologies and medical devices developed within the scope of the intellectual property rights.

When members enter into an agreement with a healthcare professional engaged as a consultant for clinical research services, they must make reference to a written research protocol or a written business schedule, and must have received all of the required permissions, authorizations and approvals.

5.4 Royalties

HCPs, acting individually or as part of a group in which they are an active participant, often make valuable contributions that improve products or medical technologies. They may develop intellectual property, for example, patents, trade secrets, or know-how, under a product or technology development or intellectual property licensing agreement.

A royalty arrangement between a member and a HCP should be entered into only where HCP is expected to make or has made a novel, significant, or innovative contribution to product, such that the healthcare professional would be considered to be the sole or joint owner of such intellectual property under applicable laws and regulations.

Therefore, arrangements involving the payment of royalties by or on behalf of members to a HCP must be set out in a written agreement providing appropriate and reasonable remuneration in accordance with applicable laws and regulations. For example, royalties paid in exchange for intellectual property should be conditional on:

- A requirement that the HCP purchase, order or recommend any product, services or medical technology of the member or any product or technology produced as a result of the development project.
- A requirement to market the product or medical technology upon commercialisation.

Members should exclude from the calculation of royalties the criteria of the number of units purchased, prescribed, used or ordered by the HCP and/or official authority or institution the HCP practices for.

This arrangement does not cover intellectual property rights of healthcare professionals, which are covered by consulting or speaking services that Members receive.

5.5 Ban on Gifts and Incentives

Healthcare professionals or technicians working in the field of medical devices in healthcare institutions and organisations cannot be provided with incentives for the prescription, use, purchase or suggestion of medical devices through money or gifts, or any material or financial benefits or advantages, or a promise of benefit or award.

5.6. Grants

5.6.1. Members may provide grants with respect to scientific support, prestige or reputation, charity activities or other philanthropic purposes. Grants may be made to charity organizations or to public institutions or bodies and non-profit organizations authorized to accept grants / financial aid in accordance with the applicable laws and regulations. Individual grants cannot be made directly or indirectly to healthcare professionals.

Donations to be made by members must be made in line with a documented initiative, including a written donation request made by the institution or organization that accepts the donation or an objective assessment of the information by the Members.

Grants can be made in cash and/or in kind for the purpose of conducting general activities and operations of an institution or maintenance of its ongoing projects. Grants made for the purposes of charity or reputation must in no event be associated with or conditioned upon the past, present or potential future use of products or services of members.

Grants may be made to associations, foundations and societies founded by or involving healthcare professionals, and/or that are offering healthcare services or aiming to support these services, that are engaged in training, education or research, and that are authorized to receive grants pursuant to the applicable laws and regulations, and to public healthcare institutions or establishments, only upon satisfaction of the following conditions:

- To have at least one of the aims of supporting a scientific research, training or patient care, or provision of a particular public health service.

- To receive a prior consent of the administration of the recipient institution or organisation.
- Signing a written contract certifying the terms and conditions of donation with the institution or organization that will accept the donation.
- To document and record the grant by the member.
- To receive a delivery receipt verifying that the grant is received by and credited to the account of the party receiving the grant.
- Not to incentivize or encourage the recommendation, prescription, purchase, sale, distribution, promotion or use of a medical device.
- Not to pave the way for a non-ethical application or practice which may be linked to sales of medical devices.
- Not to affect the award of contract in bid tenders for medical devices.
- To be for the general use of the party receiving the grant, rather than serving the use of an individual.
- If the grant is in cash, it should be directly deposited in the name and account of the party receiving the grant. Grants in cash should be paid into the bank account of the recipient party by means of bank transfer.
- Not to donate to any institution or organization in the direct request of the HCP. The only exception is that the HCP is an employee or an official of the official authority or institution that accepts the donation and the request for the donation is made on behalf of the institution or organization concerned in written by the same HCP.

5.6.2. Medical devices, laboratory kits and other similar items to be granted for use in clinical research studies must be delivered directly to the responsible researcher in the clinical study.

