MEDAK

CODE OF ETHICAL BUSINESS PRACTICE

TABLE OF CONTENTS

INTRODUCTION

Medical Technology Industry Association of Kenya ("MEDAK") is a medical devices, imaging and diagnostics trade association representing medical technology manufacturers, distributors, and consultancies across Kenya.

The Code sets out the minimum standards appropriate to the various types of activities carried out by Member Companies. The Code is not intended to supplant or supersede supranational, national laws or regulations and professional codes (including company codes) that may impose more stringent requirements upon Member Companies. All Member Companies should independently ascertain that their activities comply with the current national and local laws, regulations and professional codes. In addition, any internal more stringent rules of Member Companies shall apply.

Member Companies should require that Third-Party intermediaries acting on behalf of the Member Companies, both sales intermediaries and other Third-Party agents, including but not limited to, consultants, distributors, sales agents, marketing agents, brokers, commissioner commercial agents and independent sales representatives, who interact with Healthcare Professionals and Healthcare Organizations in connection with the sale, promotion or any other activity involving members' products, comply with the Medak Code of Ethical Business Practice. Accordingly, where such arrangements are entered, the relevant contractual documentation must impose obligations upon the Third-Party to comply with the Medak Code of Ethical Business Practice.

Medak underlines compliance with the following laws and regulations as having relevance to the medical technology industry:

a) Safety, Quality and Performance Laws;
b) Advertising and Promotion Laws'
c) Data Privacy & Protection Laws;
d) Anti-corruption Laws;
e) Environmental Health and Safety Laws; and
f) Competition Laws.

Aims and Principles of the Code

The interaction between Member Companies and Healthcare Professionals and Healthcare Organizations is an important feature in achieving the Medak mission to make safe, innovative, and reliable technology and related services available to more people such as:

- **Advancement of Medical Technologies:**
  The development of innovative medical devices, technologies and *in vitro* diagnostics and the improvement of existing products require collaboration between Member Companies and Healthcare Professionals (as defined in the attached Glossary) and Healthcare Organizations (as defined in the attached Glossary). Innovation and creativity are essential to the development and evolution of medical technologies and/or related services often occurring outside the facilities of medical device companies.
- **Safe and Effective Use of Medical Technology**
  The safe and effective use of medical technology and related services requires Member Companies to offer Healthcare Professionals and Healthcare Organizations appropriate

instruction, education, training, service, and technical support. Regulators may also require this type of training as a condition of product approval and as per local laws.

- **Research and Education**
  Member Companies' support of bona fide medical research and education serves to enhance Healthcare Professionals' clinical skills and thereby contribute to patient safety and increase access to new technologies and/or related services.

In each such interaction Member Companies, must continue to respect the obligation of Healthcare Professionals to make independent decisions regarding treatment and safeguard the environment in which the interaction takes place to ensure the integrity of the industry. To achieve this aim, the present Code provides guidance on the interactions of Member Companies with both Healthcare Professionals and Healthcare Organizations, based upon the following underlying principles:

- **The Principle of Image and Perception**
  Member Companies should, always consider the image and perception of the medical technology industry that will be projected to the public when interacting with Healthcare Professionals and Healthcare Organizations.
- **The Principle of Separation**
  Interaction between industry and Healthcare Professionals / Healthcare Organizations must not be misused to influence through undue or improper advantages, purchasing decisions, nor should such interaction be contingent upon sales transactions or use or recommendation of Member Companies' products.
- **The Principle of Transparency**
  Interaction between industry and Healthcare Professionals / Healthcare Organizations must be transparent and comply with national and local laws, regulations, or professional codes of conduct. In countries where specific provision is not made, Member Companies shall nevertheless maintain appropriate transparency by requiring prior written notification to the hospital administration, the Healthcare Professional's superior or other locally designated competent authority, fully disclosing the purpose and scope of the interaction.
- **The Principle of Equivalence**
  Where Healthcare Professionals are engaged by a Member Company to perform a service for or on behalf of a Member Company, the remuneration paid by the Member Company must be commensurate with, and represent a fair market value for, the services performed by the Healthcare Professional.
- **The Principle of Documentation**
  For interactions between a Member Company and a Healthcare Professional, such as where services are performed by a Healthcare Professional for or on behalf of a Member Company, there must be a written agreement setting out, inter alia, the purpose of the interaction, the services to be performed, the method for reimbursement of expenses as well as the remuneration to be paid by the Member Company. The activities envisaged by the agreement must be substantiated and evidenced by activity reports and the like. Adequate documentation such as the agreement, related reports, invoices etc. must be retained by the Member Company for a reasonable period to support the need for, and materiality of, the services as well as the reasonableness of the remuneration paid.

Interpreting the Code

The use of capital letters indicates that a word or expression is a defined term, the meaning of which is set out in the Glossary. Any phrase introduced by the terms: including, include or any similar expression shall be interpreted as illustrative and shall not limit the sense of the words preceding those terms.

Administering the Code

The Code operates within a Procedural Framework herein which includes procedures designed to provide an effective and efficient complaint handling process, within the geographic scope of Medak, to ensure compliance with the Code.

The compliance committee in alignment with legal team will evaluate the mechanism for complaints between Member Companies in later stage after the transition period. The appropriate committees are encouraged to carry out the discussion during the transition period to decide on the escalation procedure at the time of implementation of this code. The Code shall be reviewed at least once every year.

Implementation and Transition Period

The code will come into force in October 2022, giving Member Companies one year probationary period to internalize this code, however Member Companies are encouraged to implement the principle of this code and applicable international, national laws and regulations including requirements from other medical devices trade associations.

PART 1: Guidelines on the Interactions with Healthcare Professionals and Healthcare Organizations

CHAPTER 1: GENERAL CRITERIA FOR EVENTS

The principles and criteria set out in this Chapter shall apply to all events supported in any way by Member Companies, irrespective of who organizes the Event.

