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Code of Ethical Business Practice

Mecomed Guidelines on Interactions with Healthcare Professionals & Healthcare Organizations

Executive Committee Approved January 2021

INTRODUCTION

Mecomed is the medical devices, imaging and diagnostics trade association, serving as the voice of international medical technology manufacturers operating in countries across the Middle East & Africa (see Annex II).

The present Code 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 acting on behalf of the Member Companies, both sales intermediaries and other Third-Party agents, including but not limited to, consultants, distributors, sales agents, marketing agents, brokers, commissioner commercial agents and independent sales representatives, who interact with Healthcare Professionals and Healthcare Organizations in connection with the sale, promotion or any other activity involving members' products, comply with the Mecomed Code of Ethical Business Practice. Accordingly, where such arrangements are entered, the relevant contractual documentation must impose obligations upon the Third-Party to comply with the 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 Privacy & 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 Organizations is an important feature in achieving Mecomed's 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 requires collaboration between Member Companies and Healthcare Professionals (as defined in the attached Glossary) and Healthcare Organizations (as defined in the attached Glossary). Innovation and creativity are essential to the development and evolution of medical technologies and/or related services often occurring outside the facilities of medical device companies.

- **Safe and Effective Use of Medical Technology**
  The safe and effective use of medical technology and related services requires Member Companies to offer Healthcare Professionals and Healthcare Organizations appropriate instruction, education, training, service and technical support. Regulators may also require this type of training as a condition of product approval and as per local laws.

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

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

1. **The Principle of Image and Perception**
   Member Companies should always consider the image and perception of the medical technology industry that will be projected to the public when interacting with Healthcare Professionals and Healthcare Organizations.

2. **The Principle of Separation**
   Interaction between industry and Healthcare Professionals / Healthcare Organizations must not be misused to influence through undue or improper advantages, purchasing decisions, nor should such interaction be contingent upon sales transactions or use or recommendation of Member Companies' products.

3. **The Principle of Transparency**
   Interaction between industry and Healthcare Professionals / Healthcare Organizations must be transparent and comply with national and local laws, regulations or professional codes of conduct. In countries where specific provision is not made, Member Companies shall nevertheless maintain appropriate transparency by requiring prior written notification to the hospital administration, the Healthcare Professional's superior or other locally designated competent authority, fully disclosing the purpose and scope of the interaction. Refer to Part 1, Chapter 1.6 Transparency.

4. **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.

5. **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 foreseen 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 at least once every 3 years or earlier if needed.

Implementation and Transition Period

This edition of the Code comes into force as of January 1st, 2021.

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

CHAPTER 1. GENERAL CRITERIA FOR EVENTS

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

1.1. Event Program

The Event Program should:

1. 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;

2. Be available (in detail) sufficient time prior to the Event;

3. Present a clear schedule with no gaps during the sessions, (e.g., the minimum duration for a full day Event should be 6 hours or 3 hours for a half day Event including refreshment breaks). For the avoidance of doubt, for events lasting more than 1 day, a half day can be scheduled only on the afternoon of the first day or on the morning of the last day of the Event;

4. For Third-Party Organized Educational Events, the agenda should be under the sole control and responsibility of the Third-Party organizer;

5. For Third-Party Organized Educational Events, the Faculty must be identified;

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

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

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

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

1.2. 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 always consider the following:

1. 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.

2. 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.

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

4. For Third-Party Organized Educational Event, exceptions to the aforementioned rules related to Event venue and location suitability, can be granted by the Conference Vetting System following thorough assessment of the Event in question in order to obtain an exception on the CVS decision, the request or must submit an appeal for consideration by the Mecomed Compliance Core Committee. Such assessment shall be based on the published Conference Vetting System Assessment Criteria outlined in Part 1, Chapter 2.1.

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

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

1.4. Reasonable Hospitality

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

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. 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.

1.5. 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 Airtime, in which case business class can be considered. First class is never appropriate. (Refer to the Glossary for the definition of Airtime)

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

1.6. Transparency

1. Employer Notification

Member Company shall ensure full compliance with local laws regarding the disclosure or approval requirements associated with consultancy engagement, transfer of value or financial support provided to a healthcare professional. Where no such national requirements are prescribed, Member Companies shall nevertheless maintain appropriate transparency by requiring Employer Notification i.e. prior written notification to the hospital administration, the Healthcare Professional's superior or other locally designated competent authority. Such Employer Notification is required whenever a Member Company sponsors/engages Healthcare Professional in Company Event, Third-Party Organized Procedure Training, or as a Consultant even if no consultancy fee will be involved.

However, Incidental interactions arising in the normal course of business such as meals associated with educational or business meetings or the receipt of modest "Promotional and Educational Items" as defined in Chapter 9, related to the Healthcare Professional's practice, do not require Employer Notification.

2. Educational Grant Disclosure

Member Companies shall document and disclose all Educational Grants in accordance with the Disclosure Guidelines outlined in Part 2.

CHAPTER 2. THIRD-PARTY ORGANIZED EDUCATIONAL EVENTS

2.1. Conference Vetting System (CVS)

2.1.1 Definition and scope

CVS is an independently managed system which reviews the compliance of Third-Party Educational Events with the Mecomed Code of Ethical Business Practice to determine the appropriateness for Member Companies to provide financial support to such events in the for of:

- Educational Grants
- Commercial activities (booths, advertisement, satellite symposium, etc.)