Accordingly, where permitted by the applicable laws and regulations and the professional codes of conduct, members may provide financial and in kind assistance for the documented costs and expenses, or supply free medical devices in order to support the clinical study activities of healthcare professionals. All demands for clinic research studies must be made by the requesting parties in writing with reference to the description and objectives of the clinical study and research activities. Until a written agreement is reached and signed by and between the member and the recipient institution or organisation, the members shall not provide any grant, and this written agreement must explicitly include reporting and notification of adverse events. Any grant must be duly declared to the hospital management, managers of healthcare professionals, and other authorized institutions, and the recipient should be requested to refer to the grant and support of the member to the clinic study in all of his written or verbal presentations or papers relating to the results of clinical research.

5.6.3. Members should not have any ultimate supervision over the final use of their grants. Yet members request information about how their grants are used for the sake of source/information management.

5.6.4. Members cannot provide grants to evade the rules and principles set forth in the applicable laws and regulations, or to avoid their obligations relating to scientific and training activities, or to indirectly engage in a promotional activity.

5.6.5 Members should establish independent decision-making and evaluation processes in order to identify and counter the risks of corruption and bribery related to donations in their organizations.

5.7. Educational Grants

In addition to the grants made to healthcare institutions and establishments as described hereinabove, members may provide grants to persons who are not healthcare professionals for the purpose of development of medical science and education. However, the support of these programs or activities by members should not bring any pricing advantage, and particularly, should not encourage or incentivize the recommendation, prescription or purchasing of products or services provided to customers, or should not affect the award of contracts in bid tenders for medical devices. Therefore, members must keep all documents relating to such grants, and the grant should also be registered in the official records of the recipient. These grants should in no case be associated with or linked to past, present or potential future use of products or services of members.

All grants must be provided only to institutions and establishments authorized to receive these pursuant to the current applicable laws and regulations, and grants to individuals should not be made as per the principles of ARTED.

Grants can be provided in order to support professional training scholarships at educational institutions such as universities and other professional training institutions. Selection of scholars should be left to the sole discretion of the supported educational institutions, and members should not direct the selection of scholars.

5.8. Samples

Provision of samples to healthcare professionals for trial and assessment purposes may provide many benefits to patients in many aspects. Included among these benefits are improvement of patient care services, facilitation of secure and effective use of products, increase of patient awareness, and training of healthcare professionals with regard to the product.

Products provided to healthcare professionals for trial and assessment purposes may contain single-use or multiple-use products. These products may be provided to healthcare professionals at no charge in order to enable healthcare professionals to evaluate the appropriate use and functionality

of the relevant product, and to decide whether or when the relevant product will be used. Products provided for trial and assessment purposes are envisaged to be used in patient care services.

Medical devices which do not comply with the applicable laws and regulations or medical devices of a kind and/or a quantity which do not conform to the limitations imposed by the applicable laws and regulations cannot be provided as samples.

Members may provide for no charge medical devices and accessories which are mandatory for the administration of pharmaceutical products, such as infusion pumps, insulin injection pens, blood lancets, catheter, adapters, transfer sets and similar other peritoneal dialysis auxiliary materials or automatic blood glucose monitoring systems, and application lenses. These types of devices will not be considered and treated as samples, and training provided for their use will not be considered as medical device promotion. Members must keep records showing how many of such devices and materials are provided to whom.

Application lenses and samples of lenses may be given only to ophthalmologists.

5.9. Demonstration Products (Demos)

Demonstration products are products provided for healthcare professionals' awareness, and for provision of training and/or information on operation and use of medical devices. A demonstration product may be given in order to provide more practical information to a healthcare professional, on the condition that all relevant applicable laws and regulations have been complied with. Demonstration products must not be intended for clinical use in the scope of patient care, or must not be sold or otherwise transferred and assigned.

Demonstration products must be clearly stated to be fit only for use as a demonstration product by means of such phrases or expressions as "Demonstration Product" printed on the product itself or its pack and/or inserted in the documents delivered with the product. Demonstration products may in no case or by no means be given to healthcare professionals for use for commercial purposes in surpassing any of the aforementioned purposes or as a substitute for the primary product – even if temporarily. Members must take the required precautions to ensure that the demonstration products are not used for commercial purposes, and ensure the return of the demonstration products when required. Healthcare professionals should also be provided with documents showing that the assessment and demonstration products are free of charge.

