



Code of Ethical Business Practice

**MECOMED Guidelines on Interactions
with Healthcare Professionals & Healthcare
Organisations**

*Approved by Mecomed Executive committee,
20th June 2017*

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INTRODUCTION

MECOMED is the medical devices, imaging and diagnostics trade association; serving as the voice of international medical technology manufacturers operating in 21 countries across Middle East and North Africa. Please refer to Annex IV for MECOMED's exact geographic scope.

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

Members Companies should require that Third Party Intermediaries (refer to the Glossary) 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 (HPCs) (as defined in attached Glossary) and Healthcare Organisations (HCOs) (as defined in attached Glossary) in connection with the sale, promotion or any other activity involving members' products, comply with the MECOMED Code of Ethical Business Practice. Accordingly, where such arrangements are entered into by Member Companies, the relevant contractual documentation must impose obligations upon the third party to comply with the MECOMED Code of Ethical Business Practice.

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

- Safety, Quality and Performance Laws
- Advertising and Promotion Laws
- Data Protection Laws
- Anti-corruption Laws
- Environmental Health and Safety Laws
- Competition Laws

Aims and Principles of the Code

The interaction between Member Companies and Healthcare Professionals and Healthcare Organisations is an important feature in achieving MECOMED mission to make safe, innovative and reliable technology and related services available to more people.

For example:

➤ **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 Organisations (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 Organisations 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 Organisations, 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 Organisations.

➤ **The Principle of Separation**

Interaction between industry and Healthcare Professionals / Healthcare Organisations 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 Organisations 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. "Employer Notification" (as defined in the Glossary).

➤ **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 of time 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, in particular, 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 detailed in Part 3 herein which includes procedures designed to provide an effective and efficient complaint handling process, within the geographic scope of MECOMED, to ensure compliance with the Code.

For complaints between Member Companies, mediation should be considered seriously before further pursuit of the matter via any formal complaint handling process, either at national or MECOMED level.

The Code shall be reviewed every 5 years or earlier if needed.

Implementation and Transition Period

This edition of the Code comes into force as follows:

- The Code [i.e. Introduction, (PART 1 PART 3, PART 4, PART 5, PART 6 and PART 7) shall enter into force on January 1st2018.
- The balance of the Code (PART 2) shall enter into force on January 1st, 2019 and shall be retroactively applicable to all data collected during 2018.



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

Chapter 1. GENERAL CRITERIA FOR EVENTS

The principles and criteria set out in this Chapter 1 shall apply to all Events (refer to the Glossary) supported in any way by Member Companies, irrespective of who organizes the Event.

1. Event Programme

The Event Programme should:

- a) 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;
- b) Be available (in detail) sufficient time prior to the Event;
- c) 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);
- d) For Third Party Organized Educational Events, the agenda should be under the sole control and responsibility of the third-party organizer;
- e) For Third Party Organized Educational Events the Faculty (refer to the Glossary) must be identified

A Member Company shall not organize Events which include social, sporting and/or leisure activities or other forms of entertainment, nor support such elements where part of Third Party Organized Educational Events. Entertainment must be outside of the educational programme schedule and paid for separately by the Healthcare Professionals. 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.

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, as the case may be.

2. Event Location and Venue

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

- a) 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.
- b) The Event location and venue should be centrally located considering the place of residence of the majority of 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.
- c) Member Companies must consider the season during which the Event is held. The selected time of year must not be associated with a touristic season for the selected geographic location.
- d) It is not appropriate for Member Companies to organize or support Events at hotels centered around

leisure facilities such as golf, casinos or ski/water sports. An important factor in evaluating a hotel is its suitability for business meetings, including the availability of conference facilities. For hotels, which include minor leisure and sporting facilities, while it would not be reasonable to exclude these venues if otherwise appropriate, Member Companies must exercise caution. The Event agenda should be arranged in such a way that Healthcare Professionals attending the Event 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 enable Guests (refer to the Glossary) to use the leisure and sporting facilities, Member Companies may not make such payments on behalf of the Healthcare Professionals.

- e) For Third Party Organised Educational Event exceptions to the aforementioned rules related to Event venue suitability, can be granted by the Conference Vetting System (refer to the Glossary) following thorough assessment of the Event in question. Such assessment shall be based on the usual Conference Vetting System Assessment Criteria outlined in Annex I, taking however also into consideration other factors such as the number of expected attendees, the availability of conference facilities, the overall suitability of the selected venue, the specificity of the geographic location, logistic considerations and any other compelling justifications which could establish the granting of an exception. The rationale for granting such exceptions should be clearly documented along with the Event's assessment outcome on the Conference Vetting System (as defined in the Glossary).

3. Guest

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.

The term “facilitate” refers to the prior arrangement, organisation 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 organisation of the Guest's expenses.

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), nor is it appropriate, in the interest of maintaining the scientific exchange, 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.

Member Companies, however, may financially support Third Party Organized Educational Events which offer extra-curricular programmes/activities beyond the scientific, educational or training sessions for Guests of Healthcare Professionals (such as touristic activities and hospitality), always provided that such an extra-curricular programme /activity (including attendance of the conference dinner or a cocktail reception) is subject to a separate charge which must not be paid for, facilitated or reimbursed by, a Member Company.

4. Reasonable Hospitality

Member Companies may provide reasonable hospitality to Healthcare Professionals in the context of Company Events (refer to the Glossary) and Third Party Organized Educational Events but any hospitality offered must be subordinate in time and focus to the Event purpose.

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.

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 appearance that hospitality may be used by Member Companies as a means to induce Healthcare Professionals to purchase, prescribe or recommend Member Companies' products. 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. Please refer to the Glossary for the definition of Entertainment.

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.

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.

5. Travel

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.

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 Air Time, in which case business class can be considered. First class is never appropriate. (Please refer to the Glossary for the definition of Air Time)

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

6. Transparency

Member Company shall ensure full compliance with local laws regarding the disclosure or approval requirements associated with such financial support. Where no such national requirements are prescribed, Member Companies shall nevertheless maintain appropriate transparency by requiring Employer Notification as defined in the Glossary.

Employer Notification is required whenever a Member Company sponsors/engages Healthcare Professional in Company Event, Third Party Organised Educational Event, or as a Consultant. Incidental interactions arising in the normal course of business such as meals associated with educational or business meetings or the receipt of modest gifts related to the Healthcare Professional's practice, do not

require Employer Notification.

The Employer Notification must comply with national laws, regulations and professional Codes of conduct. In countries where specific provision is not made, there is no requirement to notify employers of the amounts involved. Under the Code, Member Companies must ensure that the level of remuneration is commensurate with the services provided and not greater than a fair market value. However, the purpose of the Employer Notification is to provide transparency on the nature of the interaction between the Member Company and the Healthcare Professional and to enable the employer to raise objections if they perceive a potential conflict or have other issues concerning the interaction.