1.1 Event Programme

1.1.1 The Event Programme should:

- Directly relate to the specialty of medical practice of the Healthcare Professional who will attend the Event or be sufficiently relevant to justify the attendance of Healthcare Professionals;
- Be available (in detail) sufficient time prior to the event;
- Present a clear schedule with no gaps during the sessions, (e.g., the minimum duration for a full day Event should be 6 hours or 3 hours for a half day Event including refreshment breaks). For the avoidance of doubt, for events lasting more than 1 day, a half day can be scheduled only on the afternoon of the first day or on the morning of the last day of the event;
- For Third-Party Organized Educational Events, the agenda should be under the sole control and responsibility of the third-party organizer; and
- For Third-Party organized Educational Events, the Faculty must be identified.

1.1.2 A Member Company shall not organize Events addressed to Healthcare Professionals which include social, sporting and/or leisure activities or other forms of entertainment, nor support such activities as part of Third-Party organized Educational Events.

1.1.3 Entertainment must be outside of the educational programme schedule and paid for separately by the Healthcare Professionals.

1.1.4 Entertainment should not dominate or interfere with the overall scientific content or the programme and must be held during times that do not overlap with a scientific session. The Entertainment should not be the main attraction of the Third-Party organized Educational Event and should not be advertised in the website/brochure of the event

1.1.5 It is also important that all supporting materials (e.g. flyers, brochures, and website) are consistent with the scientific or promotional nature of the programme content. The content of the supporting materials must focus on the scientific nature of the Event and should not emphasize on the venue and/or location of the Event.

1.2 Event Location and Venue

1.2.1 The Event location and venue should not become the main attraction of the Event. For the location and the venue, Member Companies must always consider the following considerations:

1.2.2 Potential adverse public perceptions of the location and venue for the Event. The perceived image of the location and venue must not be luxurious, tourist/holiday oriented, or that of an Entertainment venue. Events should be conducted in a clinical, laboratory, educational, conference, or other appropriate setting; including Member Companies own premises or commercially available meeting facilities, which are conducive to the effective transmission of knowledge and any required “hands on” training.

1.2.3 The Event location and venue should be centrally located considering the place of residence of most invited participants. The Event location and venue should be appropriate for hosting an Event which is conducive to the exchange of ideas and the transmission of knowledge.

1.2.4 In principle it is not appropriate for a Member Company to organize or support Events at hotels or resorts renowned for their entertainment facilities or centered around recreational or sporting activities such as golf, casinos, private beach or ski/water sports. Exceptions might be considered for venues well adapted to business meetings where there is a compelling need to use the chosen venue, for example, a lack of alternative venues or capacity or infrastructure or genuine safety or security issues. In certain circumstances, hotel accommodation separate from the Third-Party organized Event venue might be required for compliance. Where an exception is considered, the Event's promotional material should not feature the on-site leisure aspects of the conference venue as a key attraction and the Event's agenda should be arranged in such a way that attending Healthcare Professionals would not be free to make use of the leisure and sporting facilities during any significant part of a normal working day. Further, where hotels require additional payment to use the leisure or sporting facilities, Member Companies may not make such payments on behalf of the Healthcare Professionals.

1.3 Guest

1.3.1 Member Companies are not permitted to facilitate or pay for meals, travel accommodation or other expenses for Guests of Healthcare Professional or for any other person who does not have a bona fide professional interest in the information being shared at the Event.

1.3.2 The term "facilitate" refers to the prior arrangement, organization or booking of meals, travel, or accommodation by or on behalf of Member Company for a Guest of the Healthcare Professional participant. If Healthcare Professionals attending the Event wish to be accompanied by a Guest who does not have a professional interest in the information being shared, the Healthcare Professional must take sole responsibility for the payment and organization of the Guest's expenses.

1.3.3 It is not appropriate for a Guest of a Healthcare Professional to attend either Company Events (including Satellite Symposia) or Third-Party organized Educational Events (unless the individual qualifies as a participant in their own right). Furthermore, it is not appropriate for a Guest to participate in related hospitality during such Events (for example, lunches and coffee breaks) even when the Healthcare Professional pays for the Guest's expenses.

1.4 Continuous professional development (CPD) meetings

1.4.1 The principle of separation must apply. No product promotion is allowed in the CPD meeting room. Company-branded items/promotions are permissible.

1.4.2 Speakers should, in so far as possible, use the non-proprietary names of products during CPD events. Companies must make it known to speakers that the use of trade names, to promote a product, is not permitted.

1.5 Reasonable Hospitality

1.5.1 Member Companies may provide reasonable hospitality to Healthcare Professionals participating in legitimate business meetings or educational activities as described and allowed in this Code provided that any hospitality offered is subordinate in time and focus to the Event purpose.

1.5.2 Member Companies must in any Event meet the requirements governing hospitality in the country where the Healthcare Professional carries on their profession and give due consideration to the requirements in the country where the Event is being hosted.

1.5.3 The Code seeks to find a balance between the courteous and professional treatment of Healthcare Professionals by Member Companies, with the desire to avoid even the notion that hospitality may be used by Member Companies as a means to induce Healthcare Professionals to purchase, prescribe or recommend Member Companies' products.

1.5.4 Accordingly, Member Companies must assess what is "reasonable" in any given situation and regional variations will apply. As a general guideline, "reasonable" should be interpreted as the appropriate standard for the given location and must comply with the national laws, regulations, and professional Codes of conduct. The term "hospitality" includes meals and accommodation and it is important that Member Companies differentiate between "hospitality" which is permitted and Entertainment which is not. Refer to the Glossary for the definition of Entertainment.

1.5.5 Member Companies may not pay for or reimburse Healthcare Professionals' lodging expenses at inappropriate hotels as defined in point II above. For the avoidance of doubt, if the Event venue is a hotel which complies with the requirements of the Code, it would be acceptable for Member Companies to offer participants meals and accommodation at the same hotel. However, accommodation and/or other services provided to Healthcare Professionals should not cover a period of stay beyond the official duration of the Event.

1.5.6 It is not acceptable to make an advance payment (including but not limited to cash, cash equivalents, per diem or allowances) to a Healthcare Professional to cover prospective expenses. Payments should generally be made to the supplier/vendor or intermediary agency. Alternatively, Member Companies may reimburse individual Healthcare Professional expenses retrospectively against original invoices or receipts provided that any costs to be reimbursed comply with the requirements and guidelines set forth in the Code.

1.6 Travel

1.6.1 Member Companies may only pay or reimburse for reasonable and actual travel. Travel provided to Healthcare Professionals should not cover a period of stay beyond the official duration of the Event.