CVS is applicable to (international, regional and national Third-Party Educational Events) as defined in Annex I.
CVS is a mandatory process for all Mecomed Members. The decision of CVS is binding on all Mecomed members and their Third-Party Intermediaries and CVS approval must be obtained prior to supporting any Third-Party Educational event.

Excluded from CVS Assessment:

1. National in-institution activities:
National event Organized by a Health Care Organization (HCO) in a medical facility such as clinic, hospital, laboratory etc., is exempt from the CVS assessment process only if ALL following conditions are met:

- The event is of an educational content and is addressed to the Healthcare Professionals (HCPs);
- No registration fees;
- No accommodation;
- No transportation/travel.

For the avoidance of doubt, Member Companies must ensure compliance to Part 1, Chapter 1 General Criteria for Events in all cases.

2. Public Awareness Campaign:
Event Organized by HCO intended to provide information, promoting awareness and/or educating patients and the public about relevant healthcare topics or medical conditions or diseases in therapeutic areas. Such event is exempt from CVS submission.
In case any part of the agenda includes any session addressed to HCPs, the Event cannot qualify as Public Awareness Campaign.

2.1.2 CVS Criteria for Assessment

The review process is based on a set of 7 criteria of equal weight in the assessment process. The Criteria of Assessment is as follows:

- The scientific program as per Part 1, Chapter 1.
- The geographic location as per Part 1 Chapter 1.
- The conference venue as per Part 1 Chapter 1.
- Hospitality as per Part 1, Chapter 1.
- Registration fees:
  1. The registration fees should cover only the scientific program, access to the event exhibition, and reasonable hospitality of the Event.
  2. Registration must be offered to HCPs only. Any spouses, partners, family and/or Guests' packages must not be covered or facilitated by Mecomed Members
  3. Any social, sporting and/or leisure activities or other forms of entertainment must be outside of the main program and must be paid separately by delegates. Such activities should not dominate or interfere with the overall scientific content of the program and must be held during times that do not overlap with scientific sessions.

- Sponsorship packages:
  Sponsorship packages should be transparent, outlining clearly the value of the sponsorship package options, as well as the different benefits provided under each package.

  Examples of non-permissible benefits include, but are not limited to; gifts to delegates or speakers, first class tickets, business class tickets for flights less than 5 hours, touristic tours and other entertainment options, such as participation in live music or sports events etc. Such activities must be subject to a separate charge and must not be paid for, facilitated or reimbursed by, a Member Company.

  It is the responsibility of each Mecomed Member Company to ensure that any free delegate passes distributed under sponsorship packages will not be used for direct Sponsorship of HCPs without any involvement of the Member Company in the delegate selection process, in accordance with the requirements of the Mecomed Code.

  Mecomed Member Companies must ensure that the component related to the indirect sponsorship of HCPs is allocated appropriately on their books and records as Educational Grants.

- Communication support:
  Advertising support (brochures, website, and other materials) should highlight the scientific nature of the program content. They should not overly 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.

  For any Third-Party Procedure Training, additional criteria will be assessed by CVS as outlined in Part 1, Chapter 2.3.

2.1.3. CVS Submission Timeline

The submissions of an application for any Third-Party Educational Events (National, regional and international) in the CVS website is recommended to be done 75 days prior to the event starting date or earlier.

At this stage, the following information are needed as a minimum requirement:

- Name of the event
- Date of the event
- Venue name
- Location of the event

The submission of the complete set of documentation for an already registered/listed event in CVS is recommended to be done minimum (35) days prior to the event starting date (or earlier).
At this stage, in addition to the above-mentioned information, the following documentation is required:

- Detailed Program with a clear time frame format
- Communication Support (website or brochure)
- Registration Fees for delegates
- Sponsorship packages / Prospectus offered to companies to participate in the event

For events submitted aligned with the CVS timeline, where documentations or information are still missing 10 days before the Event starting date, the event will be marked as "Not assessed / insufficient information" on the CVS system.

2.1.4 CVS Appeal Process

An appeal may be filed by a Member Company or a Third-Party Educational Event Organizer to the Mecomed Compliance Officer in writing.

Any appeal must be documented and motivated with written legitimate justifications.

The Mecomed Compliance Officer will forward the appeal request to the Mecomed Compliance Core Committee as defined in Part 3, Section 4.

The Mecomed Compliance Core Committee will assess the appeal and the relevant documents/ justification and shall take a decision within a maximum of 10 working days from the receipt of the appeal request.

The security level of the venue in comparison to other venues, the number of expected attendees, the availability of conference facilities, the overall suitability of the selected venue, the specificity of the geographic location, logistics considerations and any other compelling justifications can establish the granting of a change of the CVS decision.

The rationale for amending the CVS assessment should be clearly documented along with the initial Event's assessment outcome on the CVS.

2.2. Third-Party Organized Educational Conferences

Where permitted under Local laws, regulations and professional codes of conduct, Member Companies may provide financial and/or in kind support to Third-Party Organized Educational Conferences, provided that the Third-Party Organized Educational Conference (i.e. Booth, Sponsorship or Educational Grants) has been approved via the Conference Vetting System. Support maybe provided through grants and other types of funding, such as:

- **Educational Grants**:
  Refer to Part 1, Chapter 4.