Chapter 2. THIRD PARTY ORGANIZED EDUCATIONAL EVENTS

1. Third Party Organised Educational Conferences

Member Companies may provide financial support (E.g.: Bank Transfer/Cheques) and or In kind support (refer to the Glossary), however cash and cash equivalents (E.g.: debit card/cash vouchers) must not be provided towards the Third Party Organised Educational Conferences (refer to the Glossary) which comply with:

- Chapter 1: General Criteria for Events and where applicable, has approval via the Conference Vetting System.

Where permitted under local laws, regulations and professional Codes of conduct, Member Companies may provide financial and/or In kind support to Third Party Organised Educational Conferences (always provided that the Third Party Organised Educational Conference has been approved via the Conference Vetting System) through Grants and other types of funding, such as:

1.1 Educational Grants:

Please refer to Chapter 4: Grants (refer to the Glossary) and Charitable Donations (refer to the Glossary) for guidance on Educational Grants (refer to the Glossary).

1.2 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 Organised Educational Conferences is always perceived as professional. It should never bring discredit upon or reduce confidence in the medical technology industry. Booth activities at Third Party Organised Educational Conferences should aim primarily at displaying Member Companies' products and services and related literature. Therefore, other activities should be limited and reasonable and in principle, only soft drinks and snacks should be served. The Company may participate in a booth only if the Event has been vetted compliant in the CVS.

1.3 Satellite Symposia:

Member Companies may purchase satellite symposia packages at Third Party Organised Educational Conferences and provide presentations on subjects that are consistent with the overall content of the Third Party Organised Educational Conference. Member Companies may determine the content of these satellite symposia and be responsible for speaker selection.

Member Companies must ensure compliance with the Code and when enter into a consulting agreement with the Healthcare Professional engaged to speak at the satellite symposium. The consulting agreement may include payments in respect of registration fee, travel and/or accommodation where appropriate.

2. Third Party Organised Procedure Training

Member Companies may support Third Party Organised 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 Third Party Organised 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) Has been approved via the Conference Vetting System.
- c) Third Party Organised Procedure Trainings should follow the criteria below:

2.1 Programme:

Third Party Organised 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).

2.2 Venue:

Third Party Organised Procedure Trainings are typically organised 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.

2.3 Stand-alone Event:

Third Party Organised Procedure Trainings must stand-alone. Where the majority of the Training is not given in a clinical environment, for example, where the Training is organised in connection, adjacent to or at the same time as a larger Third Party Organised Educational Conferences that Training will not qualify as a Third Party Organised Procedure Training, as defined in the Code i.e. direct sponsorship to Healthcare Professional will not be permitted in this case.

Chapter 3. COMPANY EVENTS

1. General Principles

Member Companies may invite Healthcare Professionals to Company Events. Such Events include, as defined in the Glossary:

- Product and Procedure Training and Educational Events
- Sales, Promotional and Other Business Meetings

Company Events should comply with the principles mentioned in Chapter 1: General Criteria for Events.

Where there is a legitimate business purpose, Company Events may include or take place in Member Company's manufacturing plant or Healthcare Organizations premises, used by the Member Company as reference centers. It is appropriate for Member Companies to invite Healthcare Professionals to plant or factory tours in countries outside their country of residence if there is a legitimate business purpose.

Member Companies cannot directly support travel and/or accommodation or other expenses of individual Healthcare Professionals passively participating at Company Organized Educational Events happening, during, around, in connection with or at the same time and location as a Third Party Organized Event.

On occasion, Company Organized Events, for example Advisory Boards, Clinical Investigator Meetings, publication committees, steering committees, Adverse Events Committees, Good Clinical Practice (refer to the Glossary) Meetings, may be organized at or around a Third Party Organized Event for reasons such as convenience given the presence of Healthcare Professionals at that Third Party Organized Event. In such circumstances the Member Company, may only pay for the contractual remuneration and expenses permitted for the services rendered by the HCP at the Company Organized Event but under no circumstances can a Member Company pay for registration fee, travel or any other costs relating to the Third Party Organized Event."

2. Product and Procedure Training and Educational Events

Where appropriate, in order to facilitate the safe and effective use of medical technologies, therapies and/or services, Member Companies should make product and procedure training and education available to relevant Healthcare Professionals.

Member Companies shall ensure that personnel conducting the Product and Procedure Training and Educational Events have the appropriate expertise to conduct such training.

A "Company Organized Education Event" is a Company Event as defined in the Glossary, whose objective is genuine and *bona fide* medical education, and the enhancement of professional skills. "Educational" means communicating information directly concerning or associated with the use of Member Companies' medical technologies, e.g., information about disease states and the benefits of medical technologies to certain patient populations. In all cases the information and/ or training must directly concern a Member Company's medical technologies, therapies and/or related services.

This means that a Member Company must meet the following criteria when organizing such an Event in order to be compliant with the Code:

Criteria for organizing Company Events / Product and Procedure Training and Education Event:

2.1 The entire Event must comply with the criteria of Chapters 1 and 3;

- 2.2 The programme must be rigorous from a scientific and/or educational point of view. This means that its content must include current scientific information of a nature and quality which is appropriate to the Healthcare Professionals who are attendees at the Event.
- 2.3 The programme must be genuine and bona fide educational, and therefore cannot have a primary sales and marketing objective. This means that the education part must fill most of the Programme.
- 2.4 Information on the programme, clearly indicating the name of the Company organizing the Event, should be made available sufficiently in advance in order for invited Healthcare Professionals to be able to make a reasoned judgment as to the rigor and quality of the programme, provided however that subsequent changes, deletions and additions to the programme are acceptable to the extent that such changes, deletions and additions are reasonable and do not significantly modify the quality or nature of the programme.
- 2.5 The programme should in principle involve full days, with the majority of the morning and afternoon parts dedicated to scientific and/or educational sessions, unless the Event is a half day Event, commences or ends on a mid-day or lasts less than half a day. Such half-day or less sessions are permissible, but there should not be any non-scientific or non- educational Events or activities organized for the other part of the day. Furthermore, there should be no significant gaps in the programme which would permit Healthcare Professionals to engage in non-scientific or non-educational activities. For example, early morning sessions should not be followed by late afternoon or evening sessions with large blocks of free time in between.

3. Sales, Promotional and Other Business Meetings

Where it is appropriate, Member Companies may organise Sales, Promotional and Other Business Meetings where the objective is to discuss product and related services features and benefits, conduct contract negotiations, or discuss sales terms with authorized and designated Healthcare Professional.

