mecomed

Code of Ethical Business Practice

Mecomed Guidelines on Interactions with Healthcare Professionals & Healthcare Organizations

Executive Committee Approved December 2024.

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INTRODUCTION

Mecomed is the medical devices, imaging, and diagnostics trade association, serving as the voice of international medical technology manufacturers operating in 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, regulations, or professional codes (including company codes) that may impose more stringent requirements upon Member Companies. All Member Companies should independently ascertain that their activities comply with all current national and local laws, regulations, and professional codes. In addition, any internal, more stringent rules of Member Companies shall apply.

Member Companies should require that third-Party Intermediaries acting on behalf of the Member Companies—including, but not limited to, consultants, distributors, sales agents, marketing agents, brokers, commission 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 into, 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 & Principles of the Code

The interaction between Member Companies and Healthcare Professionals and Healthcare Organizations is a key factor 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, as well as the improvement of existing products, requires collaboration between Member Companies, 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 in accordance with local laws.

RESEARCH AND EDUCATION

Member Companies' support of bona fide medical research and education enhances Healthcare Professionals' clinical skills, thereby contributing to patient safety and increasing access to new technologies and/or related services. In each interaction, Member Companies must respect the obligation of Healthcare Professionals to make independent decisions regarding treatment and 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 on the following underlying principles:

1. THE PRINCIPLE OF IMAGE & 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 the 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 provisions are not made, Member Companies must 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 must be commensurate with, and represent fair market value for, the services performed.

5. THE PRINCIPLE OF DOCUMENTATION

For interactions between a Member Company and a Healthcare Professional—such as when services are performed by a Healthcare Professional for or on behalf of a Member Company—there must be a written agreement detailing, among other things, the purpose of the interaction, the services to be performed, the method for reimbursement of expenses, and the remuneration to be paid. 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) must be retained by the Member Company for a reasonable period to support the need for & 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 terms such as "including," "include," "in particular," or any similar expression should be interpreted as illustrative and should not limit the sense of the words preceding those terms.

ADMINISTERING THE CODE

The Code operates within a Procedural Framework, detailed in Part 3, 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 pursuing the matter through any formal complaint-handling process, either at the 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 December 2024.

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) sufficiently in advance of 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, excluding refreshment/meal 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 the morning of the last day of the Event.

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

5. The faculty must be identified. 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.

6. A Member Company shall not organize Events that include social, sporting, and/or leisure activities or other forms of Entertainment, nor support such elements where part of Third-Party Organized Educational Events. For 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 of 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.

1.2. EVENT LOCATION & 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:

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.

The selection of event location and venue should consider several factors, including:

i. **Accessibility:**
The location and venue should be easily accessible to attendees, whether near public transportation or major roadways and airports. Consideration should also be given to the distance and travel time required for participants.

ii. **Capacity:**
The location and venue should be able to accommodate the expected number of attendees comfortably, ensuring sufficient seating and space for activities.

iii. **Amenities and Facilities:**
The location and venue should have suitable facilities & amenities required for the event, such as well-equipped meeting rooms, appropriate seating arrangements, and technical support for presentations.

iv. **Compliance with Local Regulations:**
Ensure that the selected location and venue comply with local regulations.

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 beaches, 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, such as a lack of alternative venues or genuine safety or security issues, or Out of Season (vacation or holiday destinations) that comply with the selection criteria in 1.2(3). 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.

For a 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 requester 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. GUESTS

Member Companies are not permitted to facilitate or pay for meals, travel, accommodation, or other expenses for Guests of a 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 a 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 practices and give due consideration to the requirements in the country where the Event is being hosted.

The Code seeks to balance the courteous and professional treatment of Healthcare Professionals by Member Companies with the desire to avoid even the appearance that hospitality may be used 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 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.

If permitted by local laws and regulations, the provision of alcohol may include modest alcohol consumption with meals. Companies may consider adopting controls, including drink type, spending limits, or taking into account HCPs' working hours. Alcohol may not be provided as a gift to Healthcare Professionals.