- **Promotional Activity:**
  Member Companies may purchase packages that may include promotional and advertising services, for example, advertisement space and booth space for company displays.

  Member Companies should ensure that the overall image projected by the promotional activity at Third-Party Organized Educational Conferences is perceived as professional always. It should never bring discredit upon or reduce confidence in the medical technology industry.

  Booth activities at Third-Party Organized Educational Conferences should aim primarily at displaying Member Companies' products and services and related literature. Therefore, only soft drinks and snacks should be served.

- **Satellite Symposium:**
  Member Companies may organize Satellite Symposium within Third-Party Organized Educational Conferences provided they are consistent with the overall content of the Event. Satellite symposium costs (e.g. time-slot cost) should be reflected in the "Sponsorship/ Commercial" part on the event's brochure / packages and not under "Educational Grants".

It is permissible for Member Companies to:
- Select Speakers for their satellite symposia
- Speaker name at company sponsored Satellite Symposia can be shown on the agenda
- Directly sponsor (i.e. pay honorarium / hospitality expenses) Speakers to their satellite symposium (in compliance with the Code related guidelines (Part 1 Chapter 1, Part 1 Chapter 5, and Part 1 Chapter 6).
- Where payment of a registration fee is required for the speaker to access the Satellite Symposium, Member Company may pay the registration fee related to the Satellite Symposium (most restricted package).
- Directly enter into contractual agreements with the Speakers.
- Member Companies can invite HCPs already attending the Third-Party Educational Event to the Company Organized Satellite Symposium provided that the Member Companies do not directly cover any cost related to Registration, Travel & Accommodation.
- It is not permissible for Member Companies to cover additional hospitality expenses for the Speaker of the Member Company's Satellite Symposium to attend the Third-Party Educational Event (e.g. accommodation for all the event days).

2.3 Third-Party Organized Procedure Training

1. Definition

An Organized Procedure Training is primarily intended to provide Healthcare Third-Party Professionals with information and hands-on training on the safe and effective performance of one or more clinical procedures in circumstances where the information and training concern:
- Specific therapeutic, diagnostic or rehabilitative procedures, namely clinical courses of action, methods or techniques (rather than the use of medical technologies); and
- Practical demonstrations and/or training for HCPs, where the majority of the training program is delivered in a clinical environment.

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

2. Scope

Member Companies may support Third-Party Organized Procedure Training either via Educational Grants (As outlined in Part 1, Chapter 4) or by providing financial support directly to individual Healthcare Professionals to cover the cost of attendance at standalone Third-Party Organized Procedure Training, provided that all applicable conditions are met.

Third Party Organized Procedure Training will not qualify as a Stand Alone if the Training is Organized in connection, adjacent to, or at the same time and location as part of a larger Third-Party Organized Educational Conference. In such case, direct sponsorship to Healthcare Professional will not be permitted.

Third-Party Organized Procedure Training must be vetted by CVS:
- In accordance with the criteria provided in Part 1, Chapter 1
- In addition to the Chapter 1, CVS will assess the Event in accordance with the below additional criteria:

Program: The program must include practical demonstrations (and/or actual live surgeries where allowed). To consider an event a Third-Party Procedure Training (TPPT), the practical sessions must in all cases represent more than 50% of the full program with hands-on by the attendees. This requirement must be clearly indicated in the program of the TPPT.

Venue: Third-Party Organized Procedure Trainings are typically Organized in a clinical environment, as opposed to, e.g., a classroom setting. For the avoidance of doubts, the adjective "clinical" includes places suitable for the simulation of medical procedures, rather than just the medical treatment of real patients.
Examples of simulation settings include conference or meeting rooms which are appropriately equipped with relevant simulation devices/systems or experimental laboratories suitable for training on cadavers, skin models, synthetic bones, live animals in accordance with applicable regulations and ethical rules, etc.

2.4 Third-Party Organized Public Awareness Campaigns

Member Companies may participate to Third-Party Organized Public Awareness Campaign by providing education grant (as outlined in Part 1, Chapter 4) and/or by having a booth provided that:

- Local laws & regulations allow direct interaction with public
- The main purpose of the booth is to share medical information
- The participation is widely advertised, allowing other companies to participate
- Tthe booths are held in a separate area than the educational session for patients

CHAPTER 3. COMPANY ORGANIZED EVENTS

3.1. General Principles

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

- Company Educational Events
- Manufacturing Site Visit
- Company Promotional Events

Company events are not subject to CVS approval. However, Member Companies shall ensure compliance of the Company Events with the principles mentioned in Part 1, Chapter 1.

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

On occasion, Company Events, 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.

3.2. Company 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 training, procedure training or education available to relevant Healthcare Professionals.
It is appropriate for Member Companies to invite Healthcare Professionals, meaning paying for their travel and accommodation.
In all cases the information and/or training must directly concern a Member Company's medical technologies, therapies and/or related services.

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

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 Educational Events

1. The entire Event must comply with the criteria of Part 1, Chapters 1 and 3.

2. The program 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.

3. The program must be genuine and bona fide educational, and therefore cannot have a sales and marketing objective. This means that the education part must fill most of the program. If the program includes a half day agenda (according to Part 1, Chapter 1). It should be a fully dedicated educational session in order to qualify as a Company Educational Events.