1.6.2 For air travel, in principle, this means that Member Companies can only pay or reimburse economy class ticket unless the flight time is of a duration equal or greater than 5 hours Airtime, in which case business class can be considered. First class is never appropriate. (Refer to the Glossary for the definition of Airtime).

1.6.3 Generally, travel and accommodation support offered by Member Companies to Healthcare Professionals should be tailored to the duration of the Event. Member Companies must always keep in mind the impression which may be created by the arrangements for any meeting

1.7 Transparency

1.7.1 Employer Notification

Member Company shall ensure full compliance with local laws regarding the disclosure or approval requirements associated with any transfer of value or financial support provided to a healthcare professional. Where no such national requirements

are prescribed, Member Companies shall nevertheless maintain appropriate transparency by requiring Employer Notification i.e. prior written notification to the hospital administration, the Healthcare Professional's superior or other locally designated competent authority.

1.7.2 Educational Grant Disclosure

Member Companies are required to follow local laws and regulations and other international standards where applicable in terms of transparency and disclosure.

CHAPTER 2: THIRD-PARTY ORGANISED EDUCATIONAL EVENTS

2.1 Third-Party Organized Educational Conferences

2.2 Conference Vetting System (CVS)

2.2.1 Member Companies are encouraged to adopt other trade associations approach in terms of centralized vetting system for 3rd party organized event. Therefore, Medak will re-evaluate the implementation of CVS (Conference Vetting System) by 2023. This section will be reviewed on annual basis based on awareness and feedback from Member Companies.

2.3 Third-Party organized Educational Events

2.3.1 Where permitted under local laws, regulations and professional codes of conduct, Member Companies may provide financial and/or in kind support to Third-Party organized Educational Events, provided that the Third-Party organized Educational Events (i.e. Booth, Sponsorship or educational grants) is meeting the criteria outlined in this code. Support maybe provided through grants and other types of funding, such as:

2.3.1.1 Educational Grants - Refer to Chapter 4: Grants and Charitable Donations for guidance on Educational Grants.

Member Companies may support Third Party Organized Procedure Training either via Educational Grants (in accordance with Chapter-X: Grants and Charitable Donations) or by providing financial support directly to individual Healthcare Professionals to cover the cost of attendance at Third Party Organized Procedure Training sessions in accordance with the following rules:

a) Must comply with the criteria provided in Chapter 1: General Criteria for Events. Member Companies may therefore pay travel, hospitality, and the registration fee.

b) Third Party organized Procedure Trainings should follow the criteria below:

- **Programme**:
  Third Party organized Procedure Trainings consist of practical, hands-on trainings, generally involving more than one provider/ manufacturer/sponsor. This must be evident by the programme of the Event. The programme, which is often referred to as a “course”, rather than a conference or seminar, must be focused on acquiring specific medical skills relevant to certain medical procedures (rather than products, or medical technologies). The programme must also include practical demonstrations (and/or actual live surgeries, where allowed).
- **Venue**:
  Third Party organized Procedure Trainings are typically organized in a clinical environment, as opposed to, e.g., a classroom setting. For the avoidance of doubts, the adjective “clinical” includes places suitable for the simulation of medical procedures, rather than just the medical treatment of real patients.
- **Stand-alone Event:**
  Third Party Organized Procedure Trainings must be stand-alone. Where the majority of the Training is not given in a clinical environment, for example, where the Training is organized in connection, adjacent to or at the same time as a larger Third Party Organized Educational Conferences that Training will not qualify as a Third Party Organized Procedure Training, as defined in the

Code i.e. direct sponsorship of Healthcare Professional without an independent decision-making/review process will not be permitted in this case.

- **Transparency**
  When meetings are sponsored by companies, other organizations or by individuals, this fact must be disclosed in the papers relating to the meetings and in any published proceedings. The declaration of sponsorship must be sufficiently prominent to ensure that readers are aware of it at the outset.
- **Promotional Activity:**
  Member Companies may purchase packages that may include promotional and advertising services, for example, advertisement space and booth space for company displays.
  Member Companies should ensure that the overall image projected by the promotional activity at Third-Party Organized Educational Events is perceived as professional always. It should never bring discredit upon or reduce confidence in the medical technology industry.
  Booth activities at Third-Party Organized Educational Events should aim primarily at displaying Member Companies' products and services and related literature therefore only refreshments should be served.
- **Satellite Symposium:**
  Member Companies may organize Satellite Symposium within Third-Party Organized Educational Events provided they are consistent with the overall content of the Event.
  Satellite symposium costs (e.g. time-slot cost) should be reflected in the "Sponsorship/Commercial" part on the event's brochure / packages and not under "Educational Grants".
  It is permissible for Member Companies to:
  - Select Speakers for their satellite symposia;
  - Speaker name at company sponsored Satellite Symposia can be shown on the agenda;
  - Directly sponsor (i.e. pay honorarium / hospitality expenses) Speakers to their satellite symposium (in compliance with the Code related guidelines (Chapter 1 "General Criteria for Events", Chapter 5 "Arrangements with Consultants" and Chapter 6 "Remuneration and Fair Market Value");
  - Where payment of a registration fee is required for the speaker to access the Satellite Symposium, Member Company may pay the registration fee related to the Satellite Symposium (most restricted package);
  - Directly enter into contractual agreements with the Speakers;
  - Member Companies can invite HCPs already attending the Third-Party Educational Event to the Company Organized Satellite Symposium provided that the Member Companies do not directly cover any cost related to Registration, Travel & Accommodation; and
  - It is not permissible for Member Companies to cover additional hospitality expenses for the Speaker of the Member Company's Satellite Symposium to attend the Third-Party Educational Event (e.g. accommodation for all the event days).

2.4 Third-Party Organized Procedure Training

2.4.1 Definition

2.4.1.1 An Organized Procedure Training is primarily intended to provide Healthcare Third-Party Professionals with information and hands-on training on the safe and effective performance of one or more clinical procedures in circumstances where the information and training concern:

- Specific therapeutic, diagnostic, or rehabilitative procedures, namely clinical courses of action, methods, or techniques (rather than the use of medical technologies); and
- Practical demonstrations and/or training for HCPs, where most of the training programme is delivered in a clinical environment.