5.10. Advertisement

Members may advertise the medical devices of which advertisement is permitted pursuant to the applicable laws and regulations. These advertisements must be in compliance with the principles set forth in the applicable legislation.

If members use “data on file” in advertisements, the advertisements should state that the accuracy of said information is verifiable and provable, and such information is confirmed as a result of their own research.

Scope of Advertisement- Regulation Article 15:

(1) Medical devices which are required to be used or applied solely and exclusively by healthcare professionals, and medical devices covered by reimbursement program cannot be directly or indirectly advertised to public through programs, films, TV series, news or similar other ways in any kind of media and communication means open to public, also including internet. Newspaper/magazine publications informing the healthcare professionals that the medical device is introduced to the market, and medical device information provided in official internet sites of sales centres, with a prior consent of the Ministry or the Institution, are outside the scope of this provision.

(2) Devices, other than those required to be used or applied solely and exclusively by healthcare professionals and covered by reimbursement program, may be advertised.

(3) Advertisements shall be in compliance with provisions of the Law on Protection of Consumers, no. 6502, dated 7/11/2013, and the Law on Foundation and Publishing Services of Radios and Televisions, no. 6112, dated 15/2/2011, and other applicable laws pertaining thereto.

(4) Advertisers, advertising agencies, channel organizations or intermediaries are under obligation to abide by the provisions set forth in this Regulation.

5.11. Digital Environment and Social Media Use

5.11.1. Medical devices may be promoted in digital channels which are accessible only by healthcare professionals and by technicians working in medical devices field in the healthcare institutions and organizations and where the scientific references with respect to the promoted product are clearly stated.

5.11.2. Members may place corporate advertisement via social media. Members may establish information platforms in social media to keep the public informed about diseases and may advertise these platforms. These platforms should not be used to promote medical devices.

Members may establish web pages aimed at raising disease awareness, where the purpose of the page is clearly stated, medical devices are not named and promoted and which do not include any messages, news or images that may be associated with promotion of devices. Firms must clearly state that they are sponsoring these pages.

On websites and social media accounts addressed to patients, colours, logos or pictures relating to brands of devices which cannot be advertised may not be used if they are of the nature to be associated with the device by the patients.

If free text boxes (comment areas) are used in pages that the members own or control the content thereof, these areas should be managed daily, and the assessment should be made on the basis of the general advertisement criteria.

Members cannot support web-based online channels where everyone may freely contribute to, and therefore, the compliance of the contents thereof with the applicable laws and regulations and to the standards set down in this Code of Ethics cannot be supervised.

5.12. Market Researches

In the scope of a market research, the main objective of which is to provide information to medical device development processes or marketing activities or to assess the potential promotion messages, information may be systematically gathered from healthcare professionals, patients or consumers.

Activities covered by the Medical Device Clinical Study Regulation, patient experience programs, and other studies conducted in order to assess the safety or efficiency of a medical device are not considered and treated as “Market Research”.

Promotional activities cannot be carried on during market researches, and market research is a non-promotional activity. These activities are conducted in order to gather information about the firm’s product or competitors’ products.

In the market research, for the sake of protection of integrity of market research, the firm’s name may not be disclosed, but it must absolutely be stated that this market research is carried on upon demand or with support of a medical device company.

Market research must cover the collection and analysis of information, and must be objective.

5.13. Promotion

5.13.a. Scope of Promotion:

Promotion covers all activities related to providing information to healthcare professionals and technicians working in medical device fields in healthcare institutions and organizations about the scientific and medical characteristics of medical devices. Promotional activities of members should be carried on in accordance with the current applicable laws and the good promotional practices.

The following activities are considered as promotional activities and should be addressed only to healthcare professionals and to technicians working in medical device fields in healthcare institutions and organizations:

- Paying of visits to healthcare professionals and technicians working in medical device fields in healthcare institutions and organizations by sales and promotion personnel, to inform them of such issues as administration and operating manual of the medical device; and distributing promotional materials to these persons during the visits.
- To give information through use of a demonstration device.
- To place advertisements in medical and professional books and magazines.
- To make announcements through direct mailing, press or other means of communication.
- To organize or support scientific meetings or training activities.
- To set-up stands in scientific meetings or organize activities in foyer area.
- To distribute samples.