In addition to the principles laid down in the Chapter 3, Section 1, Sales, Promotional and Other Business Meetings should also comply with the following more stringent requirements:

Criteria for organizing Company Events / Sales, Promotional and Other Business Meetings

- i. It is not appropriate for travel or accommodation support to be provided to Healthcare Professionals by Member Companies, except where demonstrations of non-portable equipment are necessary.

Chapter 4. GRANTS AND CHARITABLE DONATIONS

1. General Principles

- 1.1 Grants and Charitable Donations (refer to the Glossary) 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 programmes and activities by Member Companies is not viewed as a price concession, reward to favoured customers or as an inducement to purchase, lease, recommend, prescribe, use, supply or procure Member Companies' products or services.
- 1.2 Member Company shall not provide Grants or Charitable Donations to individual Healthcare Professionals. Grants and Charitable Donations must be provided directly to the qualifying organisation or entity, as the case may be. 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 organisation or entity and submits the request in writing on behalf of the qualifying organisation or entity.

- 1.3 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 particular type of Grant/Charitable Donation.
- 1.4 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 (refer to the Glossary). This process shall include a documented, prior evaluation of any such associated risks and of the relevant information concerning the intended Recipient organisation or entity.
- 1.5 In accordance with the Principle of Separation, an independent decision making process is not primarily Sales-driven and where the Member Company's sales function does not decide upon and/or approve a decision to provide a Grant or Charitable Donation. For example, such a process could be led by a Member Company's Medical Affairs, Regulatory, Professional Education, Legal, Finance or Compliance functions, operating within a robust governance framework and according to clear, consistent and transparent criteria to review decision-making.
- 1.6 Prior to deciding to provide a Grant or a Charitable Donation, the Member Company must evaluate the appropriateness of the award of the proposed Grant or Charitable Donation to the proposed Recipient.
 - 1.6.1 Such an evaluation shall consider all the circumstances including, but not limited to, consideration of the legal status and structure of the requesting (i.e. prospective recipient) organisation as well as of the nature and scope of its activities and the terms and conditions to which the Grant or Charitable Donation will be subject. The evaluation shall be documented and shall be based on information available to the Member Company, such as information or documentation available from public sources.
 - 1.6.2 For Educational Grants provided in relation to Third Party Organised Educational Events (refer to the Glossary), this may also include information of how the funds have been applied by the Recipient in relation to previous equivalent Events and whether funds have been spent in accordance with the terms and conditions of any previous Grant.
- 1.7 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 Organisation 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.
- 1.8 The written request by a requesting organisation should include as a minimum a detailed description of the scope and purpose of the programme, activity or another project, which is the object of the grant or Charitable Donation. It shall also contain a description of the proposed Recipient, its legal status and structure and where relevant a budget.
- 1.9 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.
- 1.10 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 centralised purchasing arrangements, such as, for example, tenders.

2. Charitable Donations

Member Companies may make unrestricted Charitable Donations for genuinely charitable or other philanthropic purposes. “Unrestricted” in this context means that Member Companies shall have no control over the final use of funds (or other support) they provide as Charitable Donations beyond general restrictions to ensure that the funds (or other support) are applied for charitable and/or philanthropic purposes.

Charitable Donations may be made only to charitable organisations or other non-profit entities which have charitable and/or philanthropic purposes as their main purposes and which are objectively engaged in genuine charitable or philanthropic activities. Such Charitable organisations and non-profit entities should be licensed to conduct the aforementioned activities. Charitable Donations shall always be made in accordance with the general principles set out in *Chapter 4: Grants and Charitable Donations*.

Restricted Charitable Donations to non-profit hospitals may be permissible in case of demonstrated Financial Hardship (refer to the *Glossary*), when Charitable Donations serve exclusively the benefit of the patient, are limited in value, or explicitly permitted by applicable national laws.

Under the Code it is not appropriate for a Member Company to apply conditions or restrictions to the final use of a Charitable Donation which go beyond general restrictions to ensure that the funds (or other support) are applied for charitable and/or philanthropic purposes. Member Companies may therefore impose general restrictions concerning the final use, such as the relief of a specific disaster in a particular country (e.g. for use to aid reconstruction and/or re-equipping of healthcare facilities following the earthquake in that country). However, Member Companies must take care that such general restrictions are not so specific that the Charitable Donation is no longer unrestricted. The Charitable Donation must not be misused or be perceived to influence through undue or improper advantages, purchasing decisions, nor should such donation be contingent upon sales transactions or use or recommendation of Member Companies’ products.

Under the Code it is not appropriate for a Member Company to support the favourite charity of a Healthcare Professional in response to a request by that Healthcare Professional irrespective of the underlying reasons. No exception can be made for sport Events, such as payment of the registration charge to participate in a charity run.

3. Educational Grants

Member Companies may provide restricted Educational Grants (refer to 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.

Member Companies may provide Educational Grants for the following (non-exhaustive) purposes:

3.1 Support Third Party Organised Educational Events:

As a general principle, any Third Party Organised Educational Event supported by way of an Educational Grant from a Member Company to a Healthcare Organisation must comply with Chapter 1. General Criteria for Events; and have approval via the Conference Vetting System

3.2 Support for Healthcare Professional Participation at Third Party Organised Educational Events:

Where the Educational Grant is provided for the purpose of supporting Healthcare Professionals’ attendance at Third Party Organised Educational Events, the Healthcare Organisation receiving the Grant shall be solely responsible for selection of participants and this shall be expressly reflected in the written Grant agreement.

A Member Company must ensure the following:

- a. Member Company should have an Educational Grant agreement with the Recipient organisation to include the purpose of the Educational Grant. The Member Company shall be entitled as per the clauses of the Educational Grant agreement, to verify that the Grant is in fact used for the agreed intended purpose.
- b. Member Companies may specify the participating Healthcare Professionals specialty in accordance to the specified grant. However, the Healthcare Organisation receiving the Grant shall be solely responsible for selection of participants and this shall be expressly reflected in the written Grant agreement.
- c. Member Company shall define a proper mechanism to ensure that the Educational Grant is used for the purpose mentioned in the agreement.
- d. Member Companies shall document and publicly disclose all Educational Grants in accordance with the Code's Disclosure Guidelines (refer to the Glossary), and publication shall commence no later than the end of the Transition Period. Please refer to part 2 of the code.

3.3 Support for Third Party Organised Educational Events:

Where the prospective beneficiary of an Educational Grant is the organiser of the Third Party Organised Educational Event and is also a Healthcare Organisation, the Recipient Healthcare Organisation 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 (refer to the 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.

3.4 Scholarships and Fellowships

Member Companies may provide Educational Grants on a restricted basis in the form of Grants for Scholarships and Fellowships (refer to the Glossary) to support advancement of genuine medical education of Healthcare Professionals (refer to the Glossary). Only Healthcare Organisations 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 Healthcare Professionals who will benefit from the Educational Grant and this shall be reflected in the written Grant agreement between the Member Company and the Recipient Healthcare Organisation.