2.4.1.2 For the avoidance of doubt, proctorship and preceptorship are not considered to constitute Third-Party Organized Procedure Training.

2.4.2 Scope

2.4.2.1 Member Companies may support Third-Party Organized Procedure Training either via Educational Grants (in accordance with Chapter-4: Grants and Charitable Donations) or by providing financial support directly to individual Healthcare Professionals to cover the cost of attendance at standalone Third-Party Organized Procedure Training, provided that all applicable conditions are met.

2.4.2.2 Training will not qualify as a stand-alone Third-Party Organized Procedure Training, if the Training is organized in connection, adjacent to or at the same time and location as a larger Third-Party Organized Educational Event that, i.e. direct sponsorship to Healthcare Professional will not be permitted in this case.

2.4.2.3 Applicable conditions:

- Standalone
  Third party Procedure Training Event must be Standalone.
- Programme
  The programme must include practical demonstrations (and/or actual live surgeries where allowed). To consider an event a TPPT, the practical sessions must in all cases represent more than 50% of the full programme with hands-on by the attendees. This requirement must be clearly indicated in the programme of the TPPT.
- Venue
  Third-Party Organized Procedure Trainings are typically organized in a clinical environment, as opposed to, e.g., a classroom setting. For the avoidance of doubts, the adjective “clinical” includes places suitable for the simulation of medical procedures, rather than just the medical treatment of real patients.
  Examples of simulation settings include conference or meeting rooms which are appropriately equipped with relevant simulation devices/systems or experimental laboratories suitable for training on cadavers, skin models, synthetic bones, live animals in accordance to applicable regulations and ethical rules, etc.

2.5 Third-Party Organized Public Awareness Campaigns

2.5.1 Event organized by HCO intended to provide information, promoting awareness and/or educating patients and the public about relevant healthcare topics or medical conditions or diseases in therapeutic areas.

2.5.2 Member Companies may participate to Third-Party Organized Public Awareness Campaign by providing educational grant (as described in chapter 4 of this Code) and/or by having a booth provided that:

- Local laws & regulations allow direct interaction with public;
- the main purpose of the booth is to share relevant healthcare topics or medical conditions or diseases in therapeutic areas;
- the participation is widely advertised, allowing other companies to participate; and
- the booth is held in a separate area than the educational session for patients.

CHAPTER 3: PROMOTIONAL ITEMS, ITEMS OF MEDICAL UTILITY, GIFTS, AND COMPETITIONS

3.1 General principles

3.1.1 There should be no personal enrichment of HCPs or other healthcare providers. No gift or benefit in kind, rebate, discount, kickback or any other monetary advantage shall be offered or given to members of the health professions, administrative staff, government officials or the general public as an inducement to prescribe, lease, loan, supply, stock, dispense, administer or buy any medical device.

- No items shall be provided to Healthcare Care Organization which can be considered as an overhead or infrastructure development.
- Be appropriately documented in the Member Company's books and records.
- Not for personal use e.g. no entertainment CDs/DVDs, electronic items for entertainment, tickets to attend sporting events or other forms of entertainment.
- Educational and/or of scientific value, benefit the patient and/or be relevant to the practice.
- No cash or cash equivalents (e.g. vouchers, airtime, or crypto currency) are allowed. Such items should not be part of the Healthcare Organization's normal overheads or routine costs of operation.
- Promotional items must be branded with Company name and/or Product and/or Logo.

3.2 Promotional items

3.2.1 A reasonable item that is provided by or on behalf of a Member company to Healthcare professional or healthcare organization and it is intended for promotional aids and/or brand reminders relating to the Company or its products such as company branded or non-branded calendars, notepads, mouse-pads, post-it notes, USB memory sticks, stationary items.

3.3 Educational Items of medical utility

3.3.1 An item that is provided by or on behalf of a Member company to healthcare organization, which has a genuine educational purpose that is intended to aid in the medical care of patients. Educational items Be related to the therapeutic areas in which the Member Company is interested / involved.

3.3.2 Items of medical utility, including, informational and educational materials, scientific medical reference books, journals, periodicals, and anatomical models intended for teaching or patient benefit.

3.3.3 Educational Items that due to their nature can only be provided to individual HCPs (such as medical journal subscriptions under HCP individual name) should be accompanied by an official HCP nomination letter issued by the HCO.

3.4 Gifts

3.4.1 Member Companies may not give gifts to Healthcare professional.

3.5 Prize draws

3.5.1 Prize draws and other competitions at Events are permissible if the prize awarded complies with Chapter Educational Items and Gifts. In addition, it must comply with national laws, regulations and industry and professional Codes of conduct.

CHAPTER 4: OTHER INTERACTIONS WITH HCPS

4.1 Educational grant

4.1.1 General principles:

- Grants and Charitable Donations shall not be contingent in any way on past, present or potential future purchase, lease, recommendation, prescription, use, supply or procurement of the Member Company's products or services. It is important that support of charitable and/or philanthropic programmers and activities by Member Companies is not viewed as a price concession, reward to favored customers or as an inducement to purchase, lease, recommend, prescribe, use, supply or procure Member Companies' products or services.
- A Member Company shall not provide Grants or Charitable Donations to individual Healthcare Professionals. Grants and Charitable Donations must be provided directly to the qualifying organization or entity.
- Grants and Charitable Donations shall not be provided in response to requests made by Healthcare Professionals unless the Healthcare Professional is an employee or officer of the qualifying organization or entity and submits the request in writing on behalf of the qualifying organization or entity. For avoidance of doubts clinics that operate sole proprietorship cannot be qualified as HCO to receive grants/donation by Member Companies.
- The payment (or provision of other support) by way of any Grant or Charitable Donation shall always be made out in the name of the recipient organisation and shall be paid directly to the organisation. A Member Company shall not provide Grants or Charitable Donations in the name of any Healthcare Professional. In addition, all Grants and Charitable Donations shall identify the Member Company as the provider of the Grant or Charitable Donation.
- It must in all cases be lawful under applicable national laws and regulations for the Grant or Charitable Donation recipient to receive and benefit from the Grant/Charitable Donation.
- Member Companies shall implement an independent decision-making/review process to identify, prevent and mitigate against potential bribery and corruption risks arising in connection with the provision of a Grant or a Charitable Donation to a specific prospective recipient.
- All Grants and Charitable Donations must be appropriately documented by the Member Company. Moreover, Grants and Charitable Donations shall only be provided in response to a written request submitted by the requesting organization or documented initiative from a Member Company containing sufficient information to permit an objective evaluation of the request to be carried out by the Member Company. No Grant or Charitable Donation shall be provided until a written agreement documenting the terms of this is signed by both parties.
- This section of the Code (Chapter 4: Grants and Charitable Donations) is not intended to address the legitimate practice by Member Companies of providing appropriate rebates, additional product and/or service offerings, including free of charge, or other comparable pricing incentive mechanisms ("value adds") which are included in competitive and transparent centralized purchasing arrangements, such as, for example, tenders.

