

THE ASSOCIATION OF RESEARCH-BASED MEDICAL TECHNOLOGY MANUFACTURERS (ARTED)

Code of Ethical Business Practices and Principles for Communication with Healthcare Professionals

This Code has been prepared with the purpose of defining the ethical responsibilities of Members in compliance with applicable laws and regulations. In this regard, particular attention has been paid to ensuring that ARTED's Code of Ethical Business Practices and Principles for Communication with Healthcare Professionals (the "Code of Ethics") is consistent with applicable laws and regulations. However, in the event that the provisions of the Code of Ethics conflict, or come to conflict, with laws and regulations, the relevant provisions of such laws and regulations shall apply. Provided they remain consistent with the Code of Ethics, the inclusion of more restrictive provisions in Members' internal procedures does not conflict with the principles of the Association.

The Association of Research-Based Medical Technology Manufacturers (ARTED) Code of Ethical Business Practices and Principles for Communication with Healthcare Professionals

1. INTRODUCTION



The Association of Research-Based Medical Technology Manufacturers (“ARTED”) represents the member organizations (collectively, the “Members”, individually, a “Member”) that develop, manufacture and bring to market medical products, technologies, related services and treatments (medical technology) used for the diagnosis, treatment, monitoring, management and alleviation of health problems and diseases, with the aim of supporting patients in living long and healthy lives.

ARTED is dedicated to using all of its resources to contribute to the advancement of medical science, the improvement of services provided to patients, and especially the development of high-quality and innovative medical technologies in pursuit of these objectives.

ARTED assumes the responsibility of ensuring the application of ethical rules in the relationships between its Members and Healthcare Professionals (“HCPs”), other healthcare-related professionals listed in the Regulation on the Job and Duty Definitions of Healthcare Professionals and Other Professionals Working in Health Services who do not directly perform applications on humans in the field of health, technical personnel working within healthcare institutions and organizations, hospital procurement units, employees of reimbursement bodies and other healthcare sector employees; as well as in the relationships between healthcare service providers and official institutions and organizations.

There are many different forms of relationship between Members and HCPs that develop, advance and improve services to patients in medical science. Among these relationships are the following:

Development of Medical Technologies: The development of innovative medical devices and the improvement of existing products require collaboration between Members and HCPs.

Safe and Effective Use of Medical Technologies: The safe and effective use of medical technology requires Members to provide HCPs with the necessary and appropriate instructions for use, training, education, service and technical support.

Research and Education: The support that Members provide for clinical studies, training activities and events aimed at developing professional skills contributes to patient safety and increases access to new technologies.

Supporting Charitable and Donation Activities: Members may provide monetary or non-monetary support to events organized for the public benefit. These events provide access for patient populations who would otherwise have no access, and also contribute to improving the quality of healthcare services and treatments provided.

Good Promotional Practices for Medical Devices: For the purpose of improving patient health and safety, the promotion of medical devices must be conducted within the framework of ethical rules, in a fair manner consistent with rules of competition, using evidence-based and scientific data that helps HCPs and technical personnel working in the field of medical devices within healthcare institutions and organizations to form their own opinions independently.

2. PURPOSE OF THE CODE OF ETHICS





Members are aware of the importance of working in compliance with applicable laws — in particular the Regulation on the Sale, Advertising and Promotion of Medical Devices and its associated guidelines — in adhering to ethical standards, in order to effectively maintain cooperation between the Medical Technologies and Medical Devices Industry and HCPs. Members must support the application of ethical business practices and socially responsible industry practices in their relationships with HCPs. Furthermore, they must continue to respect HCPs' obligation to make independent treatment-related decisions. ARTED acknowledges that the most important duty of HCPs is to provide the best service for the benefit of patients. Members provide the best service for the benefit of patients by cooperating with HCPs. Such cooperation must be conducted in compliance with high ethical standards, with adequate transparency, and in accordance with applicable laws and regulations. ARTED accepts the responsibility of ensuring the application of ethical rules between Members and HCPs in order to ensure that medical decisions are made with the best interests of patients in mind.



3. CORE PRINCIPLES OF THE CODE OF ETHICS



This Code of Ethics is based on the core principles set out below:

Principle of Separation: The relationship between the Medical Technologies and Medical Devices Industry and HCPs cannot be misused to obtain improper or inappropriate advantages or to influence purchasing decisions. This relationship cannot be linked to purchasing decisions or made conditional upon factors such as the recommendation of Members' products.

Principle of Transparency: The interaction between the Medical Technologies and Medical Devices Industry and HCPs must be transparent and consistent with applicable laws, regulations and the Code of Ethics.

Principle of Equivalence: Where it is permissible under applicable legislation for HCPs to be engaged to provide a service on behalf of or for a Member, the fee paid by the Member must be proportionate to or equal to the fair market value of the service provided by the Healthcare Professional.

Principle of Documentation: In a relationship between a Member and an HCP, where applicable legislation permits services to be provided by the HCP on behalf of or for the Member, there must be a mutual written contract between the parties setting out the purpose of the relationship, the services to be provided, and the details of the fees and expenses to be paid by the Member. The activities pre-defined in the contract must be confirmed and evidenced through activity reports and similar documentation. Appropriate and necessary documents — the contract, related reports, invoices, etc. — must be retained by the Member for the period required by applicable laws, in order to support both the acceptability of the fees paid and the need for the services.

Principle of Image and Perception: In all interactions with HCPs and Healthcare Institutions, Members must consider the image of the medical technology industry as it will be reflected to the public and the perception that will be formed.

4. COMPLIANCE WITH THE CODE OF ETHICS



Members must require that consultants, distributors, sub-distributors, affiliates and all other Third Party Intermediaries authorized to manage their relationships with HCPs in connection with activities such as the sale and promotion of their products comply with standards equivalent to the principles set out in Article III. Accordingly, when entering into such relationships, the contracts to be signed must impose obligations on Third Party Intermediaries to comply with this and equivalent documents. This Code of Ethics establishes the standards applicable to the various relationships established with HCPs.

In the event of non-compliance, Members may take action regarding irregularities by following the steps set out in the ARTED Complaint Procedure.

This Code of Ethics applies to all activities and interactions of Members connected with medical technology. The fact that an activity is financed or conducted by another business unit does not change the scope of the Code of Ethics. Activities partially connected with Medical Technology are also subject to this Code of Ethics. Interactions related to products or services other than Medical Technology are outside the scope of the Code of Ethics; however, the use of other business units to indirectly circumvent the requirements of the Code of Ethics is prohibited.

5. PRINCIPLES FOR COMMUNICATION WITH HEALTHCARE PROFESSIONALS, ETHICAL RULES AND BUSINESS PRACTICES

1. Meetings Organized by Members

a. Scientific Meetings and Educational Activities Organized by Members

Where permitted under applicable legislation, Members may organize Scientific Meetings and Educational Activities targeted at HCPs. Such Scientific Meetings and Educational Activities, taking into account the characteristics of the participants, must be of a nature that does not place the scientific and educational purpose of the meeting in a secondary position, and must not be used for any purpose other than to convey existing knowledge and/or present new information.

a.1) Educational Activities

- Organizations arranged by Members where the promotion of medical devices may also take place are considered Educational Activities.
- Educational Activities are organized to last no more than one day.
- Under no circumstances may registration, accommodation and travel expenses be covered by the sales center for HCPs other than those participating in the Educational Activity as training experts or as HCPs providing services to Members for a specific event.
- Speakers must have sufficient expertise to deliver the relevant training.

Event Programme:

- Must be directly related to the area of expertise and/or medical practice of the HCPs attending the event, or sufficiently relevant to justify the participation of HCPs.
- The detailed programme must be available in sufficient time before the event and must, for in-person events (including hybrid events), provide a clear schedule with no gaps during sessions (for example, a full-day in-person event must last at least 6 hours, and a half-day in-person event at least 3 hours including refreshment breaks).
- The list of speakers must be defined. In addition, it is important that all institutional communication materials (e.g. promotional brochures, flyers, websites) are consistent with the scientific or promotional nature of the programme content.
- A Member may not organize events that include social, sporting and/or entertainment activities.

Event Location and Venue:

- HCPs working in provinces sharing a land border with the province where the training is to be held, and technical personnel working in the field of medical devices within Healthcare Institutions and Organizations, may attend the Educational Activity organized.
- The event must not become primarily about the venue or location.
- When selecting the event location and venue, Members must always take into account the following considerations:
- The possibility of the event location and venue being perceived negatively by the public. The perceived image of the location and venue must not be of a luxurious, tourist/holiday-oriented or entertainment-area nature.

- The event location and venue must be in a central location, taking into account where the majority of invited participants reside.

- The event location and venue must be in or near a recognized scientific or business center conducive to the exchange of ideas and the transfer of knowledge. Considering where most participants are located, the event location and venue must be near an airport with appropriate international connections and/or a railway station, and there must be a reliable road transport infrastructure to access the venue.

- It is not appropriate for Members to organize events at, or to support events held at, hotels or holiday resorts known for entertainment activities or focused on entertainment and sports activities such as golf, private beaches or skiing/water sports. For example, in cases where the use of the chosen venue is unavoidable due to the absence of alternative venues or the existence of genuine security concerns, exceptions may be considered for venues that are appropriately located and suitable for business meetings.