3.5 Grants for Public Awareness Campaigns

Member Companies may also provide Educational Grants on a restricted basis to Healthcare organisations for the legitimate purpose of providing information, promoting awareness and/or educating patients, careers 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.

A Member Company may provide an Educational Grant to support the provision of high quality information to patients and the public about health and disease provided there is an objective patient or public need for such information and the topics covered are linked to the therapeutic areas in which the Member Company is interested and/or involved. Such disease awareness campaigns must not, however, promote the use of particular therapies, services or promote specific Healthcare Organisations, nor may they aim to stimulate demand by the public for specific therapies or for specific Healthcare Organisations.

4. Research Grants

Where permitted by national laws, regulations, national guidelines and professional Codes of conduct, Member Companies may provide restricted Research Grants (please refer to 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 organisation 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.

Chapter 5. ARRANGEMENT WITH CONSULTANTS

1. General Principles

Member Companies may engage Healthcare Professionals as consultants and advisors to provide *bona fide* consulting and other services, including but not limited to research, participation at advisory boards, presentations at Company Events and product development. Member Companies may pay Healthcare Professionals reasonable remuneration for performing these services. In all cases, consulting arrangements must be permitted under the laws and regulations of the country where the Healthcare Professional is licensed to practise and be consistent with applicable professional Codes of conduct in that country.

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

When selecting consultants, 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 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.

2. Criteria for Genuine Consulting Arrangements

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

- 2.1 Consulting arrangements must be entered into only where a legitimate business need for the services is identified in advance.
- 2.2 The number of consultants retained must not be greater than the number reasonably necessary to achieve the identified need.
- 2.3 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 Healthcare Organisation where s/he performs her/his professional activity is not a relevant criterion.
- 2.4 Consulting arrangements with Healthcare Professionals 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.
- 2.5 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.
- 2.6 The remuneration for the services rendered must be reasonable and reflect the fair market value of the services provided.
- 2.7 Member Companies must maintain records of the services, and associated work products, provided by the consultant Healthcare Professionals. Member Companies must document the use made of those services.
- 2.8 The venue and other arrangements (e.g. hospitality, travel etc.) for Member Company meetings with consultants shall follow the rules for Events set out in Chapter 1: General Criteria for Events.

Chapter 6. REMUNERATION AND FAIR MARKET VALUE

The remuneration paid to Healthcare Professionals 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 in the course of their own professional practice or that may be purchased, leased, recommended, prescribed, used, supplied or procured by HCOs where they carry on their professional activities.

Fair-market-value, in this context, 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.

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.

All payments made for services must comply with all applicable tax, statutory 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. Compensation under professional services agreements must be paid by cheque or bank transfer. Cash and cash equivalents (such as debit cards, gift cards, and gift certificates) are not permissible forms of payment.

Chapter 7. DISCLOSURE AND TRANSPARENCY

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 the use by Member Companies of Healthcare Professionals as consultants. All required consents and approvals shall be obtained, including from the hospital or other Healthcare Organisation administration or from the Healthcare Professional's superior (or locally-designated competent authority), as applicable. Where no such national requirements apply, Member Companies shall nevertheless maintain appropriate transparency by requiring the relevant Employer Notification which shall disclose the purpose and scope of the consultancy arrangement.

Member Companies shall also include appropriate obligations on the consultant to ensure that the consultant's status as a consultant for the Member Company and his/her involvement in the research for, or the preparation of, material for scientific publication is disclosed at the time of any publication or presentation.

Chapter 8. RESEARCH

1. Member Company-Initiated Research

Where there is a legitimate business need to do so, Member Companies may initiate, conduct, manage and finance scientifically valid research to generate data, whether pre-or post-market. In this context, legitimate business needs for data include medical needs, including patient safety; research and development; scientific purposes (e.g. performance indicators, comparing objective scientific parameters); regulatory, including post-market surveillance (PMS) and post-market clinical follow up (PMCF), vigilance, safety, or reimbursement and health economic, including clinical and cost-effectiveness and out-comes data relevant to health technology assessments (HTA) and reimbursement decision-making. Where a Member Company uses a Healthcare Professional as a consultant, for example to lead a study on the Member Company's behalf (i.e. act as Principal Investigator), the Member Company shall ensure that such consulting arrangements comply fully with Chapter 5: Arrangements with Consultants.

In accordance with the Documentation Principle, any arrangements made by a Member Company to procure research-related services shall be set out in a written agreement which shall reference a written research protocol; written schedule of work and provide for all required consents, approvals and authorizations to be obtained prior to the commencement of the study.

Member Companies must ensure that their research activities comply with all applicable national laws, regulations and researchers' own professional Codes of conduct, as well as with applicable Good Clinical Practice guidelines, if relevant. (Please refer to the glossary for definition of Good Clinical Practice)

In accordance with the Principles set out in the Introduction: Aims and Principles of the Code, Member Companies shall also ensure appropriate clinical trial transparency in relation to their research activities and results. As applicable this shall include appropriate disclosure of information about Member Companies' clinical trials, for example in external public registries and peer-reviewed journals.

Where Member Companies engage Third Party Intermediaries for research (e.g. contract research organisations (CROs)), they shall ensure that the research conducted by these third parties on behalf of the Member Company is carried out in accordance with all applicable legal and ethical requirements, including the applicable requirements of the Code.

2. Member Company Post-Market Product Evaluation

Where there is a legitimate business need to do so, Member Companies may initiate, post-market third party evaluation of their products, therapies and/or related services and may therefore provide Evaluation Products under a written contract for services in order to obtain defined user evaluation by Healthcare Organisations in relation to the Evaluation Products. Evaluation Products may be provided on a no charge basis in return for the requested user feedback from Healthcare Professionals at the Healthcare Organisation, which shall be formally described in a written protocol or questionnaire forming part of the contract. Such evaluation products must be given in reasonable quantities to satisfy the needs and objectives of the evaluation and according to all applicable local law.

Where the Evaluation Products are multiple-use Evaluation Products the defined period of time necessary for the evaluation and feedback to occur will depend on the frequency of anticipated use; the nature of the user evaluation feedback requested; the duration of any required training and similar considerations. Member Companies shall in all cases ensure that they retain title to multiple use Evaluation Products and that they have a process in place for promptly removing such multiple use Evaluation Products and/or any unused single-use Evaluation Products from the Healthcare Organization's location at the conclusion of the evaluation period unless these are purchased by the Healthcare Organisation.