- **Educational Grants Member Companies may provide restricted Educational Grants** (see the Glossary) for the advancement of genuine medical education. "Restricted" in this context means that Member Companies shall specify the intended purpose of the Educational Grant in the Grant agreement. A Member Company shall also ensure that the Educational Grant agreement with the recipient organization includes rights to enable it to verify that the Grant is in fact used for the agreed intended purpose.
- Member Companies shall document and publicly disclose all Educational Grants in accordance with the Code's Disclosure Guidelines, and publication shall commence no later than the end of the Transition Period. Member Companies may provide Educational Grants for the following (non-exhaustive) purposes: a. Support for Third Party Organized Educational Events: As a general principle, any Third Party Organized Educational Event supported by way of an Educational Grant from a Member Company to a Healthcare Organization must:-
  - **Support for HCP Participation at Third Party Organized Educational Events:**
    Where the Educational Grant is provided for the purpose of supporting Healthcare Professionals' attendance at Third Party Organized Educational Events, the Healthcare Organization receiving the Grant shall be solely responsible for selection of participants and this shall be expressly reflected in the written Grant agreement.
  - **Support for Third Party Organized Educational Events:**
    Where the prospective beneficiary of an Educational Grant is the organizer of the Third Party Organized Educational Event and is also a Healthcare Organization, the recipient Healthcare Organization shall be solely responsible for:
    a) The programme content;
    b) The selection of Faculty; and
    c) The payment of Faculty honoraria, if any.
    Member Companies shall not have any detailed involvement in determining the content of the educational programme for selection of Faculty (see Glossary) and this shall be reflected in the written Grant agreement. If expressly requested to do so, Member Companies may recommend speakers or comment on the programme.
  - **Scholarships and Fellowships**
    Member Companies may provide Educational Grants on a restricted basis in the form of Grants for Scholarships and Fellowships to support advancement of genuine medical education of Healthcare Professionals (see the Glossary). Only Healthcare Organizations where Healthcare Professionals are in training shall be eligible to request and/or receive such Educational Grants. A Member Company shall not provide Educational Grants to support Scholarships and Fellowships upon request of individual Healthcare Professionals. Similarly, the Member Company shall not have any involvement in any way in the selection of the HCPs who will benefit from the Educational Grant and this shall be reflected in the written Grant agreement between the Member Company and the recipient HCO.

- **Grants for Public Awareness Campaigns**

  Member Companies may also provide Educational Grants on a restricted basis to Healthcare Organizations for the legitimate purpose of providing information, promoting awareness and/or educating patients, caregivers or the general public about relevant healthcare topics or medical conditions or diseases in therapeutic areas in which the Member Company is interested and/or involved.

- **Research Grants**

  Where permitted by national laws, regulations, national guidelines and professional codes of conduct, Member Companies may provide restricted Research Grants (see the Glossary) to support clearly defined third party-initiated research studies for clinical or non-clinical research programmes in therapeutic areas in which the Member Company is interested and/or involved.

  Research Grants may include in kind or financial support for legitimate, study-related, documented expenses or services, and/or reasonable quantities of single-use and/or multiple-use free of charge product(s) for the limited duration of the research. Member Companies providing Research Grants shall ensure that they do not influence the research.

  However, in order to ensure that Research Grants are provided on a "restricted" basis, Member Companies shall clarify the intended research scope and purposes for which the Grant is requested and shall ensure that the written Grant agreement with the recipient organization includes rights for the Member Company to verify that the Grant is applied solely for the agreed intended research use.

  Such verification may include a request for study-related documentation, such as a copy of the research protocol, a copy of the ethics committee and/or regulatory approvals or a copy of the study report upon completion or earlier termination of the research. All requests for Research Grants from prospective Grant beneficiaries must

  a) be in writing; and
  b) must detail, as a minimum, the type, nature and objectives of the research activity, the milestones and budget, the approximate duration of the research, and where applicable, the requirements for ethics committee, regulatory and/or other authorizations or approvals.

  A Member Company may give consideration to a request for a Research Grant prior to ethics committee approval for the specific research project but shall not take any final decision regarding the Grant request unless and until the research receives formal ethics committee approval. Research Grant agreements shall include provisions relating to adverse event reporting where appropriate and shall require full disclosure of the Member Company and of the Grant by the Grant recipient organization and the lead-investigator in all oral or written presentations of the results.

4.2 Charitable donations

4.2.1 Charitable donations mean provision of cash, equipment, company product or relevant third-party product, for exclusive use for charitable or philanthropic purposes and/or to benefit a charitable or philanthropic cause. Charitable donations may only be made on an unrestricted basis and to bona fide charities or other non-profit entities or bodies whose main objects are genuine charitable or philanthropic purposes.

4.2.2 Charitable donations shall not be contingent in any way on past, present or potential future purchase, lease, recommendation, prescription, use, supply or procurement of the member company's products or services. It is important that support of charitable and/or philanthropic program and activities by Member Companies is not viewed as a price concession, reward to favored customers or as an inducement to purchase, lease, recommend, prescribe, use, supply or procure Member Companies' products or services.

4.2.3 Member Companies shall implement an independent decision-making/review process to identify, prevent and mitigate against potential bribery and corruption risks arising in connection with the provision of a charitable donation to a specific prospective recipient. The process shall include a documented, prior evaluation of any such associated risks and of the relevant information concerning the intended recipient organization or entity.