4. Information on the program, clearly indicating the name of the Company organizing the Event, should be made available in advance

3.3. Manufacturing Site Visit

Where there is a legitimate business purpose, Company Events may include or take place in Member Company's manufacturing plant or Healthcare Organizations, used by the Member Company as reference centers.

It is appropriate for Member Companies to invite Healthcare Professionals (meaning paying for their travel and accommodation) to plant or factory tours in countries outside their country of residence if there is a legitimate business purpose. The program must have at a minimum a full day agenda (as per Part 1, Chapter 1) and must include educational/scientific session.

3.4. Company Promotional Event

Where it is appropriate, Member Companies may organize Company Promotional Event 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(s).

Member Companies may provide reasonable and modest meals as well as land transportation to Healthcare Professionals. However It is not appropriate for Member Companies to provide air travel or accommodation support to Healthcare Professionals, except where demonstrations of non-portable equipment are necessary.

CHAPTER 4. GRANTS AND CHARITABLE DONATIONS

4.1. General Principles

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

A Member Company shall not provide Grants or Charitable Donations to individual Healthcare Professionals. Grants and Charitable Donations must be provided directly to the qualifying Organization or entity.

Grants and Charitable Donations shall not be provided in response to requests made by Healthcare Professionals unless the Healthcare Professional is an employee or officer of the qualifying Organization or entity and submits the request in writing on behalf of the qualifying Organization or entity.

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.

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. This process shall include a documented, prior evaluation of any such associated risks and of the relevant information concerning the intended recipient Organization or entity.

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 process could be led by a Member Company's responsible functions, operating within a robust governance framework and according to clear, consistent and transparent criteria to review decision-making.

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. 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) Organization 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.

2. For Educational Grants provided in relation to Third-Party Organized Educational Events, 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.

All Grants and Charitable Donations must be appropriately documented by the Member Company. Moreover, Grants and Charitable Donations shall only be provided in response to a written request submitted by the requesting Organization or documented initiative from a Member Company containing sufficient information to permit an objective evaluation of the request to be carried out by the Member Company. No Grant or Charitable Donation shall be provided until a written agreement documenting the terms of this is signed by both parties.
The written request by a requesting Organization should include as a minimum a detailed description of the scope and purpose of the program, 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. The support may be financial or in kind which must only be provided to the Healthcare Organization (HCO).
Member Companies should ensure that such in kind support does not, nor is perceived to, circumvent the prohibition of Member Companies providing direct financial support to identifiable Healthcare Professionals to attend Third Party Organized Educational Conferences.
Examples of "in kind support" which Member Companies may provide could include modest secretarial and/or logistical support to assist with meeting arrangements. For example, it would not be appropriate for Member Companies to handle the conference registration, travel, or accommodation arrangements for individual (and identifiable) Healthcare Professionals delegates at a Third- Party-Organized-Educational-Conference
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 Organization and shall be paid directly to the Organization. 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.

The Educational Grant can be provided in one of the following formats:

1. Directly to Healthcare Organizations and / or Professional Conference Organizers
2. Indirectly to Healthcare Organizations and / or Professional Conference Organizers through Third-Party Travel AgentsB)

4.2. 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 Organization 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. For the sake of clarity, public or private Hospitals or University are not considered as charitable Organization or other non-profit entities. Such Charitable Organization and non-profit entities should be licensed to conduct the aforementioned activities.

Restricted Charitable Donations to non-profit hospitals may be permissible in case of demonstrated Financial Hardship, 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.

4.3. Educational Grants

Member Companies may provide restricted Educational Grants 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:

1. **General Principles:**
   As a general principle, any Third-Party Organized Educational Event supported by way of an Educational Grant from a Member Company to a Healthcare Organization must comply with Part 1, Chapter 1. General Criteria for Events; and unless exempted as per the conditions outlined in Part 1,Chapter 2, have approval by CVS.

2. **Support for Healthcare Professional Participation at Third-Party Organized Educational Events:**
   Where the Educational Grant is provided for the purpose of supporting Healthcare Professionals' attendance at Third-Party Organized Educational Events, the Healthcare

Organization or Professional Conference Organizer receiving the Grant shall be solely responsible for selection of participants and this shall be expressly reflected in the written Grant agreement. Names of selected HCPs are not shown/disclosed in the Educational Grant request letter / agreement.

A Member Company must ensure the following:
Member Company should have an Educational Grant agreement with the recipient Organization to include the purpose of the Educational Grant. Rights to enable it to verify that the Grant is in fact used for the agreed intended purpose.

Member Companies may specify the participating Healthcare Professionals specialty in accordance with the specified grant. However, the Healthcare Organization or Professional Conference Organizer receiving the Grant shall be solely responsible for selection of participants and this shall be expressly reflected in the written Grant agreement.

Member Company shall define a proper mechanism to ensure that the Educational Grant is used for the purpose mentioned in the agreement.

Member Companies shall document and disclose all Educational Grants in accordance with the Code's Disclosure Guidelines.

3. Support for Third-Party Organized Educational Events:
Where the prospective beneficiary of an Educational Grant is the organizer of the Third-Party Organized Educational Event and is also a Healthcare Organization, the recipient Healthcare Organization shall be solely responsible for:

1. The program content;
2. The selection of Faculty; and
3. The payment of Faculty honoraria, if any.

Member Companies shall not have any detailed involvement in determining the content of the educational program or selection of Faculty and this shall be reflected in the written Grant agreement. Only if expressly requested to do so in writing, Member Companies may recommend Faculty or comment on the program.