The following activities are not considered as promotional activities and should not be used for promotion purposes:

- Commercial practices containing pricing, discounts to distribution channels, fixed terms or other sales conditions.
- Corporate information and promotions, providing that they do not contain any statement or claim with regard to medical devices.
- Information and statements addressed to public about human health or diseases, providing that they do not directly or indirectly contain any information or reference with regard to medical devices.
- Clinic support activities and technical support services.

5.13.b. Promotional Materials

All promotional materials used by sales and promotion personnel during promotional activities and/or are left to healthcare professionals and technicians working in medical device fields in healthcare institutions and organization should be in compliance with the applicable laws and regulations.

Promotional materials should be designed in such manner to enable the healthcare professionals to independently formulate their own opinions on therapeutic and diagnostic value of the promoted medical device.

The following materials will be considered and treated as promotional materials:

- Printed materials such as books, booklets and brochures containing adequate and required information on medical devices;

- Films and slides;
- Audiovisual materials offered in such storage means as flash memories and CD/DVD;
- All kinds of publications which may be used as information, data and reference sources in the relevant circles;
- Demonstration devices;
- Samples;
- Programs and materials for patient training;
- Reminder visit materials.

Members may from time to time give reminder visit materials of a symbolic value to healthcare professionals, providing that they are in compliance with the material limitations set forth in the applicable laws and regulations and professional principles and codes of conduct. Reminder materials must relate to the professional practices of healthcare professionals. Cash or cash equivalent reminder materials cannot be provided.

5.13.c. Principles for Promotion

A medical device may be promoted even if it has not yet been introduced to market following its registration and approval by TITUBB.

If the medical device has not yet been registered in and approved by TITUBB, it may be displayed in commercial fairs and exhibitions, providing that it carries a sign clearly showing that it has not yet been introduced to market and offered for sale, and it is in compliance with the applicable laws and regulations.

Promotional activities cannot be carried out in such manner to give harm to patients, users or environmental health or to endanger the security thereof.

Within the frame of the good promotion practices, medical devices may not be promoted through lotteries, games of chance or similar means where success is based on probability.

Posters or other materials containing medical device promotions that may be considered as promotional materials, cannot be placed, posted or affixed in any healthcare institution or organization. However, posters and similar other promotional materials to be used in campaigns organized by the Ministry of Health or its affiliated institutions or organizations for the purpose of encouragement of health, such as vaccination campaigns and fight against epidemic diseases, cigarette and obesity, are not included in the scope of this prohibition.

Promotions cannot be misleading or be in a manner to cause unfair competition. The following acts are considered to be misleading promotions:

- If the medical device is shown with some characteristics which in fact do not exist, or if any kind of wrong information is given about the medical device.
- If an expectation is created that success will certainly and definitely be achieved.
- If an inappropriate statement is made providing the warranty that no harmful effect will occur when the medical device is used.
- If wrong information is given about education, competences and past successes of persons manufacturing, importing, developing or marketing a medical device.
- If an untrue impression is given that the general welfare of the person will be worsened if the medical device is not used.
- If an impression is given that the medical device, other than the individual test devices covered by the Regulation on In Vitro Diagnostic Medical Devices, is fit for self diagnostics.
- If misleading, exaggerated or uncorroborated information which may unnecessarily encourage the use of medical device or may lead to unexpected risky situations is given, or interest arousing images which are not directly related to the medical device itself are used in promotion of the medical device.

5.13.d. Information, Arguments and Comparisons Used in Promotion:

Members' medical device promotional activities must provide information set forth in the applicable laws and regulations. For the sake of provability of all information given in the promotional materials, all sources quoted or used as a basis for these materials must be clearly stated. Particularly, sources must be stated in accordance with the following examples:

- **Masthead (title page) of published papers:** Authors, Title of Paper, Name of Periodical, Year, Volume, Page.
- **Abstract of an unpublished congress paper:** Authors, Title of Paper, Document Name, Name and place of congress, Date of congress, Date of publishing of the proceedings (abstract) book.
- **Quotations via internet:** Title of Paper, Authors, Name of article, Web site reference, Date of access to web.
- **Unpublished data (Data on file):** Title of paper of references.