- The season in which the event is organized must be considered, and the chosen date must not coincide with the tourist season for the relevant geographical location. Other than international meetings each held in a different country, meetings and organizations including Scientific and Educational Activities cannot be held at seaside holiday resorts between 15 June and 15 September, or at ski-resort holiday destinations between 1 December and 1 March.

- If the hotel charges an additional fee for the use of entertainment or sports facilities, Members may not make such payment on behalf of HCPs. From a perception standpoint, passenger ships or hotels containing a casino are in no way appropriate as event venues or as accommodation for HCPs under these Rules.

Web-Based Educational Activity:

- For Web-Based Meetings lasting no more than one day, the meeting type must be selected as Educational Activity in the application.

- A Web-Based Educational Activity is a meeting such as an online seminar or video conference that can be viewed over the network. In Web-Based Meetings where the meeting type is selected as Educational Activity, the rules and limitations established by legislation for Educational Activities apply to the number of attendees. Restrictions regarding the number of attendees or the provincial limitations on participation do not apply to such meetings.

a.2) Scientific Meetings Organized by Members

Members may cover the travel and accommodation expenses of HCPs for Scientific Meetings they themselves organize, but only if they provide HCP educational support as defined and permitted under applicable legislation, and duly notify the Ministry of Health of such support. In this case, the Educational Support provided to HCPs must be limited to the registration fee for the meeting, reasonable accommodation and travel costs, and meal costs. The duration and costs of travel and accommodation must also be kept reasonable.

The programme and activities must be organized at venues appropriate to the purpose of the meeting, including hotels or commercial meeting facilities that allow effective exchange of information, as well as Members' offices, facilities, training centers, clinics and laboratories. The geographical location of the event and the facility used must both comply with applicable legislation and not constitute the main attraction of the event.

Event Programme:

- The detailed programme must be available in sufficient time before the event and, for in-person events (including hybrid events), must provide a clear schedule with no gaps during sessions. For example, a full-day in-person event must last at least 6 hours, and a half-day in-person event at least 3 hours including refreshment breaks.
- The list of speakers must be defined. In addition, the content of the scientific programme related to the event (e.g. promotional brochures, flyers, websites) must be consistent with the scientific or promotional nature of the event.
- Meetings that include social, sporting and/or entertainment activities cannot be supported by Members.
- Other than international meetings each held in a different country, Scientific Meetings organized at seaside holiday resorts between 15 June and 15 September, and at ski-resort holiday destinations between 1 December and 1 March, cannot be supported. These conditions do not apply to Scientific Meetings organized or supported by the Ministry.

Event Location and Venue:

For scientific meetings organized by Third Parties, the rules regarding the event location are subject to the rules applicable to events organized by the Members.

- The event must not become primarily about the venue or location.
- Considering the possibility that the event location and venue may be perceived negatively by the public, the image of the chosen venue must not be of a luxurious, tourist/holiday-oriented or entertainment-area nature.
- Entertainment-oriented social activities should not be organized at the scientific meeting. Examples of such entertainment include dance and music events, excursions, theatre tours, sporting events or other similar leisure-time arrangements.
- The event location and venue must be in or near a recognized scientific or business center conducive to the exchange of ideas and the transfer of knowledge. Considering where most participants are located, the event location and venue must be near an airport with appropriate international connections and/or a railway station, and there must be a reliable road transport infrastructure to access the venue.

- The event location and venue must be in a central location, taking into account where the majority of invited participants reside.
- The event location and venue must be in or near a recognized scientific or business center conducive to the exchange of ideas and the transfer of knowledge. Considering where most participants are located, the event location and venue must be near an airport with appropriate international connections and/or a railway station, and there must be a reliable road transport infrastructure to access the venue.
- It is not appropriate for Members to organize events at, or to support events held at, hotels or holiday resorts known for entertainment activities or focused on entertainment and sports activities such as golf, private beaches or skiing/water sports. For example, in cases where the use of the chosen venue is unavoidable due to the absence of alternative venues or the existence of genuine security concerns, exceptions may be considered for venues that are appropriately located and suitable for business meetings.
- The season in which the event is organized must be considered, and the chosen date must not coincide with the tourist season for the relevant geographical location. Other than international meetings each held in a different country, meetings and organizations including Scientific and Educational Activities cannot be held at seaside holiday resorts between 15 June and 15 September, or at ski-resort holiday destinations between 1 December and 1 March.
- If the hotel charges an additional fee for the use of entertainment or sports facilities, Members may not make such payment on behalf of HCPs. From a perception standpoint, passenger ships or hotels containing a casino are in no way appropriate as event venues or as accommodation for HCPs under these Rules.

a.3) Common Rules for Scientific Meetings and Educational Activities Organized by Members

- Members must not allow the costs of the spouses or other accompanying persons of HCPs, or any other companion who would not professionally benefit from the information shared at the meeting, to be covered.
- Entertainment-oriented social activities must not be organized at Scientific Meetings and Educational Activities organized by Members. Examples of such entertainment include dance and music events, excursions, theatre tours, sporting events or other similar leisure-time arrangements.
- Members may provide hospitality at the Scientific Meetings and Educational Activities they organize, to the extent permitted under applicable legislation. It must be ensured that any guest who is not directly connected with the programme of the Scientific Meeting or Educational Activity does not benefit from the hospitality provided.
- The invitation of an HCP to a meeting, or, in the case of a Scientific Meeting, the support of their participation, must not be conditional on a promise to prescribe, use or recommend Members' devices or on having achieved a certain volume of sales for the relevant device. The invitation to attend and/or the support must not be related to the HCP's past services as a prescriber.
- Before providing any HCP with support for an Educational Activity and/or Scientific Meeting, Members must provide a written notification (the "Employer Notification") containing details of the support to the relevant HCP's manager, the institution's management or another duly authorized institution. Notifications of Scientific Meetings and Educational Activities to the Ministry of Health and/or the signing of contracts to which the HCP's institution is also a party satisfy this written notification requirement.

b. Other Meetings Organized by Members

Members may organize meetings outside the scope of the Public Procurement Law, in which the commercial conditions for product sales are addressed and which contain no promotional element or content related to the products in any way. Such meetings must be organized in compliance with the following rules.

- Such meetings must, as a rule, take place at the workplace of the management of the institution and organization invited to the meeting, or at a venue close to such workplace.
- Travel or accommodation support must not be provided to HCPs for such meetings.

2. Support of Scientific Meetings Organized by Third Parties

a.4) General Rules

Scientific Meetings Organized by Third Parties help to convey and share scientific information, support medical advances and enable the delivery of effective healthcare services. Members must ensure that the activities at such meetings are of a nature that does not place the scientific purpose of the meeting in a secondary position.

If the Third-Party Scientific Meeting that Members will support falls within the scope of the Conference Vetting System ("CVS") administered by the MedTech Europe Compliance Panel, Members must ensure that the Scientific Meeting they will support is CVS-approved. The relevant table, adapted from Annex 5 of the MedTech Code of Ethics, indicating in which cases CVS approval is required, is set out in Annex 3.

Members may provide support for the development of medical education. Members must specify the intended use of the support in their contracts. Members will also ensure that their contract with the recipient organization includes rights enabling verification that the support is in fact used for the agreed purpose.

Members may support Scientific Meetings Organized by Third Parties as a general sponsor of the meeting itself, by renting a stand, by renting a Satellite Symposium, as Educational Grant support to the HCP attending the meeting, or by supporting the meeting under the conditions set out below.

- It is not appropriate for Members to organize events at, or to support events held at, hotels or holiday resorts known for entertainment activities or focused on entertainment and sports activities such as golf, private beaches, skiing or water sports. However, in necessary situations such as the absence of alternative venues or the existence of genuine security risks, exceptional consideration may be given to venues that are appropriately located and suitable for business meetings. In some cases, in Scientific Meetings Organized by Third Parties, hotel accommodation being separate from the meeting venue may be necessary for compliance.
- When evaluating an exceptional case, the in-house entertainment facilities of the conference venue must not appear in the event's promotional materials, and the event programme must be arranged so that participating HCPs cannot use the entertainment and sports facilities for the majority of a normal business day.
- If the hotel charges an additional fee for the use of entertainment or sports facilities, Members may not make such payment on behalf of HCPs. From a perception standpoint, passenger ships or hotels containing a casino are in no way appropriate as event venues or as accommodation for HCPs under these rules.

b. Support of Healthcare Professionals (Educational Grant)

- **Compliance with applicable legislation:** Where permitted by applicable laws, regulations and the Code of Ethics, Members may provide financial support for the participation of HCPs in scientific meetings.
- **Scope of financial support:** The participation fee covered as part of HCP attendance support must relate solely to the scientific content of the relevant Scientific Meeting; it must not include any cost for social activities such as the opening cocktail or gala dinner. In addition, an HCP's expenses, including travel, accommodation and meals, may be covered, provided they are reasonable. Unless travel arrangements relating to scientific meetings or educational activities organized by Members at the same location following scientific meetings organized by third parties so require, the duration of supported accommodation must not exceed the duration of the meeting.
- **Indirect support:** In accordance with the MedTech Europe Code of Ethical Business Practice, HCP Educational Support for Scientific Meetings Organized by Third Parties must not be provided directly, but may be provided indirectly. Indirect Educational Support is a form of support based on the principle that the HCPs to attend Scientific Meetings Organized by Third Parties are selected not by the Members but by Healthcare Institutions and Organizations. Following the official notification to the Member of the HCPs selected by the Healthcare Institution and Organization, and after the controls and notifications required under applicable Turkish legislation are completed, educational support may be provided to the HCPs. The relationship between the Member providing the educational support and the Healthcare Institution and Organization that will select the HCP to attend the Scientific Meeting must be regulated by a contract. Although Members are subject to Scientific Meeting notifications under local legislation, they have no obligation to provide educational support to HCPs for participation in device trainings organized by third parties. Similarly, there is no obligation to provide support to HCPs who will be speakers at a Satellite Symposium. Where educational support is provided to support HCP participation in Scientific Meetings Organized by Third Parties, the recipient Healthcare Institution will be solely responsible for the selection of participants, and this will be expressly stated in the written contract. When providing educational support to support the participation of HCPs in Scientific Meetings Organized by Third Parties, Members must not actively seek to obtain the names of the HCPs benefiting from the educational support.