Member Companies may not pay for or reimburse Healthcare Professionals' lodging expenses at inappropriate hotels as defined in point 1.2 above. For clarity, if the Event venue is a hotel that complies with the Code requirements, 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 reasonable and actual travel expenses. Travel provided to Healthcare Professionals should not cover a period of stay beyond the official duration of the Event.

For air travel, in principle, Member Companies may only pay or reimburse economy-class tickets unless the flight time is equal to or greater than 5 hours of 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 that may be created by the arrangements for any meeting.

1.6. TRANSPARENCY

Employer Notification

Member Companies shall ensure full compliance with local laws and regulations regarding the disclosure or approval requirements associated with consultancy engagement, transfers 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 sending an Employer Notification, i.e., prior written notification within a reasonable time to the hospital administration, the Healthcare Professional's superior, or another locally designated competent authority. Whenever the HCO nominates, in a written communication, the HCPs who will participate in company-organized events, Employer Notification is not required.

Such Employer Notification is required whenever a Member Company sponsors/engages a Healthcare Professional in a 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. In the case of self-employed HCPs with no other employment/affiliation with another HCI/entity, Employer Notification would not be required; however, self-employment needs to be properly documented by the Member Company.

For Company-Organized Virtual Events, invitations to HCPs to participate do not require Employer Notification.

Educational Grant Disclosure

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

1.7. VIRTUAL & HYBRID EVENTS:

Virtual Events and Hybrid Events must comply with any part of the Code that is applicable to them by its nature.

Therefore, Member Companies may provide financial and/or in-kind support to Virtual & Hybrid Events in accordance with the rules of Chapters 1, 2, 3, & 4 of the Mecomed Code.

CHAPTER 2:

THIRD-PARTY ORGANIZED EDUCATIONAL EVENTS

2.1 General Guidelines

Member companies may participate at third party educational events subject to meeting the general guidelines for events as described in Part 1, Chapter 1 of this code in addition to the following:

Scientific Program:

Scientific programs of third-party educational events should be fully owned by the organizer and in line with the business specialty of member companies. Member companies should not have any influence on selecting topics, content, or speakers of the third-party event.

No Direct Sponsorship:

Member companies should refrain from directly sponsoring HCPs from attending Third party educational events.

Sponsorship packages:

Member companies should ensure that the Sponsorship packages are transparent, clearly outlining the value of the sponsorship package options, as well as the different benefits provided under each package.