Paper abstracts published in proceedings books of national and international congresses, and posters permitted to be presented in these congresses may be used as a source after the date of congress.

Opinions and results of clinical studies conducted on medical devices without a CE sign cannot be used in promotions before the study is completed or published in any scientific literature.

If the promotion is made by a documentation prepared by using quotations, adaptations, tables or other visual materials taken from medical, biomedical engineering, relevant discipline or professional magazines, journals or other scientific publications, these materials may be used on the condition that they stay loyal to the original material and/or by adapting the same and by making full reference to the sourced used therein. If a change is required to be made in the quotation, it must absolutely and clearly be stated in the promotional material that the quotation, graphic or table is adapted, modified, shortened or changed. However, the adaptation should not distort or change the meaning of quotation.

When data on file is shown as a source in promotional materials, the parts of such data pertaining to the argument or proposition must be provided without delay upon demand of the Ministry of Health or its affiliated institutions or the relevant healthcare professional. If the said data on file is used to support an argument as a part of the promotion, it will be subject to provability principle under the good promotion practices. If members do not wish to disclose the source of such data even upon demand, they should not use these data as a base for promotion.

Texts, pictures, tables, photographs and graphics used therein should be in conformity with the applicable laws and regulations and ARTED's good promotion principles. Graphics and tables should be presented so as to give a clear, correct and balanced opinion on the relevant issue.

Graphics, designs and drawings used therein must not give rise to a misconception about use of the medical device, and must not contain comparisons which may be perceived misleadingly. The distortion of results through use of statistically meaningless information, imperfect data or knowledge, or misleading scales can be given as an example for such comparisons. A product cannot be promoted by using images which are not directly related to the product itself and which are used solely for the sake of drawing interest.

Adjectives expressing superiority (such as, extraordinary, ultra, superlative, most reliable, most effective, perfect, unparalleled, unrivalled, sole or single) cannot be used if such claims are not provable.

A comparison between different medical devices must cover only "comparable features". In comparisons, what is described should be clearly stated together with the limits of comparison. An additional reference is not required for information and data included in the Instruction Book of the medical device registered in TITUBB. Side effect and adverse event data must have been supported by clinic experiences.

In the following cases, promotional materials may contain comparisons without any reference to trademarks:

- If they are not misleading,

- If medical devices and services addressed to the same needs or purposes are compared,
- If interrelated, proven and meaningful features are compared,
- If comparisons are not used particularly in such manner to make a confusion,
- If it does not contain any humiliating or disparaging statement about competitor products and brands,
- If an unfair advantage is not derived from the reputation of a competitor.

6. PUBLIC DISCLOSURE OF TRANSFERS OF VALUE

6.1 Scope

The rules of public disclosure of transfers of value stated below apply to the interactions of the Member Companies with healthcare organisations registered in the MedTech Europe Geographic Area.

Separate entities belonging to the same multinational company ("Affiliates") – which could be the parent company (e.g. the headquarters, principal office, or controlling company of a commercial enterprise), subsidiary company or any other form of enterprise or organisation – shall be deemed to constitute a single company, and are as such committed to compliance with the Code of Ethics rules on public disclosure of transfers of value.

Supports and grants provided to third party organized scientific meetings are within the scope of public disclosure of transfers of value. Transfers made other than these are not obliged to be disclosed to public.

Member Companies need not to report the same information twice due to being bound by national laws, regulations or professional codes imposing disclosure obligations equivalent to the ones imposed by the Code of Ethics.

6.2 Disclosure Obligation

Subject to terms of public disclosure of transfers of value, each Member shall document and disclose all the payments related to supports for scientific meetings and grants made to healthcare institutions and organizations based or registered in Europe/Turkey, without limitation of value.

The disclosure of transfers of value provided by Affiliates of the Member Company described above, but which are not registered in the MedTech Europe Geographic Area shall be made by the Member registered in the MedTech Europe Geographic Area.