- **Notifications:**

Members must fully comply with the laws and regulations regarding disclosure or approval requirements for such support, and must maintain transparency by, in addition to the notification required to be made to the official authorities under applicable legislation, providing an Employer Notification containing detailed disclosure of the support to the HCP's manager and/or the institution's management. Notifications of support to the Ministry of Health and/or the signing of support contracts to which the HCP's institution is also a party satisfy this written notification requirement. The participation and/or support fee must not be paid directly to the HCP.

- Must be directly related to the area of expertise and/or medical practice of the HCPs attending the event, or sufficiently relevant to justify the participation of HCPs.
- Members must not allow the costs of accompanying persons of HCPs, or any other companion who would not professionally benefit from the information shared at the meeting, to be covered.
- Support for the participation of an HCP in a Scientific Meeting must not be conditional on a promise to prescribe, use or recommend Members' devices or on having achieved a certain volume of sales for the relevant device. The support must not be related to the HCP's past services as a prescriber, user and/or recommender of the device.

c. Promotional Channels and Stands

Members may carry out promotion through various channels or by renting stand space.

d. Support for Scientific Meetings

Members may provide support to the meeting organizer in order to reduce the general costs related to meeting attendance. A written request must be made by the meeting organizer to the Member, and the amount of support must be paid directly to the healthcare organization, association or event agencies authorized by the meeting organizer. The meeting organizer is solely responsible for the programme content and the selection of the staff to perform duties. Members must not, beyond suggesting speakers when requested or commenting on the programme, intervene further in the content of the programme. It must be ensured that the characteristics of the meetings to be supported by Members are consistent with applicable legislation. Members must in particular ensure that the meeting complies with the general rules set forth in Article 2.a.

e. Satellite Symposium

- Members may sponsor a Satellite Symposium at Scientific Meetings and may make presentations on topics consistent with the general scope of the meeting, provided that all information is selected fairly, in a balanced manner and with scientific care. Members may determine the content of these events and may be responsible for selecting speakers. The arrangement must be documented by a written contract, and all materials related to the satellite event must indicate that the relevant session is being held with the support of the Member.
- Rules for HCPs authorized to speak during a Satellite Symposium supported by Members at Scientific Meetings Organized by Third Parties or in the stand area:
- The Scientific Meeting registration fee for an HCP authorized as a speaker may be covered only where the HCP's access to the Satellite Symposium or to the stand at the event is conditional on payment of the registration fee. In such case, the registration fee must, to the extent possible, be determined proportionate to the actual time of attendance required to perform the necessary services. For example, if the Satellite Symposium is held only on one day of a three-day event and a one-day registration option is available, that option must be selected.
- Coverage of the speaker's flight and accommodation expenses is possible only if the HCP is not benefiting from HCP educational support provided by the sponsoring Member.

f. Web-Based Scientific Meeting

- Notifications to the authority are not required for web-based meetings where no technical equipment support is provided (any device, apparatus, software, etc.) and/or no transfer of value takes place. If any of these supports are provided, the notifications under this legislation must be made.
- For scientific meetings organized via web that last more than one day, the meeting type to be notified must be selected as scientific meeting.
- A Web-based Scientific Meeting is a meeting such as an online seminar or video conference that can be viewed over the network. In web-based meetings where the meeting type is selected as scientific meeting, the rules and limitations established by legislation for Scientific Meetings apply to the number of attendees.

Conference Vetting System (CVS):

CVS is the system that examines the compliance of Scientific Meetings Organized by Third Parties with the code through a centralized decision-making process, administered independently of MedTech Europe under the supervision of the MedTech Europe Compliance Panel. The process for these applications must be carried out by Members in accordance with the procedure set out in the annex to this Code (see Annex 3).

3. Provision of Consultancy Services by Healthcare Professionals

Where permitted by the legislation to which they are subject, HCPs may serve as consultants to Members by providing services such as market research, participation in advisory boards, product development, training and educational activities sponsored by Members, or making presentations at scientific meetings. Where permitted by the professional principles and legislation to which HCPs are subject, a written consultancy services contract complying with the application rules set out below must be signed between the Members and HCPs by all relevant parties:

- Before contacting a potential HCP consultant and requesting services, Members must clearly identify a Legitimate Need for the relevant service and consultancy. In selecting a consultant, the consultant's qualifications and expertise relevant to the defined purpose must be the basis. A Legitimate Need refers to a current and actual business objective pursued by Members, such as medical education, clinical research and/or the safe and effective use of Members' medical technology. Engaging with an HCP or healthcare organization with the purpose of directly or indirectly causing the prescription, recommendation, purchase, ordering, supply, use, sale or rental of Members' medical technologies or related services by such HCP or healthcare organization is not regarded as a Legitimate Need.
- The number of consultants engaged must not exceed the reasonable number of consultants required for the consultancy need described above.
- The selection of an HCP for the provision of consultancy services must in no way be linked to the HCP's past, current or future product purchase, rental, recommendation, prescription, use or supply.
- The services to be provided by the consultant must be specified in detail.
- Payments to HCPs must not be made in return for any explicit or tacit understanding or arrangement that Members' products will be used, purchased, rented, supplied, applied, ordered, prescribed, recommended, listed in a codex or otherwise granted any privileged or qualified status.
- The fee to be paid in return for the services to be provided by the consultant must be clearly specified. Where the relevant service takes the form of participation as a speaker or the presentation of a written/oral paper, an Honorarium may be set for such service.

- **Fair Market Value: A fee at fair market value for the services of HCPs must be paid solely by bank transfer in accordance with applicable legislation. This fee applies in circumstances where each party transacts independently in a free market, neither party is compelled to buy or sell, and both parties have reasonable knowledge of the relevant matters. A documented internal methodology must be used by Members in determining fair market value. If an HCP does not request any payment for their services, this must be expressly stated in the contract. All payments must be made in accordance with applicable tax laws and other legal regulations.**
- If the consultant works at a public institution or a public university, the fee to be paid must be paid to the institution or to the institution's revolving fund. It must be ensured that such institution is aware that the relevant HCP will provide services under this contract and/or has given approval.
- If the HCP does not work at a public institution or public university and is authorized to issue a self-employment receipt, the payment for the consultancy services may be made directly to the HCP against a receipt.
- Members may cover documented reasonable travel, meal and accommodation expenses incurred by consultants in the course of providing the services that are the subject of their engagement. Such expenses must comply with local laws and regulations. The written consultancy contract must clearly specify which expenses the consultant may claim and the basis on which the Member will pay these expenses.
- Members must comply with the disclosure and approval requirements for the engagement of HCPs as consultants in accordance with applicable laws and regulations.

- Members must provide a written employer notification to the manager and/or the institution's management of the HCP to be engaged as a consultant, containing explanations of the purpose and scope of the consultancy relationship. The signing of contracts to which the HCP's institution is also a party satisfies this written notification requirement.
- The location and conditions of meetings with consultants must be appropriate to the main subject of the consultancy. Meetings must be organized in venues appropriate to the purpose of the meeting, including hotels or commercial meeting facilities allowing effective exchange of information, as well as the offices, facilities and training centers of Members, and clinics and laboratories.
- Hospitality provided for a consultant meeting must be reasonable in monetary value, consistent in duration with the meeting programme, and focused on the purpose of the meeting.
- Where Members enter into an agreement with an HCP to develop a work subject to intellectual property rights, where permitted by the legislation to which the HCP is subject, they must enter into a written contract providing for payment at Fair Market Value. However, Members must not, under any circumstances, provide any financial benefit to the HCP in respect of medical devices likely to be purchased in the future, including new medical technologies and medical devices developed under intellectual property rights or those previously prescribed by the HCP.
- Where Members enter into a contract with an HCP serving as a consultant for clinical research services, they must reference a written research protocol or a written work schedule, and must have obtained all necessary permits and approvals.

- **Conflict of Interest: When engaging an HCP or healthcare organization as a consultant, Members must be alert to potential conflicts of interest that may arise from the project itself or particularly from engaging this HCP or Healthcare Institution. A conflict of interest is a situation in which a person or institution has personal, financial or other secondary interests that may affect (or may be perceived to affect) their professional decisions, responsibilities or impartiality.**

4. Royalties

HCPs, individually or as part of an active group, can make significant contributions to the development of products or medical technologies. Under product/technology development contracts or royalty license contracts, they may develop information subject to intellectual property rights such as patents, trade secrets or know-how.