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

3. Third Party-Initiated Research

Please refer to [Chapter 4: Grants and Charitable Donations: Research Grants](#)

Chapter 9. ROYALTIES

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

A royalty arrangement between a Member Company and a Healthcare Professional should be entered only where the Healthcare Professional is expected to make or has made a novel, significant, or innovative contribution to, for example, the development of a product, technology, process, or method, such that the Healthcare Professional would be considered to be the sole or joint owner of such intellectual property under applicable laws and regulations. The foregoing is without prejudice to Member Companies' obligations to comply with any applicable obligations to pay royalties which may arise under applicable laws and regulations in some countries.

Arrangements involving the payment of royalties by or on behalf of Member Companies to a Healthcare Professional must be set out in a written agreement providing appropriate and reasonable remuneration in accordance with applicable laws and regulations.

For example, royalties paid in exchange for intellectual property should not be conditional on:

- A requirement that the Healthcare Professional purchase, order or recommend any product, services or medical technology of the Member Company or any product or technology produced as a result of the development project; or
- A requirement to market the product or medical technology upon commercialisation.

Subject to national regulations and requirements, Member Companies should exclude from the calculation of royalties the number of units purchased, prescribed, used, or ordered by the Healthcare Professional and/or members of the Healthcare Professional's practice or Healthcare Organisation.

Chapter 10. EDUCATIONAL ITEMS AND GIFTS

1. General Principles

Member Companies occasionally may provide:

- 1.1 Educational items and/or gifts may be provided; however, these must relate to the Healthcare Professional's practice, or benefit patients, or serve a genuine educational function.
- 1.2 No educational items and/or gifts should be provided in response to requests initiated by Healthcare Professionals.
- 1.3 Educational items and/or gifts must not be given in the form of cash or cash equivalents. (e.g. debit cards, gift cards and gift certificates)
- 1.4 Provision of educational items and/or gifts must not improperly reward, incentivise and/or encourage Healthcare Professionals to purchase, lease, recommend, prescribe, use, supply or procure the Member Company's products or services.
- 1.5 Member Companies must not provide any gift to Healthcare Professionals engaged as consultants or speakers in lieu of a professional fee for their services.
- 1.6 Member Companies may provide to an HCP, in accordance to the Code guidelines, however, limited to 1 gift per HCP per year.

2. PROMOTIONAL AIDS/BRAND REMINDER

Inexpensive promotional aids and/or brand reminder, in accordance with national laws, regulations and industry and professional Codes of conduct of the country where the Healthcare Professional is licensed to practice.

Member Companies may only provide such items in accordance with the following principles:

- 2.1 Must be modest in value, and can be branded or non-branded items. Examples of such gifts include but not limited to: stationery items, calendars, diaries for business use and clinical items such as wipes, nail brushes, surgical gloves and tourniquets. Food, alcohol and items which are primarily for use in the home or car are not appropriate as they are not related to the Healthcare Professional's practice nor are they for the benefit of patients.
- 2.2 Modest gifts provided in this context to the Healthcare Professionals, do not require Employer Notification.

3. EDUCATIONAL GIFTS/MEDICAL UTILITIES

A Member Company may exceptionally provide educational items to a Healthcare Organisations. Examples of educational items include but not limited to: Medical Textbooks, Medical journal subscriptions etc. Such items shall not be provided to Healthcare Professionals for their own personal use or benefit. The item shall also be related to the therapeutic areas in which the Member Company is interested and/or involved.

For educational items, Member Companies must maintain appropriate records of their provision of such educational items to Healthcare Organisations. Such items should not be part of the Healthcare Organisation's normal overheads or routine costs of operation.

Cultural gifts are not allowed: Gifts or flowers for major life Events (birth, promotion, wedding, etc....) are not allowed.

4. Prize draws

Prize draws and other competitions at Events are permissible if the prize awarded complies with Chapter 10. Educational Items and Gifts. In addition, it must comply with national laws, regulations and industry and professional Codes of conduct.

Chapter 11. DEMONSTRATION PRODUCTS & SAMPLES

1. General Principles

Member Companies may provide their own products as Demonstration Products and/or Samples (refer to the glossary) at no charge in order to enable Healthcare Professionals and/or Healthcare Organisations (as applicable) to evaluate and/or familiarise 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.

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 in order 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.

Provision of Demonstration Products and/or Samples must not improperly reward, induce and/or encourage Healthcare Professionals and/or Healthcare Organisations 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.

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 Organisations, 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 organisations 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 Organisations shall be in writing.

This Chapter is limited to the provision of Demonstration Products and/or Samples and related services at no charge and is not intended to apply to provision of products or related services under any other arrangements, for example (but not limited to) provision within the framework for clinical trials and/or other research or commercial supplies by way of rebates or pricing incentives in a public procurement context.

2. Demonstration Products (Demo)

Member Companies may provide examples of their products to Healthcare Professionals and/or Healthcare Organisations 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.

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 Organisations 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 Organisations be in writing.

3. Samples

Member Companies may provide a reasonable number of Samples at no charge to allow Healthcare Professionals and/or Healthcare Organisations to familiarise 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.

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

For Samples, which are multiple-use products, the specific length of time necessary for a Healthcare Professional to familiarise 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 in 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 familiarisation period.



PART 2: Disclosure Guidelines

Chapter 1. Preamble

Under the Mecomed Code of Ethical Business Practice (the “Code”), Member Companies are not permitted to pay registration fees, travel or hospitality expenses directly to individual Healthcare Professionals for their participation in Third Party Organised Educational Conferences.

Medical Education may be supported through the provision of Educational Grants to Healthcare Organisations in compliance with the rules set out in the Code. To prevent abuses, specific safeguards when providing Educational Grants have been developed, including the obligation to disclose these Educational Grants.

Section 3 of Chapter 4 of the Code states that Member Companies shall document and publicly disclose all Educational Grants in accordance with these Disclosure Guidelines. These Disclosure Guidelines are therefore an integral part of the Code, and need to be interpreted as such.

For the avoidance of doubt, all funds provided by a Member Company for the advancement of genuine educational purposes to a Healthcare Organization or a Professional Conference Organiser (“PCO”) acting on behalf of any Healthcare Organisation or independently, fall under the scope of these Disclosure Guidelines and are subject to the same conditions as Educational Grants. Whenever these Disclosure Guidelines refer to Healthcare Organisations, these shall also include Professional Conference Organiser’s.

Chapter 2. Applicability of these Guidelines

1. Scope

These Disclosure Guidelines apply to Member Companies in their interactions with Healthcare Organisations based or registered in the Mecomed Geographic Area.

Separate entities belonging to the same multinational company (“Affiliates”) – which could be the parent company (e.g. the headquarters, principal office, or controlling company of a commercial enterprise), subsidiary company or any other form of enterprise or organization – shall be deemed to constitute a single company, and are as such committed to compliance with these Disclosure Guidelines.