6.3 Aggregate Disclosure

Transfers of value shall be disclosed on an aggregate basis. Each member shall disclose for each clearly identifiable and separate recipient, the amounts paid as transfers of value to such recipient in each Reporting Period which can be reasonably allocated to one of the categories set out below. Such amounts will be aggregated on a category-by-category basis, set out below. However, itemised disclosure shall be made available, as deemed necessary, upon request by (i) the relevant recipient or (ii) the relevant authorities.

Member Companies shall disclose an aggregate amount related to any of the categories set forth below:

A. Supports Provided to Scientific Meetings Organized By Third Parties (including Support for HCP Participation at Third Party Organised Educational Events) and,
B. Grants to Healthcare Organisations (including Scholarships, and/or Grants for Public Awareness Campaigns).

6.4 Optional Object Specification

If desired, Member Companies may indicate the object of the educational supports and grants disclosed.

6.5 Methodology

Each Member Company shall create a note summarising the methodologies used by it in preparing the disclosures and identifying each transfers of value for each category indicated as (A) and (B) and described in the Article of 6.3. An example of this note in English is attached to the Code of Ethics under the Annex-1.

The note, including a general summary and/or country specific considerations, shall describe the recognition methodologies applied, and should include the treatment of VAT and other tax aspects, currency aspects and other issues related to the timing and amount of Educational Grants in line with the purposes of the provisions set forth in Code of Ethics, as applicable. This methodology note shall be made available by Members upon request by an interested party.

6.6 Form of Disclosure

6.6.1 Reporting Period

Disclosures shall be made on an annual basis and each Reporting Period shall cover a full calendar year.

6.6.2 Time of Disclosure

Disclosures shall be made by each Member within 6 months after the end of the relevant Reporting Period.

6.6.3 Time of Publication

The disclosures shall be made public at the time of publication. The time of publication is on 31st August of the year of the relevant time of disclosure.

6.6.4 Template and Language of Disclosure

For consistency purposes, disclosures made pursuant to Code of Ethics shall be made in English using the template set forth in the Annex-2.

6.6.5 Platform of Disclosure

Disclosures shall be made on the Ethical MedTech website by the Members.

Members will remain liable for the accuracy of the disclosed data. ARTED or MedTech shall not be held liable for

(i) maintaining, correcting, deleting the published data nor

(ii) for the storage of data after the three years period of disclosure.

6.6.6 Retention and Modification of the Disclosures

Members shall be able to modify, delete or in any way alter their disclosures at any time before or after the time of publication.

The information disclosed shall remain in the public domain for 3 years after the time such information is first published.

6.6.7 Enquiries Regarding Reported Disclosures

Members shall make available to Healthcare Organization upon request any data concerning their common contractual relations published at any time while the disclosed information remains in the public domain.

ANNEX-1: EXAMPLE NOTE FOR SUMMARISING THE METHODOLOGİES

Structure

- Introduction
- Executive summary of the methodologies used for disclosure purposes and countries specificities
- Definitions
    - Recipients
    - Types of Educational Grants
- Disclosure scope and timelines
- Disclosures in case of partial performance or cancellation
- Cross-border activities
- Specific considerations:
    - Multi-year agreements
    - Consent management (please note that some jurisdictions may require the legal entity's consent for publication of data)
        - Consent collection
        - Management of recipient consent withdrawal
        - Management of recipient's request
        - Partial consent
- Disclosure Form
    - Date of submission
    - Currency in case of aggregated payments made in different currencies
    - VAT included or excluded and any other tax aspects
- Disclosure financial data and amount of Educational Grants provided
- Calculation rules

ANNEX-2: EXAMPLE TEMPLATE FOR PUBLIC DISCLOSURE

TEMPLATE								
Full HCO Name	HCOs: city where registered	Country of Principal Practice / Activity	Registered Address	Unique country local identifier	A. Educational Grants to Support Third Party Organised Events /or to Support HCP Participation at Third Party Organised Educational Events)	Object (Optional)	B. Other Educational Grants to HCOs (including Scholarships, Fellowships and Grants for Public Awareness Campaigns).	Object (Optional)
HCO/PCO 1					Yearly amount	Optional	Yearly amount	Optional
HCO/PCO 2					Yearly amount	Optional	Yearly amount	Optional
etc.					Yearly amount	Optional	Yearly amount	Optional