However, where an HCP makes or is expected to make a significant or innovative contribution to the development of a product, technology or process to such an extent that, under applicable legislation, the HCP would be considered the sole or joint owner of the work, royalty contracts on products and processes must be concluded between Members and HCPs.

In this regard, the arrangements for royalty payments to be made by or on behalf of Members to HCPs must be documented by a written agreement. Under such agreement, an appropriate and reasonable fee must be established in accordance with applicable legislation and regulations. For example, royalty payments to be made in return for intellectual property rights must not be conditional on the following:

- The HCP purchasing, ordering or recommending any product, service or medical technology of Members or any product or medical technology to be produced as a result of the development project. Promotion and marketing of the developed product or medical technology when it is brought to market. When calculating royalty payments, Members must not take as a criterion the number of products ordered, prescribed, used or ordered by the HCP and/or the Healthcare Institution or Organization to which the HCP is affiliated.
- This arrangement does not cover HCP intellectual property rights falling within the scope of consultancy or speaker services obtained by Members.

5. Prohibition on Gifts and Incentives

In promotional activities, HCPs or technical personnel working in the field of medical devices within healthcare institutions and organizations may not be incentivized to prescribe, use, purchase or recommend the device by giving money or gifts, providing any material gain, or making promises of benefit or reward.

6. Donations

Members must have no control over the ultimate use of the donations they make. However, Members may, for resource/information management purposes, request information regarding how the donation has been used.

Members must not make donations in order to circumvent the rules established by legislation, to avoid their obligations regarding Scientific and Educational Activities, or to indirectly carry out a promotional activity.

Members must establish independent decision-making and evaluation processes within their organizations in order to identify and take precautions against the risks of bribery and corruption associated with donations.

a. General rules

Members may make donations in connection with scientific support, prestige, charity or other charitable matters. Donations may be made to charities or to public institutions or organizations and not-for-profit organizations authorized to receive aid/donations under applicable laws and regulations. Direct or indirect personal donations to HCPs may not be made.

Donations to be made by Members must be made either pursuant to a prior written donation request from the institution or organization receiving the donation, or pursuant to a documented initiative by the Members containing information allowing for an objective assessment. The request must, at a minimum, contain a detailed description of the purpose, programme and scope of the project, activity or undertaking for which the donation is requested. It must also include a description of the donation recipient, its legal status and structure, and where relevant, its budget. No donation must be made without a donation contract signed by both parties.

Donations may be made in kind and/or in cash for the purpose of enabling an organization to carry on its general activities or continue the projects it has undertaken. Charitable and prestige donations must in no way be linked, in the past, present or future, to the use of Members' products or services.

Donations to associations, foundations and institutions established by, or involving, HCPs and intended to provide healthcare services or to support such services, that conduct education or research, and that are authorized to receive donations under applicable legislation, and to public-owned healthcare institutions and organizations, may be made only if the following conditions are met:

- Carry at least one of the purposes of supporting scientific research, education or patient care, or the provision of a specific public health service.
- Obtain prior approval from the administration to which the institution or organization receiving the donation is affiliated.
- Sign a written contract documenting the terms and conditions of the donation with the institution or organization that will accept the donation.
- Document and record the donation by the donor Member.
- Obtain a delivery receipt showing that the donation was received by the recipient and credited to its account.
- Not be aimed at promoting the recommendation, prescription, purchase, sale, distribution, promotion or use of a device.
- Not give rise to any unethical practice that may be associated with device sales.
- Not influence device tender decisions.
- Be intended for the general use of the recipient and not solely for the use of an individual.
- If the donation is in cash, be made by direct bank transfer to the bank account of the requesting party in the name and on behalf of the recipient.
- Not be made to any institution or organization upon the direct request of an HCP. The only exception to this is where the HCP is an employee or representative of the institution or organization that will receive the donation, and the donation request is made in writing on behalf of the relevant institution or organization.

b. Donations in clinical research

Donations of devices, laboratory kits and similar items intended for use in clinical research must be made directly to the investigator responsible for the clinical research. All clinical research donation requests from potential donation beneficiaries must be in writing, and such request must detail the type, nature and objectives of the research activity, the targeted programme and budget, and the approximate duration of the research. Considering that the requesting researcher is at all times responsible for compliance with local laws and regulations, the donation request for a specific research project may be evaluated by the Member prior to ethics committee approval.

In this regard, where permitted by laws, regulations and the code of ethics, Members may provide financial and in-kind aid for documented expenses or provide free devices in order to support the clinical research activities of HCPs. All requests for clinical research must be made in writing by the applicants, specifying the nature and purpose of the research activity. No donation must be made until a written contract has been signed by the donating Member and the institution or organization receiving the donation, and such written contract must include the reporting of adverse event notifications. Appropriate disclosure regarding the donation must be made to the hospital management, the HCP's manager and other authorized institutions, and in all oral or written presentations of the results by the recipient, the donation support of the Member to the research must be required to be acknowledged.

c. In-kind donations

Donations may also be made in kind. To the extent possible and practicable, the Member must determine the amount of the in-kind contribution and quantitatively express its value in the donation contract.

The basic principle in the valuation of in-kind contributions must be the cost to the Member; to the extent possible and practicable, logistics, documentation and training costs must also be included in this value.

Cash payments to a third party who will provide an in-kind donation also fall within the scope of in-kind donation.

All in-kind donations must comply with the principles set out in the code of ethics and must serve at least one of the purposes defined in legislation.

The following examples are considered as in-kind donations:

- Goods such as computers, furniture, electronic equipment, X-ray protective clothing, masks and office equipment;
- Services such as photocopying, administrative services, access to digital platforms (Zoom, Teams, etc.);
- Members may provide skills and resources requiring expertise such as technical support, analysis or studies; however, such support must be intended only for the conduct of educational activities.
- Member products: commercially saleable products, reusable training products and equipment that may be returned to the Member after use.

The following examples cannot be considered as in-kind donations:

- Free samples and demonstration products
- Products or services provided as part of a commercial agreement (for example, samples that must be provided pursuant to a public tender procedure)
- Products and services that may be used in clinical activities

7. Educational Aid for Persons Who Are Not Healthcare Professionals

In addition to donations to Healthcare Institutions and Organizations as described above, Members may provide aid to persons who are not HCPs for the advancement of medical science and education. However, the support of such programmes or events by Members must not be of a nature that promotes a price preference, particularly the recommendation, prescription or purchase of products or services provided to customers, or that influences medical device tender decisions. Therefore, Members must retain documentation regarding all aid provided, and the aid must be entered into the official records of the recipient. Aid must in no way be linked, in the past, present or future, to the use of Members' products or services.

Aid must be provided only to institutions and organizations authorized to receive such aid under applicable laws and regulations and, in accordance with the principles in Article III, no personal donations must be made. Aid may be provided to support professional educational scholarships at educational institutions such as universities and educational professional organizations. The selection of the scholarship recipient must be left to the discretion of the recipient organization or educational institution, and Members must not direct in any way who the scholarship is awarded to.

8. Advertising

Members may advertise devices permitted under applicable legislation. Such advertisements must comply with the principles set out in applicable legislation.

Where Members use “Data on File” in advertisements, statements must be included indicating that the accuracy of such information can be evidenced and that this information has been verified through their own research.

9. Use of Digital Media and Social Media

The promotion of medical devices may be conducted only on digital channels accessible solely to HCPs and to technical personnel working in the field of medical devices within healthcare institutions and organizations, and on which the scientific references related to the promoted product are clearly stated.

Members may carry out corporate advertising on social media.

Members may open information platforms aimed at raising awareness about disease on social media and may advertise these platforms. Device promotion must not be carried out on these platforms.

Members may set up disease awareness pages on which the purpose of the page is clearly stated, on which device names do not appear, no device promotion is made, and which contain no message, news or image that could be associated with device promotion. Members must clearly indicate that they are sponsors of these pages.

On websites and social media accounts intended for patients, colors, logos or images relating to the brand of devices that cannot be advertised may not be used if they are of a nature that would lead patients to associate them with the device.

Where free-text comment boxes (comment areas) are used on pages owned by, or under the content control of, Members, these areas must be managed on a current basis and assessed based on general advertising criteria.

Members may not support web-based online channels to which anyone may freely contribute content and where the compliance of the content with the standards set out in the relevant legislation and code of ethics cannot therefore be controlled.

10. Promotion

a. Scope of Promotion

Promotion includes all information-providing activities to be carried out toward HCPs or technical personnel working in the field of medical devices within healthcare institutions and organizations regarding the scientific and medical features of devices. Promotional activities to be conducted by Members must be carried out within the framework of applicable legislation and Good Promotional Practices.

The following activities fall within the scope of promotion and must be carried out only toward HCPs or technical personnel working in the field of medical devices within healthcare institutions and organizations:

- Sales and promotion staff visiting HCPs or technical personnel working in the field of medical devices within healthcare institutions and organizations to provide information on subjects such as the application and instructions for use of the device; distributing Promotional Materials to such persons during these visits.
- Providing information with a demo device
- Placing advertisements in medical and professional books and journals.
- Making announcements via direct mail, the press or other communication channels.
- Organizing or supporting scientific meetings or educational activities.
- Setting up stands at Scientific Meetings or holding activities in the foyer area.
- Distributing free samples.