4.2.4 Financial donations to charities or other institutions may be made if properly recorded and approved by the responsible person(s) in each company or organization. Donations grants and benefits in kind to institutions, organizations or associations are only allowed provided:

a) They are made for supporting healthcare or research;
b) They are documented and kept on record by the donor/grantor; and
c) Donations must not be paid directly to HCPs or to healthcare administration staff.

4.2.5 Companies are encouraged to make available publicly, information about donations, grants or benefits in kind made by them as covered in this section, through press release, in their websites etc.

CHAPTER 5: ARRANGEMENTS WITH CONSULTANTS

5.1 General principles

5.1.1 Member Companies may engage HCPs as consultants and advisors to provide bona fide consulting and other services, including but not limited to research, participation on advisory boards, presentations at company events and product development. Member Companies may pay HCPs remuneration of fair market value for performing these services. In all cases, consulting arrangements must be permitted under the laws and regulations of the country where the HCP is licensed to practice and be consistent with applicable professional codes of conduct in that country.

5.1.2 The principles in this chapter are applicable to all consulting arrangements between HCPs and Member Companies including where a consultant HCP declines a fee for provision of their services.

5.1.3 Consulting arrangements shall not be contingent in any way on the prospective consultant's past, present or potential future purchase, lease, recommendation, prescription, use, supply or procurement of the member company's products or services.

5.1.4 When selecting consultants, Member Companies shall implement an internal independent decision-making/review process to identify, prevent and mitigate against potential bribery and corruption risks arising in connection with use of consultants. This process shall include a documented prior evaluation of any such associated risks and of the relevant background information concerning each prospective consultant.

5.2 Criteria for genuine consulting arrangements

5.2.1 In addition to the general principles above, the arrangements which cover genuine consultancy or other services must, to the extent relevant to the arrangement, fulfill all the following criteria:

- Consulting arrangements must be entered only where a legitimate business need for the services is identified in advance.
- The number of consultants retained must not be greater than the number reasonably necessary to achieve the identified need.
- Selection of consultants must be based on criteria directly related to the identified business need and the relevance of the consultant's qualifications, expertise, and experience to address the identified need. The volume or value of business generated by a prospective consultant or the HCO where they perform their professional activity is not a relevant criterion.
- Consulting arrangements with HCPs must be documented in a written agreement, signed by the parties in advance of the commencement of the services, which must specify the nature of the services to be provided and the basis for payment for those services.
- The hiring of the consultant must not be an inducement to purchase, lease, recommend, prescribe, use, supply or procure the member company's products or services.
- The remuneration for the services rendered must be reasonable and reflect the fair market value of the services provided.

- Member Companies must maintain records of the services, and associated work products provided by the consultant HCPs and of the use made of those services by the member company.
- The venue and other arrangements (e.g. hospitality, travel etc.) for member company meetings with consultants shall follow the rules for such arrangements as set out in Chapter 1: General Criteria for Events.

5.3 Remuneration and fair market value

5.3.1 The remuneration paid to HCPs engaged as consultants by Member Companies shall reflect fair market value for the services provided. It shall not be in any way contingent upon the value of products or services which consultants may purchase, lease, recommend, prescribe, use, supply or procure during their own professional practice or that may be purchased, leased, recommended, prescribed, used, supplied or procured by HCOs where they perform their professional activities.

5.3.2 Fair market value (FMV) definition

5.3.2.1 Fair market value is the value of the specified consultancy services which would be paid by the member company to the consultant, each dealing at arm's length in an open and unrestricted market, and when neither party is under any compulsion to buy or sell, and both parties have reasonable knowledge of the relevant facts.

5.3.2.2 A Member Company must be able to demonstrate internal methodology to determine fair market value. Amongst other matters this shall take account of the consultant's qualifications, expertise, and experience as well as the actual services to be provided to the Member Company.

5.4 Payments

5.4.1 All payments made for services must comply with all applicable tax and other legal requirements. Member Companies may pay for expenses reasonably incurred by consultants in providing the services which are the subject of the consulting agreement including reasonable travel, meals and accommodation expenses incurred by consultants if attending meetings with or on behalf of Member Companies. The written consulting agreement must detail which expenses can be claimed by the consultant in relation to the provision of the services and the basis for payment of these by the member company.

5.5 Disclosure and transparency

5.5.1 Member Companies shall ensure they fully comply with all applicable national laws, regulations and professional codes of conduct requiring any publication, disclosure, or approval in connection with their use of HCPs as consultants. All required consents and approvals shall be obtained, including from the hospital or other HCO administration or from the HCP's superior (or designated competent authority), as applicable.

CHAPTER 6: DEMONSTRATION PRODUCTS & SAMPLES

6.1 General Principles

6.1.1 Member Companies may provide their own products as Demonstration Products and/or Samples (refer to the glossary) at no charge to enable Healthcare Professionals and/or Healthcare Organizations (as applicable) to evaluate and/or familiarize themselves with the safe, effective, and appropriate use and functionality of the product and/or related service and to determine whether, or when, to use, order, purchase, prescribe or recommend the product and/or service in the future.

6.1.2 Demonstration Products and/or Samples may be either single or multiple-use products. Member Companies may also provide products from another company in conjunction with the Member Company's own Demonstration Products and/or Samples on an exceptional basis if those other company's products are required to properly and effectively demonstrate, evaluate, or use the Member Company's products, e.g. computer hardware and software produced by a company other than the Member Company.

6.1.3 Provision of Demonstration Products and/or Samples must not improperly reward, induce and/or encourage Healthcare Professionals and/or Healthcare Organizations to purchase, lease, recommend, prescribe, use, supply or procure Member Companies' products or services. Any offer and/or supply of such products shall always be done in full compliance with applicable national laws, regulations and industry and professional Codes of conduct.

6.1.4 Member Companies shall in all cases maintain appropriate records in relation to the provision of Demonstration Products and/or Samples to Healthcare Professionals and/or Healthcare Organizations, for example recording proof of delivery for any Demonstration Products and/or Samples provided and receipt of return for multiple-use Demonstration Products and/or Samples. Member Companies shall clearly record in the Member Company's records as well as clearly disclose to Healthcare Professionals and/or Healthcare organizations the no-charge basis and other conditions applicable for the supply of such Demonstration Products and/or Samples no later than the time of the supply. The disclosure to Healthcare Professionals and Healthcare Organizations shall be in writing.