4. Support of Faculty for Third-Party Organized Educational Events:
Member Companies may provide Educational Grants to HCOs/PCOs for the support of Faculty as part of the agenda of Third-Party Educational Events. The Recipient HCO/PCO in that case will be solely responsible for all related arrangements (honorarium, hospitality....)
Member Companies shall obtain the minimum required information and documents by the Recipient HCO/PCO, to ensure the Educational Grant is consistent with the Member Company's Fair Market Value guidelines.

However, Member Companies may not request/receive resumés/CVs or other information leading to identifiable HCPs of the Faculty supported through the Educational Grant by the HCO/PCO.

Member Companies shall not directly pay honorarium / hospitality expenses to the Faculty or enter into a contractual agreement with the Faculty, unless this is required under applicable laws and regulations.

In any case, Member Companies may not provide Educational Grants to HCOs/PCOs for the support of Faculty at a Third-Party Educational Event if it has not been approved by CVS.

Educational Grants paid to support Faculty at a Third-Party Educational Events must be of an educational nature and must be appropriately recorded in Member Companies' books and records, as an Educational Grant (not under "Sponsorship/Commercial" packages), and should be reflected in the event's brochure / packages.

5. Scholarships and Fellowships:

Member Companies may provide Educational Grants on a restricted basis in the form of Grants for Scholarships and Fellowships to support advancement of genuine medical education of Healthcare Professionals.

Only Healthcare Organizations where Healthcare Professionals are in training shall be eligible to request and/or receive such Educational Grants.

A Member Company shall not provide Educational Grants to support Scholarships and Fellowships upon request of individual Healthcare Professionals. Similarly, the Member Company shall not have any involvement in any way in the selection of the 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 Organization.

6. Public Awareness Campaigns:

A Public Awareness Campaign is an event Organized for the legitimate purpose of providing information, promoting awareness and/or educating patients 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.

Such disease awareness campaigns must not, however, have a primarily objective to promote the use of particular therapies, services or promote specific Healthcare Organizations, nor may they aim to stimulate demand by the public for specific therapies or for specific Healthcare Organizations.

A Member Company may provide an Educational Grant for the general support of the event only to support the provision of high-quality information to patients and the public about health and disease provided the following:

- there is a 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.

- For the avoidance of doubt, Member Companies are allowed to have their company logo displayed on the materials related to the Public Awareness Campaign. For these events, CVS approval would not be required.

4.4. Research Grants

Where permitted by national laws, regulations, national guidelines and professional codes of conduct, Member Companies may provide restricted Research Grants to support clearly defined Third-Party-initiated research studies for clinical or non-clinical research programs 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 document the intended research scope and purposes for which the Grant is requested and shall ensure that the written Grant agreement with the recipient Organization includes rights for the Member Company to verify that the Grant is applied solely for the agreed intended research use.

Such verification may include a request for study-related documentation, such as a copy of the research protocol, a copy of the ethics committee and/or regulatory approvals or a copy of the study report upon completion or earlier termination of the research.

CHAPTER 5. ARRANGEMENT WITH CONSULTANTS

5.1. 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 on 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 including but not limited to transparency requirements and Employer Notification.

The principles in this Chapter are applicable to all consulting arrangements between Healthcare Professionals and Member Companies even when no honorarium is paid to the consultant HCP.

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.

5.2. Criteria for Consulting Arrangements

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

1. Consulting arrangements must be entered into only where a legitimate business need for the services is identified in advance.

2. The number of consultants retained must not be greater than the number reasonably necessary to achieve the identified need.

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 Organization where they perform their professional activity is not a relevant criterion.

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.

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.

6. The remuneration for the services rendered must be reasonable and reflect the fair market value of the services provided.

7. Member Companies must maintain records of the services, and associated work products, provided by the consultant Healthcare Professionals and of the use made of those services by the Member Company.

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 Part 1, Chapter 1. Events.

CHAPTER 6. REMUNERATION AND FAIR MARKET VALUE

The remuneration paid to HCPs engaged as consultants by Member Companies shall reflect fair-market-value for the services provided. It shall not be in any way contingent upon the value of products or services which consultants may purchase, lease, recommend, prescribe, use, supply or procure 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. RESEARCH

7.1. 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 Part 1, Chapter 5.

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. (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 Organization (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.

7.2. 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 Organization 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 Organization 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 Organization.

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

7.3. Third-Party-Initiated Research

Refer to Part 1 Chapter 4.4

CHAPTER 8. 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 commercialization.

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 Organization.

CHAPTER 9. PROMOTIONAL & EDUCATIONAL ITEMS PROVIDED TO HCOs/HCPs

9.1. Definitions

1. **Promotional Items:**
   Include, among others, inexpensive promotional aids and brand reminders such as company branded or non-branded calendars, notepads, mouse-pads, post-it notes, USB memory sticks, stationary items.
   All Promotional Items should comply with the general principles in this section and can be provided either to HCOs or directly to HCPs.