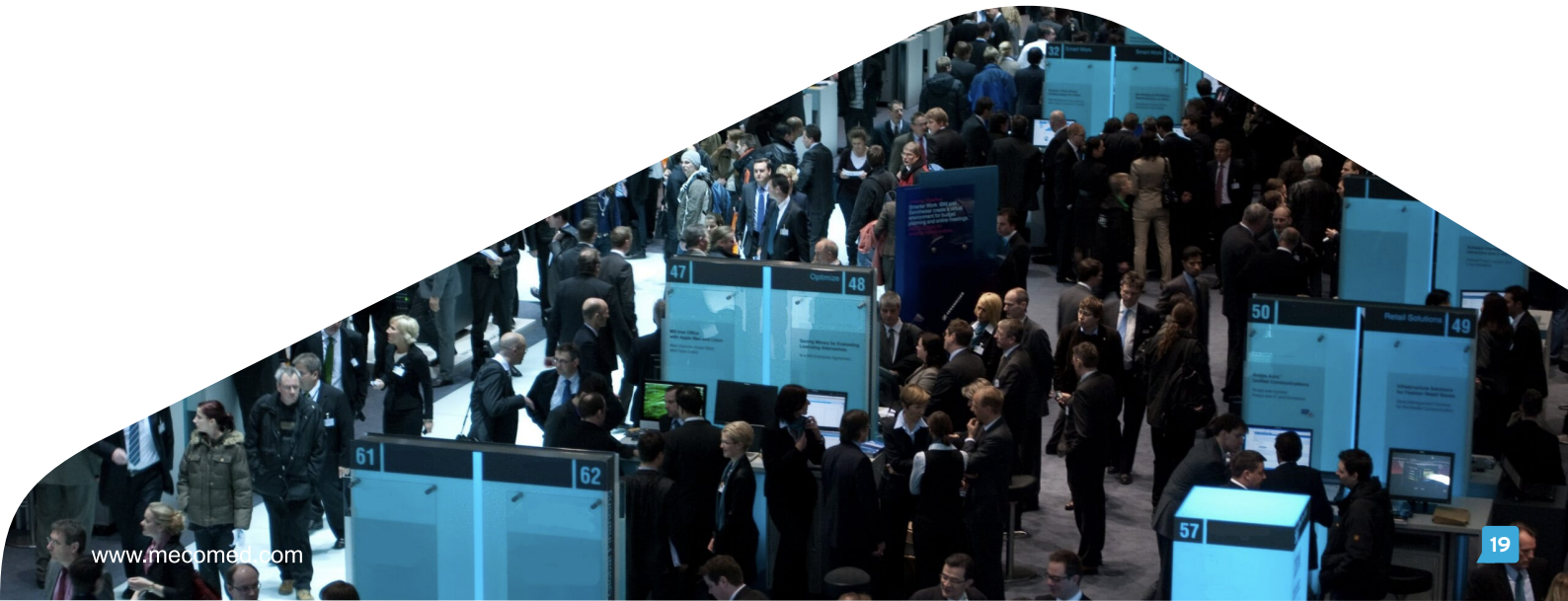
Examples of non-permissible benefits include, but are not limited to; gifts to delegates or speakers, first class tickets, business class tickets for flights less than 5 hours, touristic tours and other entertainment options, such as participation in live music or sports events etc. Such activities must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

For the avoidance of doubt, if the PCO offers to select HCPs on behalf of the Member Company, a requirement to follow this educational grant process is mandatory. Mecomed Member Companies must ensure that the component related to the indirect sponsorship of HCPs is allocated appropriately to their books and records as Educational Grants.

CVS approval:

Member companies must ensure that the third-party educational event has been vetted and approved by CVS as described in more detail in clause 2.2.



2.2.1. Conference Vetting System (CVS)

2.2.1 DEFINITION AND SCOPE

The CVS is an independently managed system that 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 form of:

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 in the scope of CVS assessment.

2.2.2. Excluded from CVS

A. NATIONAL THIRD-PARTY IN-INSTITUTION ACTIVITIES

National Third-Party events organized by an HCO on its premises (in-institution activities) are exempt from the CVS assessment process.

The event must be organized on the HCO's premises (medical facilities such as clinics, hospitals, laboratories, etc.)maintaining expensive machinery.

The event must have medical educational content and be addressed to the Healthcare Professionals of the organizing HCO or to other HCPs from other HCOs in the same country (National).

Any type of support provided by Mecomed Member Companies or their Third-Party Intermediaries should be offered to the HCO itself and not to individual HCPs, in accordance with Chapter 4 of the Mecomed Code (Educational Grants).

Any support provided by Member Companies or their Third-Party Intermediaries should be modest and appropriate.

The vetting of the event (i.e., program, etc.) is the sole responsibility of the Member Company supporting the event, ensuring that the General Criteria outlined in Chapter 1 of the Mecomed Code apply. Appropriate & adequate documentation must be retained by the Member Company.

For clarity, National Third-Party events held at an external venue, other than HCO premises or medical facilities, must still be submitted to CVS for assessment and must obtain a compliant decision from CVS before participation.

B. PUBLIC AWARENESS CAMPAIGN

Events organized by HCOs aimed at providing information, promoting awareness, and/or educating patients and the public about relevant healthcare topics or medical conditions or diseases are exempt from CVS submission. If any part of the agenda includes a session addressed to HCPs, the event cannot qualify as a Public Awareness Campaign.

C. COMPANY ORGANIZED EVENTS

D. VIRTUAL EVENTS FOR THIRD-PARTY ORGANIZED EVENTS:

CVS approval is not required; however, Member Companies must ensure their participation and/or support complies with the Mecomed Code.