The following activities fall outside the scope of promotion and must not be used for promotional purposes:

- Commercial practices including pricing, discounts to distribution channels, payment terms or other sales conditions.
- Corporate information and presentations, provided they do not contain any claim or assertion regarding devices.
- Information and explanations to the general public regarding human health or diseases, provided they do not contain any direct or indirect information or reference to devices.
- Clinical support activities and technical service services.

b. Promotional Materials

All promotional materials used by Members' sales and promotion staff during promotion and/or left with HCPs or technical personnel working in the field of medical devices within healthcare institutions and organizations must comply with applicable legislation.

Promotional materials must be designed in such a way as to enable HCPs to form their own opinions independently regarding the therapeutic and diagnostic value of the device being promoted.

The following materials are considered promotional materials:

- Printed materials such as books, booklets and brochures containing sufficient and necessary information about devices,
- Films and slides,

- Visual or audio materials presented via storage devices such as flash drives and CDs/DVDs,
- Any publication that may be used by relevant audiences as a source of information, data or reference,
- Demo devices,
- Free samples,
- Programmes and materials for patient education,
- Reminder visit materials.

Members may from time to time provide HCPs with reminder visit materials of symbolic value, provided they comply with the monetary limitations set out in laws and regulations and with the code of ethics. Reminder materials must be related to the professional practice of HCPs. Cash or cash-equivalent reminder materials may not be given.

c. Free Samples

The provision of “free samples” to HCPs for trial and evaluation purposes can benefit patients in many ways. This includes the improvement of patient services, the facilitation of safe and effective use of products, the increase of patient awareness and the education of HCPs in connection with the product.

Products provided to HCPs for trial and evaluation purposes may include single-use and multi-use products. Such products may be provided to HCPs free of charge so that they may evaluate the appropriate use and functionality of the product and decide whether to use the product and when. Products provided for trial and evaluation purposes are foreseen to be used in the provision of patient services.

In particular under the provisions of the Regulation on the Sale, Advertising and Promotion of Medical Devices and its associated guidelines, devices that do not comply with applicable legislation, or that are not of a nature and/or quantity compliant with the limitations introduced under the relevant legislation, may not be provided as free samples.

Members may provide free of charge devices and accessories that must necessarily accompany the use of medications — such as infusion pumps, insulin pens, needle tips, catheters, adapters, transfer sets and similar peritoneal dialysis ancillary materials, self-monitoring blood glucose systems — and application lenses. Such devices are not considered Free Samples, nor is the training provided for their use considered device promotion. Members must keep records of who is provided with such devices and materials supplied in this way and the quantities. In this regard, application lenses and lenses to be given free of charge may be provided only to physicians specialized in the field of ophthalmology.

d. Demo (Demonstration) Products

Demonstration products are products used to raise the awareness level of HCPs and to provide training and/or information regarding the operation and application of the device. To provide HCPs with more practical information, Members may leave a demonstration product, provided that it complies with applicable legislation. Demonstration products must not be used for any clinical application in terms of patient care, and must not be the subject of sale or transfer.

It must be indicated on the demonstration products and/or on the document accompanying the product that they are suitable only for use as demonstration products, with descriptions such as “Demonstration Product” printed on the product or its packaging. It is prohibited to provide demonstration products to HCPs in any way for commercial purposes that exceed the abovementioned purpose, or to substitute, even temporarily, the actual product. Members must take the necessary measures to ensure that demonstration products are not used for commercial purposes and must ensure the return of the demonstration product when required. Documentation must be provided alongside the demonstration products given to HCPs indicating that the evaluation and demonstration products are free of charge.

e. Principles and Bases of Promotion

It is possible to carry out the promotion of a device even before its placement on the market following its registration and approval in the Product Tracking System (UTS).

If the device's UTS registration and approval has not yet been completed, the device may be displayed at locations such as commercial fairs and exhibitions, provided it bears a sign clearly indicating that the relevant device has not been placed on the market and cannot be put into service, and provided it complies with the requirements of applicable legislation.

No promotional activity may be carried out in a way that may damage or threaten the safety of patients, users or environmental health.

Within the framework of good promotional practices, devices may not be promoted by means such as draws, games of chance or similar means where success depends on probability.

Posters or other materials containing device promotion that may be considered promotional materials may not be placed, hung or affixed at any Healthcare Institution or Organization. However, posters and similar promotional materials to be used in campaigns conducted by the Ministry of Health or its affiliated organizations for health promotion purposes such as vaccination campaigns, epidemic diseases, the fight against smoking and obesity are not considered within the scope of this prohibition.

Promotion that may give rise to unfair competition or that is misleading may not be carried out. Misleading promotion is considered to have occurred in the following cases;

- Where features that the device does not possess are presented as if they exist, or where any false information about the device is provided.
- Where an expectation is created that success will definitely be achieved.
- Where an inappropriate statement is included indicating that no harmful effect will arise in the use of the device.
- Where false information is provided about the education, qualifications and achievements of those who manufacture, import, develop or market a device.
- Where the impression is created, contrary to the truth, that the person's general well-being will be reduced if the device is not used.

- Where the impression is given that self-diagnosis is appropriate, except for personal test devices falling within the scope of the Regulation on Medical In Vitro Diagnostic Devices.
- Where, in the promotion of the device, misleading, exaggerated or unproven information is given that would unnecessarily encourage the use of the device or could lead to unexpected risky situations, or where attention-grabbing images that are not directly related to the device itself are used.

f. Information, Claims and Comparisons Used in Promotion

- Promotion of devices to be carried out by Members must include the information required by legislation. To ensure the verifiability of all information given in promotional materials, all sources used as a basis for, or quoted in, such materials must be clearly stated. In particular, sources must be cited in accordance with the following examples:
- **Citation details for published articles: authors, title of article, journal name, year, volume, page.**
- **Unpublished congress paper abstract: authors, title of paper, name of document, location and name of congress, congress date, paper (abstract) book**
publication date.
- **For citations from the internet: title of paper, authors, name of article, web (network) site reference, date of access to the network.**
- **Unpublished data (Data on file): title of references.**
- Paper abstracts published in the abstract booklets of national and international congresses, and posters that have been allowed to be presented at such congresses, may be used as sources after the date of the congress.
- Opinions and conclusions of clinical research conducted with devices not bearing the CE mark may not be used in promotion before the research is completed or published in any scientific literature.

- Where the promotion is made through documentation prepared using citations, adaptations, tables and other visual materials taken from medicine, biomedical engineering, related sciences or professional journals or other scientific studies, such materials may be used remaining faithful to the original and/or adapted, and with full attribution of sources. If a modification to the citation is necessary, it must always be clearly stated in the promotional material that the citation, graphic or table has been adapted, modified, abbreviated or adjusted. Adaptations made must not distort or alter the meaning of the citation.
- Where Data on File is cited as a source in promotional materials, the portions of such data relevant to the claim must be made available without delay upon the request of the Ministry of Health, its affiliated organizations or the HCP. If such Data on File is being used to support a claim within the scope of promotion, it will be subject to the verifiability principle within the scope of good promotional practices. If Members do not wish to disclose such data even upon request, they must not use such data as a basis for promotion.
- The texts, images, tables, photographs and graphics used must comply with applicable legislation and the code of ethics.
- The documents used must be presented in such a way as to give a clear, accurate and balanced view on the relevant subject.
- Graphics, designs or images to be used must not direct toward an incorrect idea about the use of the device and must not contain comparisons that may be misleadingly perceived. Examples of such comparisons include statistically meaningless information, missing information, or distortion of results by using misleading scales.
- Promotion may not be carried out using images that are not directly related to the product itself and that are used solely to attract attention.
- Superlative adjectives (such as extraordinary, ultra, the most superior, most reliable, most effective, perfect, unmatched, unique, sole) may not be used unless they are verifiable.
- Comparison between different medical devices must cover “comparable features”. In comparisons, what is being defined and the limits of the comparison must be clearly stated. No additional reference is required for information and data set forth in the device's Instructions for Use registered in UTS. Side effect and adverse event information must be supported by clinical experience.

Comparisons may be made in Promotional Materials in the following circumstances.

- If they are not misleading,
- If medical devices and services targeting the same needs or purposes are being compared,
- If related, proven and meaningful features are being compared,
- If the comparisons are not used in a way that creates particular confusion,
- If they do not contain disparaging or denigrating expressions about the competing product or competing brand,
- If unfair benefit is not derived from a competitor's reputation.

11. Market Research and Cooperative Research

a. Market Research:

Within the scope of research whose principal purpose is to provide information for the development processes or marketing activities of devices or to evaluate potential promotional messages, information may be systematically collected from HCPs, patients or consumers.

All activities falling within the scope of the Regulation on Medical Device Clinical Research, patient experience programmes, and other studies conducted to evaluate the safety or efficacy of a device are not considered within the scope of "Market Research".

Promotional activity may not be carried out during market research, and market research is an activity that does not have a promotional purpose. Such studies are conducted for the purpose of collecting information about the company's product or competing products.

When conducting market research, the company's name may not be disclosed in order to maintain the integrity of the research, but it must always be stated that the research is being conducted at the request or with the support of a medical device company.

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

b. Cooperative Research:

Where necessary and to the extent permitted by local laws and regulations, Members and non-industry stakeholders may cooperate to develop and/or conduct scientific research, provided there is a legitimate purpose.