2. **Educational Items:**
   Include, among others, medical textbooks, medical journal subscriptions and medical utilities that are beneficial to enhancing the provision of medical services and patient care.
   In addition to complying with the general principles in this section, Educational Items should also:

- Be related to the therapeutic areas in which the Member Company is interested / involved.

- Be appropriately documented in the Member Company's books and records.
- Be provided to HCOs only.

  Educational Items that due to their nature can only be provided to individual HCPs (such as medical journal subscriptions under HCP individual name) should be accompanied by an official HCP nomination letter issued by the HCO.
  Such items should not be part of the Healthcare Organization's normal overheads or routine costs of operation.

9.2. General Principles

1. Promotional and Educational Items:

- Should comply with national laws, regulations and industry and professional codes of conduct
- Should relate to the HCP's practice, or benefit patients, or serve a genuine educational function
- Should not be for the personal benefit of the HCPs such as items primarily used at home/in the car
- Should not be provided in response to requests initiated by HCPs
- Should not be given in the form of cash or cash equivalents (e.g. debit/gift cards/gift certificates)
- Should not be provided with the purpose of rewarding, incentivizing and/or encouraging HCPs to purchase, lease, recommend, prescribe, use, supply or procure the Member Company's products or services.
- Should not be provided to HCPs engaged as consultants/speakers in lieu of a professional fee for their services.
- Should not be offered on more than an occasional basis, even if each individual item is appropriate
- Should not be provided for personal benefit or out of cultural courtesy (e.g. life events, promotion, birthdays etc.)
- Do not require Employer Notification

2. Prize draws:

Prize draws and other competitions held at Events addressed to HCPs / HCOs are permissible if the prize awarded complies with the aforementioned principles. On an exceptional basis, due to the nature of the prize draw, prizes can be provided either to HCOs or directly to HCPs.

Chapter 10. DEMONSTRATION PRODUCTS & SAMPLES

10.1. General Principles

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

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 Organizations to purchase, lease, recommend, prescribe, use, supply or procure Member companies' products or services. Any offer and/or supply of such products shall always be done in full compliance with applicable national laws, regulations and industry and professional codes of conduct.
Member Companies shall in all cases maintain appropriate records in relation to the provision of Demonstration Products and/or Samples to Healthcare Professionals and/or

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

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.

10.2. Demonstration Products (Demo)

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

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 books and records as well as clearly disclose to Healthcare professionals and/or Healthcare Organizations the no-charge basis and other conditions applicable for the supply of such demonstration Products no later than the time of the supply. It is recommended that the disclosure to Healthcare Professionals and Healthcare Organizations be in writing.

10.3. Samples

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

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

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

PART 2: Disclosure Guidelines

2.1 Preamble

Medical education may be supported through the provision of Educational Grants to Healthcare Organizations in compliance with the rules outlined in the Code. To prevent abuses, specific safeguards when providing Educational Grants have been developed, including the obligation to disclose these Educational Grants. (Refer to Part 1, Chapter 4)

Member Companies are not permitted to pay registration fees, travel or hospitality expenses directly to individual Healthcare Professionals for their participation in educational event Organized by third parties.

Member Companies shall document and disclose all Educational Grants in accordance with these Disclosure Guidelines. (Refer to Part 1, Chapter 4.3)

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 Organizer ("PCO") acting on behalf of any Healthcare Organization 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 Organizations, these shall also include Professional Conference Organizers.

2.1 Applicability of these guidelines

2.2.1 Scope

These Disclosure Guidelines apply to Member Companies in their interactions with Healthcare Organizations based or registered in the Mecomed geographic area. (see Annex II)
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 comply with these Disclosure Guidelines.
Transfers of value, which are not included in the definition of Educational Grants (refer to Part 1, Chapter 4.3) and that consequently cannot be allocated to any of the categories set forth (in Part 1, Chapter 2.2), Aggregate Disclosure are not within the scope of these Disclosure Guidelines.

The annual applicable geographic scope of disclosure shall be updated on the Mecomed Disclosure platform.

2.2.2 Applicability of these Disclosure Guidelines

Member Companies shall not be required to report the same information twice due to being bound by national laws, regulations or professional codes imposing disclosure obligations regarding Educational Grants (refer to Part 1, Chapter 4.3) equivalent to the ones imposed by these Disclosure Guidelines, therefore whenever a member company is required by local law to disclose the same information it is exempted from Mecomed reporting.

Transactions paid by Third-Party Intermediaries which will be reimbursed by member companies are to be disclosed. In case reimbursement is for partial contribution to a certain grant, member company needs to disclose the reimbursable part only.
For the avoidance of doubt, transactions paid by Third-Party Intermediaries Educational grants that is not reimbursed by member companies are exempt from Mecomed disclosure requirement.

2.3 Disclosure Obligation

2.3.1 General Obligation

Subject to the terms of these Disclosure Guidelines, each Member Company shall document and disclose all payments related to Educational Grants (refer to Part 1, Chapter 4.3) that it makes to a Healthcare Organization/PCO based or registered in Mecomed Geographic Area, without limitation of value.

To the best extend, Member Companies must disclose Educational Grants paid by their Affiliates to HCOs and/or PCOs, provided that the ultimate beneficial recipients are located within the geographical scope of Mecomed and as long as such Educational Grants are not disclosed or reported through other transparency requirements/tools.