6.2 Samples

6.2.1 Member Companies may provide a reasonable number of Samples at no charge to allow Healthcare Professionals and/or Healthcare Organizations to familiarize themselves with the products and/or related services, to acquire experience in dealing with them safely and effectively in clinical use and to determine whether, or when, to use, order, purchase, prescribe or recommend the product and/or service in the future.

6.2.2 For Samples, which are single-use products, the quantity provided for purposes of familiarization must not exceed the amount reasonably necessary for the Healthcare Professionals/Healthcare Organization to acquire adequate experience in dealing with the products.

6.2.3 For Samples, which are multiple-use products, the specific length of time necessary for a Healthcare Professional to familiarize him/herself with the product will depend on the frequency of anticipated use; the duration of required training; the number of Healthcare Professionals who will need to acquire experience and dealing with the

product and similar considerations. Member Companies shall in all cases ensure that they retain title to multiple-use Samples and that they have a process in place for promptly removing such multiple use Samples from the Healthcare Professional's location at the conclusion of the familiarization period.

6.3 Demonstration Products (Demo)

6.3.1 Member Companies may provide examples of their products to Healthcare Professionals and/or Healthcare Organizations in the form of mock-ups (such as unsterilized single use products) that are used for Healthcare Professionals and patient awareness, education, and training. For example, a Healthcare Professional may use a Demonstration Product to show a patient the type of technology which will be implanted in the patient or may use the Demo to train other Healthcare Professionals in the use of the product.

6.3.2 Demonstration Products are not intended for clinical use in any patient care nor are they intended for on sale or other transfer. Member Companies shall clearly record in the Member Company's records as well as clearly disclose to Healthcare professionals and/or Healthcare Organizations the no-charge basis and other conditions applicable for the supply of such demonstration Products no later than the time of the supply. It is recommended that the disclosure to Healthcare Professionals and Healthcare Organizations be in writing.

Part 2: Glossary and Definitions

GLOSSARY

Airtime: Includes the time the aircraft spends in flight, excluding ground time, connection time and transportation time from location to the airport

Charitable Donations: Means provision of cash, equipment, company product or relevant third-party product, for exclusive use for charitable or philanthropic purposes and/or to benefit a charitable or philanthropic cause. Charitable Donations may only be made on an unrestricted basis and to bona fide charities or other non-profit entities or bodies whose main objects are genuine charitable or philanthropic purposes.

Company Events: Means activities of any type that are planned, budgeted, managed, and executed in whole or in part by or on behalf of Member Companies to fulfil a legitimate, documented business need of the Member Company, including but not limited to a legitimate business need to interact with customers including Healthcare Professionals and/or Healthcare Organizations.

Conference Vetting System (CVS): Means the centralized decision-making process which reviews the compliance of Third Party Organized Educational Events with the Code and which is managed independently of MedTech Europe and MEDAK under the supervision of the MedTech Europe Compliance Panel and in accordance to the MEDAK Code in MEDAK geographical scope. For more information, see: http://www.ethicalmedtech.eu.

Code: means this MEDAK Code of Ethical Business Practice, the Disclosure Guidelines, MEDAK internal escalation procedure and the Third-Party Intermediaries Compliance & Due diligence.

Disclosure Guidelines: Means the Code provisions setting out the public disclosure requirements under the Code.

Demonstration Products (Demos): Means either single-use or multiple-use products provided free of charge by or on behalf of a Member Company to HCOs or HCPs, who are equipped and qualified to use them. Demos are supplied solely for the purpose of demonstrating safe and effective use and appropriate functionality of a product and are not intended for clinical use. Demos do not include the following:

a) Samples.
b) Evaluation Products.
c) Products provided at no charge as part of a Charitable Donation or as part of a Research or
d) Educational Grant: or Products provided at no additional charge as part of the overall purchase price in a commercial supply arrangement, e.g. as part of an agreed discount arrangement, or as substitute products provided pursuant to a warranty agreement.

Educational Grants: Means provision of funding, Member Company, or third-party products or other in kind support to a Healthcare Organization by or on behalf of a Member Company on a restricted basis for use solely for the support and the advancement of genuine medical education of Healthcare Professionals, patients and/or the public on clinical, scientific and/or healthcare topics relevant to the therapeutic areas in which the Member Company is interested and/or involved.

Employer Notification: Means the prior written notification provided to a Healthcare Organization (e.g. hospital administration), a Healthcare Professional's superior or other locally designated competent authority of any interaction, collaboration or other matter

concerning any Member Company and any Healthcare Professional, the purpose and/or scope of which requires notification under this Code.

Entertainment: Entertainment includes, but is not limited to, dancing or arrangements where live music is the main attraction, sight-seeing trips, theatre excursions, sporting Events (e.g. skiing, golf, or football match) and other leisure arrangements. For the avoidance of doubt, incidental, background music shall not constitute Entertainment.

Escalation Committee: Is formed of the head of MEDAK Compliance Steering Group in addition to two compliance officers who have completed at least 2 years in the compliance role and regularly attending the MEDAK face to face meetings. In case one or more Escalation Committee members are employed with the Recipient or the Reporter, the MEDAK Compliance Steering Group shall be notified to replace these members and appoint, by voting, new members to the Escalation Committee to ensure objective follow-up of the incident.

Evaluation Products: Means either single-use or multiple-use products and/or equipment provided free of charge to a healthcare institution by or on behalf of a Member Company for purposes of obtaining defined, evaluative user feedback over a defined period of use when used within the scope of their intended purpose, as per the authorization in the country where the supply occurs. Evaluation Products do not include the following:

a) Demos.
b) Samples.
c) Products provided at no charge as part of a Charitable Donation or as part of a Research or
d) Educational Grant; or
e) Products provided at no additional charge as part of the overall purchase price in a commercial supply arrangement, e.g. as part of an agreed discount arrangement, or as substitute products provided pursuant to a warranty agreement.

Event: Means either a Company Event or Third Party Organized Educational Event.