Cooperative research may be conducted before, during or after the licensing of a drug, medical technology, therapy or related service. Each cooperation partner must provide significant skill, experience and/or resources of a complementary nature to the cooperation, and must actively contribute to the study; for example, study objectives and design, methodology, protocol development, conduct of the study, statistical analysis plan, clinical study report and publication. Before commencing research collaborations, it is critical for Members to consider review and approval/authorization processes, the necessary review criteria, budgeting and contracting processes, permitted interactions during the conduct of the research and other relevant matters.

Elements that fall within and outside the scope of the cooperation must be identified in such a way as to clearly demonstrate why a research project is considered cooperative research.

All arrangements for cooperative research conducted by a Member must be set out in a written agreement in which roles and responsibilities are transparently defined in accordance with the study protocol. Examples include identification of the study sponsor, intellectual property ownership, financial support, transparency of the parties' involvement, reporting, rights over data, publication registry, adverse event notification procedures and dispute resolution.

Members must ensure that the pooling of skills, experience and/or resources of all cooperation partners is clearly stated in the cooperative research agreement. All activities falling within the Member's area of responsibility must be performed in accordance with applicable national laws and regulations and the requirements of the Code of Ethics.

6. PUBLIC DISCLOSURE OF TRANSFERS OF VALUE



1. Scope

The rules on public disclosure of transfers of value set out below apply to Members' interactions with Healthcare Institutions and Organizations registered in the MedTech Europe Geographical Area.

Different organizations belonging to the same multinational company ("Affiliated Companies") (which may be the parent company (e.g. headquarters, head office, or controlling company of a commercial business), a subsidiary or any other company or organization) are considered as a single company, and each of these organizations has undertaken to comply with the public disclosure rules on transfers of value of the code of ethics.

Support and donations made for Scientific Meetings Organized by Third Parties are included within the scope of public disclosure of transfers of value. There is no obligation to publicly disclose other transfers.

Where rules equivalent to the public disclosure obligations set out in the Code of Ethics provide for the public disclosure of transfers of value under national laws, regulations or professional rules, Members are not required to publicly disclose the same information twice.

2. Public Disclosure Obligation

Subject to the requirements for public disclosure of transfers of value, each member shall document and publicly disclose all payments related to Scientific Meeting support and donations made to Healthcare Institutions and Organizations established or registered in Europe/Turkey, without any limit on amount.

The disclosure of transfers of value described above but not registered in the MedTech Europe Geographical Area, made by Affiliated Companies of a Member, shall be made by the Member registered in the MedTech Europe Geographical Area.

3. Aggregate Public Disclosure

Transfers of value will be publicly disclosed in aggregate. Each member shall, for each separately identified recipient, disclose transfers of value paid to the recipient during the Reporting Period that fall under one of the categories listed below. The amounts paid must be publicly disclosed grouped under the categories listed below. However, a detailed disclosure must be made available so that it can be provided upon request from (i) the relevant recipient or (ii) the relevant authority.

Members shall disclose the total amount of transfers of value made in the categories specified below:

- A. Support for Scientific Meetings Organized by Third Parties (including HCP Educational Support for Scientific Meetings Organized by Third Parties)
- B. Donations to Healthcare Organizations (including Scholarships and/or Support for Public Awareness Campaigns)

4. Optional Statement of Purpose

If desired by Members, the purpose of the publicly disclosed educational aid and donation may be specified.

5. Methodology

Each Member shall prepare a note summarizing the methodology used in preparing the disclosure of transfers of value and how each transfer of value has been categorized within the categories described in Article VI.3 as (A) and (B). A sample of this note is attached in English at the end of Annex-1 of the Code of Ethics.

This note, containing a general summary and/or country-specific considerations, must describe the identification methodologies applied and, to the extent applicable for the purposes of the public disclosure provisions of the Code of Ethics, must include VAT and other tax elements, currencies and other matters relating to the timing and amount of transfers of value. This methodology note shall be provided by Members upon the request of any relevant person.

6. Transfer of Value Public Disclosure Form

6.6.1 Reporting Period

Public disclosure of transfers of value shall be made annually, and a reporting period shall cover a full year.

6.6.2 Time of Public Disclosure

Public disclosure shall be made by each Member within 6 months following the end of the relevant reporting period.

6.6.3. Time of Publication

Public disclosure becomes accessible to the public upon publication. The publication time is 31 August of the year in which the relevant public disclosure time falls.

6.6.4 Public Disclosure Template and Language

For consistency, public disclosures made under the Code of Ethics shall be made in English using the template specified in Annex-2.

6.6.5 Public Disclosure Platform

Public disclosure shall be made by Members on the Ethical MedTech website. Members are responsible for the accuracy of the data disclosed. ARTED or MedTech Europe cannot be held responsible for

(i) the protection, correction or deletion of published data or (ii) the retention of the data for three years following public disclosure.

6.6.6. Retention and Modification of the Public Disclosure

Members may make modifications or corrections to the public disclosure or delete information before or after the publication of the public disclosure. Public disclosures will remain accessible to the public for three years from publication.

6.6.7 Investigations Concerning Public Disclosures

Members shall, at any time during which the public disclosure is accessible to the public, provide the relevant data to the Healthcare Organization upon request from the relevant Healthcare Organizations for any data publicly disclosed in connection with their joint contractual relationships.

7. OBLIGATIONS REGARDING THIRD PARTY INTERMEDIARIES



Third Party Intermediaries means any legal or natural person that markets, sells, promotes or otherwise delivers Members' products or related services to end users. Distributors, wholesalers, distribution or sales agents, marketing agents, brokers, commercial agents and independent sales representatives fall within the scope of Third Party Intermediaries.

Members must be aware that they may be responsible for the activities of Third Party Intermediaries who interact with HCPs or healthcare organizations in connection with sales, promotion or other activities involving Members' products and/or services.

Accordingly, to the extent permitted by legislation, Members must include in the contracts they sign with Third Party Intermediaries a provision regarding the requirement to comply with the Code of Ethics and must provide appropriate oversight to ensure that Third Party Intermediaries duly apply the Code of Ethics.

Before establishing a relationship with Third Party Intermediaries, Members must conduct a risk-based pre-engagement and due-diligence process to identify, prevent and mitigate the risks associated with the market in which the Third Party Intermediaries operate. Members must also conduct due diligence during the performance of the contract and in any case where required by local laws and regulations, in order to continuously update all information related to Third Party Intermediary activities.

Members must update training materials accordingly, taking into account these standards regarding the engagement of and training for Third Party Intermediaries. Therefore, Members must conduct a current assessment of the training needs of all Third Party Intermediaries from whom they obtain services, and ensure that Third Party Intermediaries are regularly trained on new rules, requirements and standards regarding the activities they conduct on behalf of Members. For example, Members must provide Third Party Intermediaries with access to relevant training materials.

Contracts entered into by Members with Third Party Intermediaries must include provisions requiring the application of the Member's anti-corruption policy and providing adequate controls in respect of such application. A few provisions that may be included in the contracts in this regard are set out below:

Compliance with applicable laws, sector or professional rules, principles of good practice and member policies;

The right to conduct independent audits, including, where possible, access to the relevant books and records;

The right of early termination on grounds of failure to comply with applicable laws, sector or professional rules, principles of good practice and/or member policies.

Members must, where applicable, exercise reasonable efforts to conduct routine monitoring, auditing or other assessments to verify the compliance of Third Party Intermediaries with applicable laws, sector and professional rules, principles of good practice, the Member's internal policies and the relevant contract terms. They must request regular confirmation of the compliance of Third Party Intermediaries with applicable laws, sector and professional rules, principles of good practice, the Member's internal policies and the relevant contract terms.

In the event that a Third Party Intermediary fails to comply with applicable laws, sector or professional rules, principles of good practice, Members' internal policies and/or applicable contract terms, or fails to comply with any agreement, Members are recommended to take the necessary and appropriate corrective measures consistent with applicable local laws.

ANNEX-1: SAMPLE METHODOLOGY NOTE

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: SAMPLE PUBLIC DISCLOSURE TEMPLATE

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

ANNEX-3 WHEN IS CVS REVIEW REQUIRED?