Transfers of value that are not included in the definition of Educational Grants (as described in Chapter 4, Section 4.3 of the Code) and that consequently cannot be allocated to any of the categories set forth in Section 2.2.2 Aggregate Disclosure are not within the scope of these Disclosure Guidelines.

2. Applicability of these Disclosure Guidelines

Member Companies need not to report the same information twice due to being bound by national laws, regulations or professional Codes imposing disclosure obligations regarding Educational Grants (as described in Chapter 4, section 4.3 of the Code) equivalent to the ones imposed by these Disclosure Guidelines.

These Disclosure Guidelines are also applicable to Third Party Intermediaries whenever Educational Grants are provided through such entities on behalf of a Member Company. “On behalf of a Member Company” in this context, means following a Member Company’s initiation, guidance, instruction, control or supervision – irrespective of whether or not the Educational Grant will be reimbursed later by the Member Company or financially covered entirely by the Third Party Intermediary. Nevertheless, it is recommended to document arrangements concluded between Member Companies and Third Party Intermediaries in order to comply with the provisions set out in the Code.

3. Applicability to Non-Member Companies

Non-Member Companies may implement these Disclosure Guidelines provided they are committed to ethical standards equivalent to those enshrined in the Code.

Chapter 3. Disclosure Obligation

1. General Obligation

Subject to the terms of these Disclosure Guidelines, each Member Company shall document and disclose all payments related to Educational Grants (as described in Chapter 4, section 3 of the Code) that it makes to a Healthcare Organisation based or registered in Mecomed Geographic Area, without limitation of value.

The disclosure of Educational Grants provided by Affiliates of the Member Company described above, but which are not registered in the Mecomed Geographic Area shall be made by any of the Affiliates comprising said Member Company that are registered in the Mecomed Geographic Area.

2. Aggregate disclosure

Educational Grants shall be disclosed on aggregated basis. Each affiliate of a Member Company shall disclose, for each clearly identifiable and separate Recipient, the amounts paid as Educational Grants to such Recipient in reporting period which can be reasonable allocated to one of the categories set out below. Such amounts will be aggregated on a category-by category basis, but itemized disclosure shall be made available upon request by the Member Company, as deemed necessary to (i) the relevant Recipient and/or (ii) the relevant authorities. Member Companies shall disclose an aggregate amount related to any of the categories set forth below:

Educational Grants to support Third Party Organised Events (including support for HCP Participations at the Third Party organised Educational Events) and,

Other Educational Grants to Healthcare Organisation (including Scholarships, fellowship and/or Grants for public Awareness Campaigns)

To facilitate the tracking of Educational Grants made to individual Healthcare Organisations, it is recommended that the Affiliate making the payment in relation to a particular Educational Grant is the one disclosing the Educational Grant, but this is an internal decision of each Member Company.

A Member Company may choose to use internal arrangements of its choice to report the aggregated sum in relation to Educational Grants made by each legal entity composing the company (Affiliates) to a particular Healthcare Organisation during a disclosure period

3. Optional Object Specification

If desired, Member Companies may indicate the object of the Educational Grants disclosed for one or both categories set forth in Section 2.2 Aggregate Disclosure.

4. Methodology

Each Member Company shall create a note summarizing the methodologies used by it in preparing the disclosures and identifying Educational Grants for each category described in Section 2.2 Aggregate Disclosure. The note, including a general summary and/or country specific considerations, shall describe the recognition methodologies applied, and should include the treatment of VAT and other tax aspects, currency aspects and other issues related to the timing and amount of Educational Grants for the purposes of these Disclosure Guidelines, as applicable. This Methodology Note shall be made available upon request by an interested party.

Chapter 4. Form of Disclosure

1. Reporting Period

Disclosures shall be made on an annual basis and each Reporting Period shall cover a full calendar year. The calendar year of Mecomed starts 1st January and ends 31st December every year.

According to Chapter 4, Section 3 of the Mecomed Code of Ethical Business Practice, Part 2 of the Code shall enter into force on January 1st, 2019 and shall be retroactively applicable to all data collected during 2018. (i.e. The first disclosure should cover records occurred during the period from January 1st to December 31st, 2018 and records should be reported according to the set timeframe in section 2 below).

2. Time of Disclosure

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

3. Time of publication

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

4. Template and Language of Disclosure

For consistency purposes, disclosures made pursuant to these Disclosure Guidelines shall be made in English using the template set forth in the Annex II.

5. Disclosure Platform

Disclosures shall be made on the [Ethical MedTech website](#) unless the Member Company is already bound by national laws, regulations or professional Codes as regulated in Section 1.2 Applicability of these Disclosure Guidelines. Member Companies will remain liable for the accuracy of the disclosed data. For the avoidance of doubt, Mecomed shall not be held liable for (i) maintaining, correcting, deleting the published data nor (ii) for the storage of data after the three years period of disclosure in the public domain.

6. Disclosures Retention and Modification

Member Companies shall be able to modify, delete or in any way alter their disclosures at any time before the time of publication. Any modifications after the time of publication should be addressed with appropriate justification to the Mecomed Compliance Committee.

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

7. Enquiries Regarding Reported Disclosures

Member Companies shall make available to Healthcare Organizations upon request any data concerning their common contractual relations published in accordance with these Disclosure Guidelines at any time while the disclosed information remains in the public domain as stated in Section 2.3.3 Time of Publication.

Disclosed amounts should be in the currency used in the payment. In the Event the aggregate amount includes Educational Grants made in different currencies, the reporting company may choose in which currency they wish to disclose the aggregate amount, and keep appropriate record of the exchange rate used to convert the different currencies. This information will then be included in their Methodology Note.



PART 3: Procedural Framework

Chapter 1. Preamble

The principles set out below are intended to design an effective and efficient complaint-handling process, the object of which is to ensure compliance with the Mecomed Code of Ethical Business Practice (“the Code”) by Member Companies and any Third-Party Intermediaries (refer to the glossary). It is based on principles of proportionality, speed, due process, fairness and transparency. This Procedural Framework shall be reviewed every 5 years or earlier, if required.

Chapter 2. Transposition Obligations

Member Companies shall transpose the provisions of this Code internally by January 1st, 2018. No later than 1 January 2018, Member Companies shall cease direct financial and In kind support to individual HCPs to cover the costs of their attendance at Third Party Organised Educational Events. New Member Companies of Mecomed will be subject to the same obligations as current Member Companies. As soon as a Member Company transposes the Code internally it shall notify Mecomed, specifying the date on which such transposition became effective. Mecomed shall appropriately document and maintain records of all such notifications for statistical purposes.