2.3.2 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 the reporting period which can be reasonably allocated to one of the categories set out below.

Educational Grants to support Third-Party Organized Events (including but not limited to support HCP Participations at the Third-Party Organized Educational Events) and, Other Educational Grants to Healthcare Organization (including Scholarships, Fellowships and/or Grants for Public Awareness Campaigns).

2.3.3 Optional Object Specification

If desired, Member Companies may indicate the object of the Educational Grants disclosed for one or both categories set forth (in Part 1, Chapter 2.2).

2.3.4 Methodology

Each Member Company shall create a note summarizing the methodologies used in preparing the disclosure and identifying Educational Grants for each category outlined in Part 1, Chapter 2.3.2
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 purposes of these Disclosure Guidelines, as applicable.

2.4 Form of Disclosure

2.4.1 Reporting Period

Disclosure 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.
The annual disclosure timeframe and mechanism shall be according to the schedule published on the Mecomed disclosure platform.

2.4.2 Time of Disclosure

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

2.4.3 Time of Publication

The disclosure shall be made available to Mecomed Members from 1st September of the disclosure year.

2.4.4 Template and Language of Disclosure

For consistency purposes, disclosure made pursuant to these Disclosure Guidelines shall be made in English using the template set forth on Mecomed Disclosure platform.

2.4.5 Disclosure Platform

Disclosure shall be made on the Mecomed Disclosure platform unless the Member Company is already bound by national laws, regulations or professional codes as regulated in Part 2, Chapter 2.2. 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 Mecomed disclosure platform.

2.4.6 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 Core Committee.
The information disclosed shall remain in the Mecomed platform for 3 years after the time of publication.

2.4.7 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 Mecomed domain as stated (Part 2, Chapter 2.4.3).

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 (refer to Part 2, Chapter 2.3.4)

PART 3: Procedural Framework / Governance

3.1 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 present Code by Member Companies and any Third-Party Intermediaries.
It is based on principles of proportionality, fairness and transparency.

3.2 Transposition Obligations

Member Companies shall transpose the provisions of this Code internally.
From January 1, 2018, Member Companies shall cease direct financial and in-kind support to individual HCPs to cover the costs of their attendance at Third-Party Organized Educational Events.
New Member Companies of Mecomed will be subject to the same obligations as current Member Companies.

3.3 Code Applicability

3.3.1 This Code applies to all Mecomed Member Companies as well as to their Third-Party Intermediaries.

3.3.2 Member Companies must comply with the Code, as amended from time to time, as a minimum standard when:

- Member Companies or their Third-Party Intermediaries which interact with Healthcare Professionals and Healthcare Organizations registered and practicing in the Mecomed geographic scope irrespective of where the activity takes place; and/or
- Activities take place in the Mecomed geographic scope irrespective of where Healthcare Professionals and Healthcare Organizations are registered and practicing.
- The Code shall be directly applicable to all activities of Member Companies and their affiliated
- companies in the Mecomed geographic scope.
- Any activity or interaction within Mecomed geographic scope conducted by an affiliated company of a Member Company located outside the Mecomed geographic scope will be deemed attributable to said Member Company.

3.4 Mecomed Compliance Core Committee

The Mecomed Compliance Core Committee shall consist of 8 members including:

Permanent Members:

- Chair of Compliance Steering Committee
- Vice Chairs of Compliance Steering Committee
- Compliance Officer of Mecomed
- Appointed members from the Mecomed Compliance Committee

The Mecomed Compliance Core Committee is responsible for the:

- Mecomed Code review
- Training/roadshow on the Code
- Appeal of CVS decision (As outlined on Part 1, Chapter 2)
- Escalations

Ad Hoc Members:

- Compliance Officers from the Compliance Steering Committee can participate to Ad Hoc projects and initiative.

3.5 Mecomed Escalation Procedure

3.5.1 Introduction

This escalation procedure is set to provide with guiding information for addressing incidents or events that violate the present Code, aiming to:

1. Create a venue for addressing violations, issues and concerns among the members freely (and anonymously if requested by the involved parties)
2. Improve communication among Member Companies in regard to addressing any issues Provide necessary support to Reporter as well as Respondents when needed
3. Following up the escalated issues till they are resolved
4. Raising the awareness of certain issues among Member Companies
5. Sharing best practice, as deemed appropriate among Member Companies

3.5.2 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.

3.5.3 Reporting of Incidents

Any incident shall be reported as per the 2 following options:

1. Directly to the compliance officer of the accused Member Company verbally or in writing
2. Via an email sent to the below email address: Escalation@mecomed.com

The Mecomed Compliance officer have access to the above email address.

In any case, the communication must include the following information at a minimum:

1. Description of the Violation
2. Venue and date of the violation.

Complaints shall be handled confidentially by all parties involved in the procedure. All involved Member Companies must have the right to be heard fairly.

In case the allegation was shared through the above-mentioned email address, the Mecomed Compliance officer will contact the Compliance officer of the Member Company who allegedly made the violation (The "Respondent").

In any case, the Respondent should investigate the alleged violation according to his/her company internal procedures.

In case of reporting through a.1) the Respondent should provide a feedback to the Mecomed Compliance officer to confirm that the alleged violation has been handled.

The Mecomed Compliance officer should update the Compliance Officer of the Member Company raising up the alleged violation accordingly.