Faculty: Means a podium speaker, moderator and/or chair, who presents during a Third Party Organized Educational Event. Poster- and abstract-presenters are not considered to be Faculty.

Financial Hardship: Means in relation to a Healthcare Organization extreme and unavoidable financial distress resulting from matters outside the Healthcare Organization's control where the Healthcare Organization is unable to operate and where patient care is consequently jeopardized. Financial distress resulting in whole or in part from mismanagement of the Healthcare Organization's funds or other matters within its control is not considered to be Financial Hardship. Financial Hardship must be documented and objectively substantiated.

Good Clinical Practice (GCP) is an international ethical and scientific standard for the design, conduct, performance, monitoring, auditing, recording, analyses, and reporting of clinical trials that provides assurance that the data and reported results are credible and accurate, and that the rights, integrity, and confidentiality of trial subjects are protected.

Grants: Means either an Educational Grant or a Research Grant, or both.

Guests: Means spouses, partners, family or Guests of Healthcare Professionals, or any other person who does not have a bona fide professional interest in the information being shared at an Event.

Healthcare Organization (HCO): Means any legal entity or body (irrespective of its legal or organizational form) that is a healthcare, medical or scientific association or organization

which may have a direct or indirect influence on the prescription, recommendation, purchase, order, supply, utilization, sale, or lease of medical technologies or related services such as a hospital or group purchasing organization, clinic, laboratory, pharmacy, research institution, foundation, university, or other teaching institution or learned or professional society (except for patient organizations); or through which one or more Healthcare Professionals provide services.

Healthcare Professional (HCP): Means any individual (with a clinical or non-clinical role; whether a government official, or employee or representative of a government agency or other public or private sector organization; including but not limited to, physicians, nurses, technicians, laboratory scientists, researchers, research coordinators or procurement professionals) that during their professional activities may directly or indirectly purchase, lease, recommend, administer, use, supply, procure or determine the purchase or lease of, or who may prescribe medical technologies or related services.

In kind support: Must only be provided to the Healthcare Organization (HCO) and Member Companies should ensure that any such In kind support does not, nor is perceived to, circumvent the prohibition of Member Companies providing direct financial support to identifiable Healthcare Professionals to attend Third Party Organized Educational Conferences. Examples of "In kind support" which Member Companies may provide could include modest secretarial and/or logistical support to assist with meeting arrangements. For example, it would not be appropriate for Member Companies to handle the conference registration, travel, or accommodation arrangements for individual (and identifiable) Healthcare Professionals delegates at a Third Party-Organized-Educational-Conference.

Professional Conference Organizer (PCO): A for-profit company or organization which specializes in the management of congresses, conferences, seminars, and similar Events.

Product and Procedure Training and Education Event: Means a type of Company Event that is primarily intended to provide Healthcare Professionals with genuine education, including information and/or training on:

a) The safe and effective use of medical technologies, therapies and/or related services, and/or
b) The safe and effective performance of clinical procedures, and/or
c) Related disease areas.

In all cases the information and/or training should directly concern a Member Company's medical technologies, therapies and/or related services.

Reporter: Is the MEDAK member that noticed or became aware of the violation made by another MEDAK member.

Recipient: Is the MEDAK member that receives the information from the reporter.

Research Grants: Means the provision by or on behalf of a Member Company of funding, products/equipment and/or in kind services to any organization that conducts research which is made for the sole, restrictive purpose of supporting the development or furtherance of bona fide, scientifically valid and legitimate research by the Recipient the purpose of which is to advance medical, scientific and healthcare knowledge, medical technologies and/or clinical techniques designed to improve patient outcomes.

Sales, Promotional and Other Business Meetings: Means any type of Company Event the objective of which is to affect the sale and/or promotion of a Members Company's medical technologies and/or related services, including meetings to discuss product features, benefits and use and/or commercial terms of supply.

Samples: Means single-use or multiple-use products provided free of charge by or on behalf of a Member Company to HCOs or HCPs who are equipped and qualified to use them to enable HCPs to familiarize themselves with the products in clinical use. Samples do not include the following:

a) Demos.
b) Evaluation Products (refer to the Glossary).
c) Products provided at no charge as part of a Charitable Donation or as part of a Research or
d) Educational Grant; or
e) Products provided at no additional charge as part of the overall purchase price in a commercial supply arrangement, e.g. as part of an agreed discount arrangement, or as substitute products provided pursuant to a warranty agreement.

Scholarships and Fellowships Means Educational Grants provided to a Healthcare Organization by or on behalf of a Member Company to support fellowships or scholarships offered by the Healthcare Organization.

Scholarships in this context means an Educational Grant provided to support a medical school undergraduate whereas a fellowship is a period of intensive training for post-graduate physicians in a chosen clinical subspecialty (e.g. medical training after a residency). “Scholars” and “Fellows” shall be understood accordingly.

Third Party Organized Educational Events: Means activities of any type that are planned, budgeted, managed and executed in whole or in part by or on behalf of a person or entity other than a Member Company to fulfil Healthcare Professional medical educational needs.

Third Party Organized Educational Conferences: Means a type of Third Party Organized Educational Event that is a genuine, independent, educational, scientific, or policy-making conference organized to promote scientific knowledge, medical advancement and/or the delivery of effective healthcare and are consistent with relevant guidelines established by professional societies or organizations for such educational meetings. These typically include conferences organized by national, regional, or specialty medical associations/societies, hospitals, Professional Conference Organizer’s (PCOs), patients’ organizations or accredited continuing medical education providers.

Third Party Intermediaries: Any third-party intermediaries who interact with Healthcare Professionals or Healthcare Organizations in connection with the sale, promotion or other activity involving Member Companies’ products or services, on behalf of the Member Companies.

Third Party Organized Procedure Training: Means a type of Third Party Organized Educational Event that is primarily intended to provide Healthcare Professionals with information and training on the safe and effective performance of one or more clinical procedures in circumstances where the information and training concern:

a) Specific therapeutic, diagnostic, or rehabilitative procedures, namely clinical courses of action, methods or techniques (rather than the use of medical technologies); and
b) Practical demonstrations and/or training for HCPs, where most of the training programme is delivered in a clinical environment.

For the avoidance of doubt, proctorship and preceptorship are not considered to constitute Third Party Organized Procedure Training.