Chapter 3. Code Applicability

- 3.1. This Code applies to all Mecomed Member Companies as well as to all Third Party Intermediaries.
- 3.2. Member Companies must comply with the Code, as amended from time to time, as a minimum standard when:
 - a. Member Companies or their aforementioned Third Party Intermediaries which interact with Healthcare Professionals and Healthcare Organisations registered and practising in the Mecomed geographic scope irrespective of where the activity takes place; and/or
 - b. Activities take place in the Mecomed geographic scope irrespective of where Healthcare Professionals and Healthcare Organisations are registered and practicing.
 - c. The Code shall be directly applicable to all activities of Member Companies and their affiliated companies in the Mecomed geographic scope.
 - d. Any activity or interaction described under this Section 3. and conducted by an affiliated company of a Member Company located outside the Mecomed geographic scope will be deemed attributable to said Member Company.

Chapter 4. MECOMED Escalation Procedure

1. Introduction

This escalation procedure is set to provide members with guiding information for addressing certain incidents or Events that violate the MECOMED Code of business practice, aiming to:

- a. Create a venue for addressing violations, issues and concerns among the members freely (and anonymously if requested by the involved parties)
- b. Improve communication among members in regards to addressing any issues
- c. Provide necessary support to Reporter (refer to the Glossary) as well as Recipients when needed
- d. Following up the escalated issues till they are resolved

- e. Raising the awareness of certain issues among members
- f. Sharing best practice, as deemed appropriate among members

2. Scope

This procedure is applicable to all Member Companies and shall apply to all violations, or alleged violations conducted by Member Companies or by any of their Third Party Intermediaries.

3. Reporting of Incidents

- a. Any member can report verbally or in writing any violation to the Mecomed assigned Escalation Committee (refer to the Glossary) providing the following information at a minimum:
 - 1. Description of the Violation
 - 2. Venue and date of the violation.
- b. Complaints shall be handled confidentially by all parties involved in the procedure. All involved Member Companies must be heard fairly.
- c. The Escalation Committee will contact the Compliance officer of the Member Company who allegedly made the violation (The "Recipient")
- d. The Recipient should investigate the alleged violation according to his/her company internal procedures
- e. The Recipient should provide a feedback to the Escalation Committee whether the issue has been substantiated or not
- f. If issue has been substantiated, the Recipient should take necessary corrective and preventive actions
- g. If issue hasn't been substantiated, The Recipient should inform the Reporter how the issue is seen at his/her company and why the Recipient company believes that the reported allegation is invalid
- h. The Escalation Committee would be responsible to follow up the with both Reporter and Recipient till issue is resolved
- i. In case of recurrence of the same incident, the Head of Mecomed Compliance Steering Group along with the Escalation Committee, would have the right to reach out to the headquarter of the Recipient Company addressing all related cases. If incident still found to repeat, issue will be addressed to the local Trade Association of the Headquarter of the Recipient Company

The aforementioned procedure should not be initiated or should be suspended in case of a formal investigation by law enforcement authorities or commencement of proceedings at ordinary courts with respect to the same or a substantially similar subject matter.

4. Incident Reporting

After an incident reported is closed, a summary will be shared to the rest of Mecomed Compliance Steering Group on anonymous bases. The Reporter shouldn't share the reported/alleged incident with any third parties without a written consent from the Recipient. Summary of the reported cases and sanctions -if applicable- shall be shared annually with Mecomed Executive Committee.



PART 4: Third Party Intermediaries Compliance & Due Diligence

Member Companies are requested to have appropriate effective and efficient Compliance Program covering their business partners, i.e. intermediaries, distributors, suppliers, etc. The selection and hiring of the business partners should be made based on the result of a risk-based due diligence process.

1. Due Diligence Minimum Requirements

The minimum requirements of such Due Diligence process should typically contain a review of the following:

- Years of Experience
- Proof of Status (TL/ CR/etc.)
- Owners & Shareholders names as per passport copies and legal documents (ID's, CV's of key personnel)
- Ties with Government Officials and Healthcare Professionals.
- Screening against public database

2. Recommended Requirements

- Organization Chart
- Owner's ID (e.g. passport copy)
- Company profile
- Historical information regarding good conduct and references
- Site visit by the Member Company's representative.

During the Site Visit MECOMED members should conduct interviews with key personnel and carefully review the warehousing facilities. The premises of the Third Parties intermediaries should be in a representable condition and equipped in a way that allows conducting business in an orderly manner.

3. Screening

In order to get a level of confidence in the business ethics of the potential business partner the following issues should also be taken into consideration:

- Transparency index for the relevant country
- Obtain outside references report
- Media/reputation check
- Sanctions/scandals check
- Investigations or litigations

4. Training:

All Member Companies which retain or oversee third party relationships, including anyone acting on their behalf, (e.g. vendors, suppliers, consultants, agents, co-promotional partners, etc.), should take appropriate and necessary measures to inform/train such third parties of the requirements of the "Code". Such measures may extend to include:

- 4.4.1. Appropriate contractual provisions and other controls as needed.
- 4.4.2. Development and communication of clear expectations and guidelines, including compliance with the "Code" and its requirements.
- 4.4.3. Development of training materials and the conduct of training programs as deemed appropriate and necessary. The training curriculum may be computer-based, interactive and live.

5. Contractual Obligations

- Acknowledgement & consent from business partner to Member Companies Compliance program.
- Contractual protections in third party agreements & general T&Cs.
- Amending existing agreements with Code of Conduct reference.

6. Basic steps for all business partners:

- Measures should take into account the results of your risk assessment.
- Enhanced due diligence, which is also in several levels, e.g. Third party questionnaires, verification against watch lists
- Basic, medium and high diligence reports
- Third party diligence process should be auditable

7. Due Diligence Renewal:

Member Companies should monitor all interactions with their business partners and should maintain a due diligence renewal more often as circumstances change – Each Member Company to set the frequency of due diligence renewal based on risk assessment basis.

Air time: 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 Organisations.

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

Code: means this MECOMED Code of Ethical Business Practice, the Disclosure Guidelines, MECOMED 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:

- Samples;
 - Evaluation Products;
 - Products provided at no charge as part of a Charitable Donation or as part of a Research or 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 Organisation 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 Organisation (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 Mecomed Compliance Steering Group in addition to two compliance officers who have completed at least 2 years in the compliance role and regularly attending the Mecomed face to face meetings. In case one or more Escalation Committee members are employed with the Recipient or the Reporter, the Mecomed 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 authorisation in the country where the supply occurs. Evaluation Products do not include the following:

- Demos;
 - Samples;
 - Products provided at no charge as part of a Charitable Donation or as part of a Research or 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.
-

Event: means either a Company Event or Third Party Organised Educational Event.