		ÖNCEDEN CVS BAŞVURUSU			
		MEDTECH EUROPE COĞRAFI ALANINDA		MEDTECH EUROPE COĞRAFI ALANI DIŞINDA	
ÜYE FİRMALAR, ÜÇÜNCÜ TARAF LARCA DÜZENLENEN EĞİTİM ETKİNLİKLERİNE NE TÜR DESTEKLER SAĞLAYABİLİR?		<u>ULUSAL</u> Yalnızca yerel SMM olan katılımcıların katıldığı Üçüncü Taraf larca Düzenlenen Eğitim Etkinlikleri)	<u>ULUSLARARASI</u> (MedTech Europe Coğrafi Alanında yer alan en az iki ülkeden gelen katılımcıların katıldığı Üçüncü Taraf larca Düzenlenen Eğitim Etkinlikleri ^{1,2})	<u>ULUSLARARASI</u> (MedTech Europe Coğrafi Alanında kayıtlı ve faaliyet gösteren Sağlık Mesleği Mensupları olan Katılımcıların katıldığı Üçüncü Taraf larca Düzenlenen Eğitim Etkinlikleri ³)	<u>ULUSLARARASI</u> (MedTech Europe Coğrafi Alanında kayıtlı ve faaliyet gösteren hiçbir Sağlık Mesleği Mensubunun konuşmacı veya katılımcı olarak katılmadığı, Üçüncü Taraf larca Düzenlenen Eğitim Etkinlikleri)
ÜÇÜNCÜ TARAF LARCA DÜZENLENEN KONFERANSLARI DESTEKLEM EK İÇİN SAĞ LANAN EĞİTİM HİBELERİ ⁴	Konferansın genel işleyişini desteklemek amaçlı Eğitim Hibesi	CVS onayı gerekli değildir, ancak Kurallar ve yerel yasalar ve düzenlemeler yine de geçerlidir	CVS kararna tabidir	İzin verilir. CVS kararna tabi değildir	Kuralların uygulama kapsamı dışında ⁵
	SMM lerin konferansa katılımını desteklemek için fonlar içeren Eğitim Hibeleri	CVS onayı gerekli değildir, ancak Kurallar ve yerel yasalar ve düzenlemeler yine de geçerlidir	CVS kararna tabidir	CVS kararna tabidir	Geçerli değil
	Eğitim uzmanlarını desteklemek için fonlar içeren Eğitim Hibeleri	CVS onayı gerekli değildir, ancak Kurallar ve yerel yasalar ve düzenlemeler yine de geçerlidir	CVS kararna tabidir	İzin verilir. CVS kararna tabi değildir	Geçerli değil
TİCARİ FAALİYETLER	Uydu sempozyumlarında konuşmacılar için danışmanlık anlaşmaları	CVS onayı gerekli değildir, ancak Kurallar ve yerel yasalar ve düzenlemeler yine de geçerlidir	CVS kararna tabidir	İzin verilir. CVS kararna tabi değildir	Geçerli değil
	Üye Firma Temsilcilerinin Katılımı	Üye Firma, Kuralların ilkelerine karşı önceden dahili inceleme yapmalıdır	Üye Firma, Kuralların ilkelerine karşı önceden dahili inceleme yapmalıdır	Üye Firma, Kuralların ilkelerine karşı önceden dahili inceleme yapmalıdır	Üye Firma, Kuralların ilkelerine karşı önceden dahili inceleme yapmalıdır
	Standlar/reklam	CVS onayı gerekli değildir, ancak Kurallar ve yerel yasalar ve düzenlemeler yine de geçerlidir	CVS kararna tabidir	İzin verilir. CVS kararna tabi değildir	Üye Firma, Kuralların ilkelerine karşı önceden dahili inceleme yapmalıdır
MEDTECH EUROPE COĞRAFI ALANINDA KAYITLI VE FAALİYET GÖSTEREN SAĞ LIK MESLEĞ İ MEN SUP LARININ DOĞ RU DAN SPONSORLU Ğ U	Katılımcı olarak Sağlık Mesleği Mensuplarının doğrudan sponsorluğu (pasif katılım)	İzin verilmez	İzin verilmez	İzin verilmez	Geçerli değil
	Eğitim uzmanı olarak Sağlık Mesleği Mensuplarının doğrudan sponsorluğu (aktif katılım)	İzin verilmez	İzin verilmez	İzin verilmez	Geçerli değil

1) MedTech Europe Coğrafi Alanı, Avrupa Ekonomik Alanında (AEA) yer alan ülkeler ve Üye Derneklerin bulunduğu yerlerdeki diğer ülkeleri kapsar.

2) Daha önce "Sınır ötesi etkinlikler" olarak adlandırılmaktaydı.

3) Züpheye mahal vermemek adına, 2018 yılında, "MedTech Europe Coğrafi Alanında kayıtlı ve faaliyet gösteren Sağlık Mesleği Mensupları olan Katılımcıların katıldığı Üçüncü Taraf larca Düzenlenen Eğitim Etkinlikleri" kategorisi, yalnızca MedTech Europe Coğrafi Alanından Eğitim Hibesi alan Sağlık Mesleği Mensuplarını kapsadığı şeklinde anlaşılmıştır.

4) Eğitim Hibeleri: Üye Firma ürünlerinin veya üçüncü taraf ürünlerinin veya diğer aynı nitelikli desteklerin, Üye Firma tarafından veya Üye Firma adına, yalnızca Üye Firmasının ilgilendiği ve/veya faaliyet gösterdiği tedavi alanlarıyla ilgili klinik, bilimsel ve/veya sağlık konularında Sağlık Mesleği Mensuplarının, hastaların ve/veya halkın gerçek toplu eğitimini desteklemek ve ilerletmek amacıyla Sağlık Kurumuna sağlanması anlamına gelir ve bu tür destekler yalnızca bu kategori içinde belirtilen belirli bir amaç için sağlanır.

5) Kapsam Dışı: Üye Firmasının MedTech Europe Coğrafi Alanında kayıtlı, faaliyet gösteren ve/veya çalışan bir SMM veya SK ile etkileşimde bulunmaması ve faaliyetin MedTech Europe Coğrafi Alanında gerçekleştirilmesi durumunda Kuralların uygulanmayacağı anlamına gelir.

GLOSSARY AND DEFINITIONS

Fair Market Value: Refers to the value of the specified services (or products, if applicable) that the Member would pay to the other party (e.g. an HCP or a Healthcare Institution), in circumstances where each is transacting on equal terms in an open and unrestricted market, neither party is under any obligation to buy or sell, and both parties have reasonable knowledge of the relevant facts.

Free Samples: Refers to single-use or multi-use products provided free of charge by or on behalf of a Member to Healthcare Organizations or HCPs that have the equipment and qualifications to use them, in order for HCPs to become familiar with the products in clinical use. The phrase “Free promotional sample, not for sale.” appears visibly on at least one surface of the outer packaging of free samples. Where it can be printed, this information is also included identically on the inner packaging.

Samples do not include:

- Promotional Materials;
- Products provided free of charge under a donation or under research or educational support;
- Products that are included in the total purchase price as part of a commercial supply agreement and for which no additional charge is made, for example, replacement products provided as part of an agreed discount agreement or under a warranty agreement.
- Manufacturers or importers may provide free of charge devices and accessories that must necessarily accompany the use of medications — such as infusion pumps, insulin pens, needle tips, catheters, adapters, transfer sets and similar peritoneal dialysis ancillary materials, self-monitoring blood glucose systems — and application lenses. Such devices cannot be considered within the scope of Free Samples, nor can the training provided for their use be considered as device promotion.
- Samples requested to be supplied in device tenders are not considered as free samples.

Conference Vetting System (CVS): Refers to the centralized decision-making process administered, independently of MedTech Europe, under the supervision of the MedTech Europe Compliance Panel, which examines the compliance of Educational Events Organized by Third Parties with the Code. For more information, see: <https://www.ethicalmedtech.eu/>

Conflict of Interest: A situation where a person or institution has personal, financial or other secondary interests that may affect (or may be perceived to affect) their professional decisions, responsibilities or impartiality.

- **Educational Support:** Means the provision by or on behalf of a Member of Member's products, third-party products or other in-kind support to a Healthcare Institution, solely for the purpose of supporting and advancing genuine medical education of HCPs, patients and/or the public on clinical, scientific and/or healthcare topics related to the therapy areas with which the Member is involved and/or in which the Member operates, with such support being provided only for a specific purpose specified within this category. Under the MedTech Europe Code of Ethical Business Practices, this is regulated under the heading "Educational Grant", and within the framework of our local legislation, it is addressed within the scope of support for scientific meetings.
- **Entertainment:** Entertainment includes, but is not limited to: events where dance or live music is in the foreground, city tours, theatre tours, sporting events (e.g. skiing, golf or football matches) and other entertainment events. For the avoidance of doubt, background music will not be considered within the scope of entertainment.
- **Honorarium:** Honorary speaker payments made to HCPs for participation as a speaker or for the presentation of a written/oral paper.
- **Image and Perception Principle:** Refers to the obligation of Members to consider the public reputation, credibility and professional perception of the medical technologies industry in all their interactions with HCPs and Healthcare Institutions, and to ensure that these interactions are conducted within an ethical, transparent and professional framework.
- **Employer Notification:** Means a prior written notification to the Healthcare Institution (e.g. hospital management), the manager to whom the HCP reports, or other authorities locally designated, regarding any interactions, cooperation or other matters involving any Member and any HCP that must be notified under the Code of Ethics.
- **Participant:** Refers to HCPs other than those participating in any Scientific Meeting or Educational Activity as a training expert or as HCPs providing services to Members for a specific event.