If issue has been substantiated, the Respondent should take necessary corrective and preventive actions.

In case of recurrence of the same incident, the Chair of Mecomed Compliance Steering Committee, would have the right to reach out to the Chief compliance Officer or equivalent of the headquarter of the Respondent 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.

3.5.4 Incident Reporting

A yearly report of the allegations shared through the email address (mentioned in Part 3, Chapter 3.5.3) will be shared with the Mecomed Compliance Steering Committee on anonymous basis. The Reporter should not share the reported/alleged incident with any third parties without a written consent from the Respondent.

PART 4: Third-Party Intermediaries Compliance & Due Diligence

As a member of MECOMED, Member Companies are requested to have appropriate effective and efficient compliance program covering member's 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.

4.1 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 GO's & HCP's
- Screening against public database

4.2 Recommended Requirements

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

During the site visit, Mecomed members should conduct interviews with key personnel and carefully review the warehousing facilities. The premises of the Third-Party Intermediaries should be in a representable condition and equipped in a way that allows conducting business in an orderly manner.

4.3 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

4.4 Training

All Member Companies which retain or oversee Third-Party Intermediaries 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:

- Appropriate contractual provisions and other controls as needed.
- Development and communication of clear expectations and guidelines, including compliance with the "Code" and its requirements.
- 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.

4.5 Contractual Obligations

- Acknowledgement & consent from business partner to members compliance program.
- Contractual protections in Third-Party Intermediary agreements & general T&Cs.
- Amending existing agreements with code of conduct reference.

4.6 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 Intermediary questionnaires, verification against watch lists
- Basic, medium and high diligence reports
- Third-Party Intermediary diligence process should be auditable

4.7 Due Diligence Renewal

Members 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 bases.

PART 5: Glossary and Definitions

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

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Charitable Donations: means provision of monetary funds, 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 Educational Event: A Company Organized 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,
- The safe and effective performance of clinical procedures, and/or
- Related disease areas.

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 directly concern a Member Company's medical technologies, therapies and/or related services.

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

Company Promotional Event: A Company Organized Event 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(s).

Conference Vetting System (CVS): Means the centralized decision-making process which reviews the compliance of Third Party Organized Educational Events with the Mecomed Code of Ethical Business Practice and which is managed independently by MECOMED. The CVS system in Mecomed region operates under the supervision of the Mecomed Compliance Core Committee, for more information, see: http://www.ethicalmedtech.eu.

Code: Means this Mecomed Code of Ethical Business Practice, including its annexes.

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 Organization by or on behalf of a Member Company on a restricted basis for use solely for the support and the advancement of genuine medical education of Healthcare Professionals, patients and/or the public on clinical, scientific and/or healthcare topics relevant to the therapeutic areas in which the Member Company is interested and/or involved.

Employer Notification: Means the prior written notification provided to a Healthcare Organization (e.g. hospital administration), a Healthcare Professional's superior or other locally designated competent authority of any interaction, collaboration or other matter concerning any Member Company and any Healthcare Professional, the purpose and/or scope of which requires notification under this Code.

Entertainment: 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 as Entertainment.

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

- 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.

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

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

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

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

Healthcare Organization (HCO): Means any legal entity or body (irrespective of its legal or Organizational form) that is a healthcare, medical or scientific association or Organization which may have a direct or indirect influence on the prescription, recommendation, purchase, order, supply, utilization, sale or lease of medical technologies or related services such as a hospital or group purchasing Organization, clinic, laboratory, pharmacy, research institution, foundation, university or other teaching institution or learned or professional society (except for patient Organizations); or through which one or more Healthcare Professionals provide services.

Healthcare Professional (HCP): Means any individual (with a clinical or non-clinical role; whether a government official, or employee or representative of a government agency or other public or private sector Organization; including but not limited to, physicians, nurses, technicians, laboratory scientists, researchers, research coordinators or procurement professionals) that 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.

Manufacturing Site Visit: A Company Organized Event which takes place in Member Company's manufacturing plant or Healthcare Organizations, used by the Member Company as reference centers.

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

Public Awareness Campaign: An event Organized for the legitimate purpose of providing information, promoting awareness and/or educating patients 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.

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

Respondent: Is the Mecomed member that receives the information from the Reporter.

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

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
- 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 Organization by or on behalf of a Member Company to support Fellowships or Scholarships offered by the Healthcare Organization. Scholarships in this context means an Educational Grant provided to support a medical school undergraduate whereas a fellowship is a period of intensive training for post-graduate physicians in a chosen clinical sub-specialty (e.g. medical training after a residency). "Scholars" and "Fellows" shall be understood accordingly.

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

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

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

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

- 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 program is delivered in a clinical environment.

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

ANNEX I
CVS SCOPE: When are CVS assessments required?

Mecomed Geographic Area				
WHICH TYPE OF SUPPORT CAN MEMBER COMPANIES PROVIDE TO WHICH THIRD-PARTY ORGANIZED EDUCATIONAL EVENTS?		NATIONAL Third-Party Organized Educational Events attended by delegates which are local HCPs only)	REGIONAL Third-Party Organized Educational Events attended by delegates coming from at least two countries of the Mecomed geographic area.	INTERNATIONAL Third-Party Organized 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 ORGANIZED 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**
	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**

ANNEX II

Mecomed Geographical Area