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

Financial Hardship: means in relation to a Healthcare Organisation extreme and unavoidable financial distress resulting from matters outside the Healthcare Organisation's control where the Healthcare Organisation is unable to operate and where patient care is consequently jeopardised. Financial distress resulting in whole or in part from mismanagement of the Healthcare Organisation'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 Organisation (HCO): means any legal entity or body (irrespective of its legal or organisational form) that is a healthcare, medical or scientific association or organisation which may have a direct or indirect influence on the prescription, recommendation, purchase, order, supply, utilisation, sale or lease of medical technologies or related services such as a hospital or group purchasing organisation, clinic, laboratory, pharmacy, research institution, foundation, university or other teaching institution or learned or professional society (except for patient organisations); 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 organisation; including but not limited to, physicians, nurses, technicians, laboratory scientists, researchers, research co-ordinators or procurement professionals) that in the course of 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 Organisation (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 Organised 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-Organised-Educational-Conference.

Professional Conference Organiser (PCO): a for-profit company or organisation which specialises 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:

- The safe and effective use of medical technologies, therapies and/or related services, and/or
- The safe and effective performance of clinical procedures, and/or
- 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 Mecomed member that noticed or became aware of the violation made by another Mecomed member.

Recipient: Is the Mecomed 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 organisation 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 in order to enable HCPs to familiarise themselves with the products in clinical use. Samples do not include the following:

- Demos;
 - Evaluation Products (refer to the Glossary);
 - Products provided at no charge as part of a Charitable Donation or as part of a Research or 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.
-

Scholarships and Fellowships: means Educational Grants provided to a Healthcare Organisation by or on behalf of a Member Company to support fellowships or scholarships offered by the Healthcare Organisation. 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 sub-specialty (e.g. medical training after a residency). "Scholars" and "Fellows" shall be understood accordingly.

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

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

Third Party Organised Procedure Training: means a type of Third Party Organised 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:

- 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 the majority 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 Organised Procedure Training.

Transition Period: June 2018 - Pilot phase, January 2019 – Mandatory to all Member Companies for the data of 2018. To be reported annually

ANNEX I

CVS SCOPE: When are CVS assessments required

Mecomed Geographic Area				
WHICH TYPE OF SUPPORT CAN MEMBER COMPANIES PROVIDE TO WHICH THIRD PARTY ORGANISED EDUCATIONAL EVENTS?		<u>NATIONAL</u> Third Party Organised Educational Events attended by delegates which are local HCPs only)	<u>Regional</u> Third Party Organised Educational Events attended by delegates coming from at least two countries of the Mecomed geographic area.	<u>INTERNATIONAL</u> Third Party Organised Educational Events attended by delegates coming from at least two countries of the Mecomed and MedTech Europe geographic area.
EDUCATIONAL GRANTS PROVIDED TO SUPPORT A THIRD PARTY ORGANISED CONFERENCE	Educational Grant to support the general running of a conference	Subject to CVS Decision	Subject to CVS Decision	Subject to CVS Decision
	Educational Grants that includes funds to support HCP attendance to the conference	Subject to CVS Decision	Subject to CVS Decision	Subject to CVS Decision
	Educational Grants that includes funds to support Faculty	Subject to CVS Decision	Subject to CVS Decision	Subject to CVS Decision
COMMERCIAL ACTIVITIES	Consultancy agreement for speakers in satellite symposia	Subject to CVS Decision	Subject to CVS Decision	Subject to CVS Decision
	Booths/advertising	Subject to CVS Decision	Subject to CVS Decision	Subject to CVS Decision

Conference Vetting System Assessment Criteria

✓ **Geographic location**

The geographic location should be in or near a city or town which is a scientific or business center conducive to exchange of ideas and the transmission of knowledge. The geographic location should not be the main attraction of the conference.

✓ **Conference venue**

The Event venue should be a business or commercial center with providing conference facilities conducive to the exchange of scientific and medical information and the transmission of knowledge. The image of the location among the public, media and authorities cannot be perceived as purely luxury, touristic/holiday and/or entertainment venue. Under no circumstances are to be considered compliant as Event venues:

- i. Resort hotels (meaning a hotel which is part of a complex offering significant recreational, amusement or sporting facilities).
- ii. Cruise ships, golf clubs (owned or operated by the hotel), spas or hotels with on-site casinos or private beach.

✓ **Proposed accommodation**

Member Companies may not pay for or reimburse HCP lodging expenses at top category, luxury or resort hotels.

Accommodation and/or other services provided to HCP delegates should not cover a period of stay beyond the official duration of the conference.

✓ **Scientific programme**

The detailed programme should present a clear schedule with no gaps during the conference scientific sessions (i.e., a minimum of 6 hours for full conference day/ 3 hours for a half day), the faculty for each session must be identified, the session topics must be serious medical subjects.

The programme content should directly relate to specialty and/or medical practice of the HCP who will attend the conference or have a sufficiently reasonable relationship to justify the attendance of the HCPs.

✓ **Guest packages**

The registration fee should cover only the scientific programme and authorized activities and hospitality.

Spouses, partners, family and/or Guests' packages may not be paid for by member Companies unless he or she is a qualified HCP with a legitimate interest in the programme

✓ **Social Programme**

Any social, sporting and/or leisure activities or other forms of entertainment must be outside of the programme schedule and paid for separately by the HCP delegates. They should not dominate or interfere with the overall scientific content of the programme and must be held during times that do not overlap with scientific session. They should not be the main attraction of the conference.

✓ **Communication**

Advertising support (brochures, website and other materials) should highlight the scientific nature of the programme content. They should not emphasize the geographic location and should not make excessive or inappropriate references to or contain images of entertainment, sporting Events or other non-scientific activities.

ANNEX II

Disclosure Guidelines Template Example*

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

*Please note that this template is for illustrative purposes only. The template to be used for reporting purposes is available in the [Transparent MedTech website](#).

ANNEX III

Example of Disclosure Guidelines Methodology Note

STRUCTURE

1- Introduction

2- Executive summary of the methodologies used for disclosure purposes and countries specificities

3- Definitions

- Recipients
- Types of Educational Grants

4 - Disclosure scope and timelines

5 - Disclosures in case of partial performance or cancellation

6 - Cross-border activities

7 - Specific considerations:

- Multi-year agreement
- 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

8 - Disclosure Form

- Date of submission
- Currency in case of aggregated payments made in different currencies
- VAT included or excluded and any other tax aspects

9- Disclosure financial data and amount of Educational Grants provided

10 - Calculation rules

Disclaimer: This Methodology note is provided as a template to support Member Companies in the implementation of these Disclosure Guidelines. Any other template may be equally valid provided it complies with the general requirements set out in Section 2.4 Methodology.

ANNEX IV

Mecomed Geographical Area



The Mecomed Geographic Area currently includes:

Algeria	Lebanon	Qatar
Bahrain	Libya	Saudi Arabia
Egypt	Mauritania	Sudan
Iran	Morocco	Syria
Iraq	Oman	Tunisia
Jordan	Pakistan	United Arab Emirates
Kuwait	Palestine	Yemen