- **MedTech Europe Geographical Area:** Includes the countries within the European Economic Area (“EEA”) and other countries in the locations where member associations are based.
- **Legitimate Business Need:** Refers to a current and actual business objective pursued by the member, such as the development of medical education, clinical research and/or the safe and effective use of the member's medical technology. Establishing a relationship with an HCP or Healthcare Institution with the purpose of directly or indirectly influencing the prescription, recommendation, purchase, ordering, supply, use, sale or rental of medical technologies or related services is never considered a Legitimate Business Need.
- **Healthcare Institution or Organization:** Refers to any public or private legal entity or institution (whatever its legal or organizational structure) that is a Healthcare Institution, medical or scientific association or organization that may have a direct or indirect influence on the prescription, recommendation, purchase, ordering, supply, use, sale or rental of medical technologies or related services. Examples include hospitals or group purchasing organizations, clinics, laboratories, pharmacies, research institutions, universities or other educational institutions, or scientific or professional communities, unions and associations operating in the field of health, foundations and non-governmental organizations established for the protection and promotion of health, or institutions where one or more HCPs provide services.
- **Healthcare Professional or HCP:** Means a physician, dentist, pharmacist, nurse, midwife and other professionals defined in additional Article 13 of Law No. 1219 dated 11/4/1928 on the Manner of Practice of Medicine and its Branches and in the Regulation on the Job and Duty Definitions of Healthcare Professionals and Other Professionals Working in Health Services published in the Official Gazette dated 22.05.2014 and numbered 29007.
- **Sales and other business meetings:** Refers to any Member event organized for the purpose of conducting the sale and/or promotion of Members' medical technologies and/or related services. These events also include meetings where product features, advantages and use, and/or commercial supply terms are discussed.
- **Promotional Materials:** Refers to printed materials such as books, booklets and brochures containing sufficient and necessary information about devices; films and slides; visual or audio materials presented via storage devices such as flash drives and CDs/DVDs; any publication that may be used as a source of information, data or reference by relevant audiences, Free Samples, Demo devices, programmes and materials for patient education; reminder visit materials — such as pens, pen holders, notepads and calendars — the monetary value of which does not exceed 2.5% of the applicable monthly gross minimum wage.

- **Demonstration Products (Demo Device):** Products used to raise the awareness level of HCPs and to provide training and/or information regarding the operation and application principles of the device, which are prohibited from being used for clinical application, patient care, sale or transfer.
- **Satellite Symposium:** A satellite symposium is a scientific/professional presentation that is part of the official programme of an event organized by third parties, does not focus on the promotion of a specific product, the content of which is the responsibility of the Member, is open to all event participants, bears the Member's brand and through which the Member can carry out promotion to its own customers.
- **Third Party Intermediary:** Means any legal entity or person that markets, sells, promotes or otherwise delivers Members' products or related services to end users, and includes distributors, wholesalers, distribution or sales agents, marketing agents, brokers, commission-based commercial agents and independent sales representatives.
- **Scientific Meeting Organized by Third Parties:** Refers to domestic or international congresses, symposia, workshops, seminars, courses and meetings organized by the Ministry, national and international specialist associations, healthcare institutions and organizations, universities, professional organizations of physicians/dentists/pharmacists or sales centers for the purpose of providing information on a scientific subject to HCPs and to technical personnel working in the field of medical devices within Healthcare Institutions and Organizations.
- **Scientific Meeting Organized by Members:** Refers to domestic or international congresses, symposia, workshops, seminars, courses and meetings organized by sales centers for the purpose of providing information on a scientific subject to HCPs and to technical personnel working in the field of medical devices within Healthcare Institutions and Organizations.
- **Educational Activities Organized by Members:** Refers to training and information-sharing meetings, which may also include the promotion of medical devices, organized by medical device sales centers for HCPs and technical personnel working in the field of medical devices within Healthcare Institutions and Organizations.
- **Member/Members:** Refers to natural or legal persons who are members of ARTED.
- **Web-Based Educational Activity/Scientific Meeting:** Refers to meetings such as online seminars, video conferences and similar that, under legislation, can be viewed over the network. These meetings are events Organized by Third Parties or by a Member, characterized solely by the participation of HCPs participating remotely.

QUESTIONS AND ANSWERS

The questions and answers in this section are quoted from the MedTech Code based on the most common examples encountered in the industry.

Q1: May Members organize an event at, or support an event at, a hotel or holiday resort that offers significant entertainment activities such as golf, casinos or skiing/water sports?

A1: In principle, no. It is not appropriate for Members to organize events at, or to support events held at, hotels or holiday resorts known for entertainment activities or focused on entertainment and sports activities such as golf, private beaches or skiing/water sports. For example, in cases where the use of the chosen venue is unavoidable due to the absence of alternative venues or the existence of genuine security concerns, exceptions may be considered for venues that are appropriately located and suitable for business meetings. In some cases, hotel accommodation being separate from the venue of a Scientific Meeting Organized by Third Parties may be necessary for compliance.

When evaluating an exceptional case, the in-house entertainment facilities of the conference venue must not appear in the event's promotional materials, and the event programme must be arranged so that participating HCPs cannot use the entertainment and sports facilities for the majority of a normal business day. In addition, if the hotel charges an additional fee for the use of entertainment or sports facilities, Members may not make such payment on behalf of HCPs. From a perception standpoint, passenger ships or hotels containing a casino are in no way appropriate as event venues or as accommodation for HCPs under these Rules.

Q2: What does “ease of access” mean under the Rules in connection with “event location and venue”?

A2: Considering where most participants are located, the event location and venue must be near an airport with appropriate international connections and/or a railway station, and there must be a reliable road transport infrastructure to access the venue.

Q3: If an HCP has a guest accompanying them at the event, may that guest attend any member event or scientific meeting organized by third parties?

A3: It is not appropriate for an HCP's guest to attend member events (including Satellite Symposia) or scientific meetings organized by third parties (unless the person attends the meeting in their own right as a participant); even if the HCP covers the guest's expenses, it is not appropriate for the guest to attend hospitality activities (e.g. lunches, industry stands and coffee breaks) during such events for the purpose of maintaining the exchange of scientific information.

Q4: How does “season” affect the assessment of an event location under the Rules?

A4: Even if a location or venue meets all other applicable requirements under the Rules, locations known as seasonal vacation or holiday locations (e.g. ski, island or beach hotels) are not appropriate for an Event during the relevant season. For this purpose, the ski season in Turkey is considered to be 1 December – 1 March and the summer season 15 June – 15 September. Similarly, other seasonally adjusted dates apply in other parts of the world. Members must not organize events in such locations, and such events must not be supported even partially, even if they take place during these seasons.

Q5: May a celebration meal or other social event be supported?

A5: No. Anniversaries, New Year's meals or similar social events cannot be supported by Members either as standalone events or as part of scientific meetings organized by third parties. For the avoidance of doubt, Members may not invite HCPs to such events with expenses covered by the Member.

Q6: Could you give examples of appropriate stand activities that will appear professional?

A6: Stand activities at scientific meetings organized by third parties must primarily aim to promote Members' medical technologies and/or related services and related literature. Therefore, other activities must be limited and reasonable, and in principle, only non-alcoholic beverages and snacks should be served.

Q7: May Members participate in scientific meetings organized by third parties that have not been deemed appropriate by the Conference Vetting System (CVS), or that have not been submitted to CVS for any reason — for example through a satellite symposium, by renting stand space, or by Members sending their representatives as participants?

A7: Refer to Annex 3 for a detailed visual on the scope of CVS and its impact on commercial activities. For the avoidance of doubt, Members' participation in scientific meetings organized by third parties offering high-value scientific content or other relevant content of objective interest to Members is in principle acceptable. Nevertheless, Members must always first review internally the compliance of any proposed participation with the principles set out in the Rules — in particular the image and perception principle — even if they are not supporting the participation of HCPs in such a Meeting.

Members must ensure that the expenditures made for the Member's participation in scientific meetings organized by third parties do not, in violation of the requirements of the Rules, provide concealed support for the participation of HCPs. For example, if the registration fees for the Member's participants are significantly higher than those of other participants, this constitutes a violation of the Rules.

Q8: May Members directly support the participation of HCPs assigned solely to speak at satellite symposia at scientific meetings organized by third parties on matters such as registration fees, travel and/or accommodation?

A8: Members must ensure that all aspects of the arrangement, including the signing of a consultancy agreement with the HCP assigned to speak at the satellite symposium, are in compliance with the Rules. Consultancy agreements may provide for payments related to travel and/or accommodation for the purpose of providing speaker services. Where registration fees must be paid in order for speakers to be able to attend satellite symposia, Members may also pay the registration fee.

Q9: How can Members in practice ensure that the educational grant is used only for Scientific Meetings Organized by Third Parties that have received a positive evaluation in CVS (where required by the Rules)?

A9: Compliance with the obligations of the Rules is the responsibility of the Members. For example, Members may consider personally submitting the relevant scientific meetings organized by third parties for CVS review, or they may decide to include in the relevant contract provisions that submission to CVS approval and a positive evaluation of the scientific meeting organized by third parties is a precondition for the educational grant.

Q10: Should the section titled Support of Scientific Meetings Organized by Third Parties (Educational Grant) also apply to public tender processes included in tender specifications by Healthcare Organizations and Procurement Bodies for the purpose of providing educational support for scientific meetings organized by third parties by Members?

A10: No. Such requests and ongoing financial or other support provided by the Member are not considered as educational grants for the purposes of the Rules. These arrangements are commercial in nature and not for charitable purposes, and must therefore be documented by a written commercial contract in accordance with normal commercial practice.

Q11: When HCPs assigned by Members as consultants or speakers do not request a professional fee for their services, is it appropriate for the Member to thank the HCP by giving a small gift such as a bottle of wine or a bouquet of flowers?

A11: No, it is not acceptable for the Member to give such a gift, as this could be misinterpreted and is highly likely to violate the Image and Perception principle. In addition, such gifts are not related to the HCP's area of practice and do not serve an educational purpose, and are therefore contrary to the rules set out in V.5.5: Prohibition on Gifts and Incentives.