E. TRADE SHOW EVENTS:

CVS approval is not required; however, Member Companies must ensure their support complies with Chapter 4 (Educational Grants) of the Mecomed Code.

F. NON- EDUCATIONAL POLICY-MAKING EVENTS

2.2.3. CVS CRITERIA FOR ASSESSMENT

The review process is based on a set of 6 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:

The registration fees should cover only the scientific program, access to the event exhibition, and reasonable hospitality of the Event.

Registration must be offered only to HCPs. Packages for spouses, partners, family, and/or guests must not be covered or facilitated by Mecomed Members.

Any social, sporting and/or leisure activities 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.

Communication support:

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

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

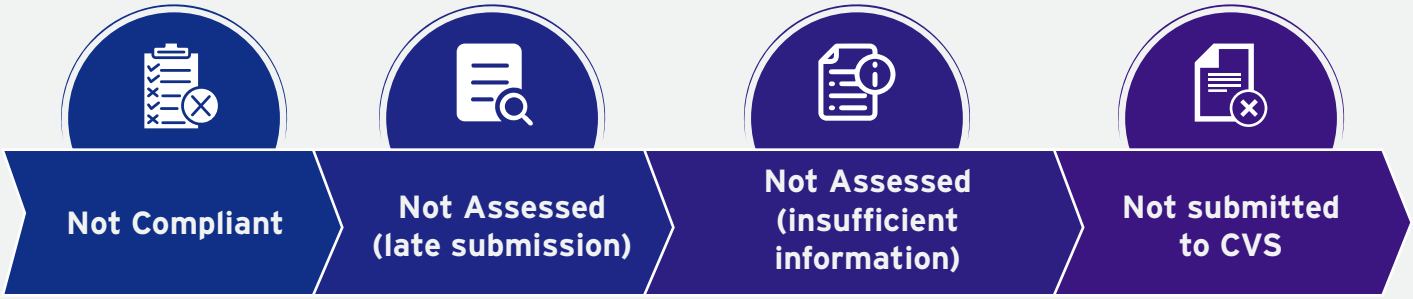
2.2.4. CVS SUBMISSION TIMELINE

The submissions of an application for any Third-Party Educational Events (National, regional, and international) on the CVS website must be done **50 days** prior to the event starting date or earlier.

The following information are needed to finalize the assessment:

- Name of the event
- Date of the event
- Venue name
- Location of the event
- Detailed program with a clear timeframe
- Communication support (website or brochure)
- Registration fees for delegates

Assessment outcomes are binding for all Member Companies. For the avoidance of doubt, Member Companies can support Third-Party Educational Events in scope for CVS, only if the final outcome is Compliant, and Can not support Third- Party Educational Events in scope for CVS if not submitted on CVS portal for assessment or the final outcome of the assessment is one of the following:



2.2.5. CVS APPEAL PROCESS

An appeal may be filed by a Member Company or a 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 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 justify the granting of a change to 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.

2.3. 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.

Member Companies should not purchase Entertainment packages that will 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. Entertainment should not be the main attraction of the Third-Party Organized Educational Event and should not be advertised on the website/brochure of the event.

Support may be 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 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 at all times. It should never bring discredit upon or reduce confidence in the medical technology industry.

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

2.3.1. SATELLITE SYMPOSIUM DURING THIRD-PARTY ORGANIZED EDUCATIONAL CONFERENCES:

Member Companies may organize a 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 of 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 for 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 Companies may pay the registration fee related to the Satellite Symposium (most restricted package). Where this applies, the registration fee must, where possible, be prorated to the actual attendance required to deliver the required services. For example, if the satellite symposium is held on a single day of a three-day event, and it is possible to choose a one-day registration, that option should be selected.

Directly enter into contractual agreements with the speakers of their symposium.

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.

Member Companies can engage with faculty already identified as a speaker in the general program of the TPEE, pay for honorarium of their services to the company, however member companies must not cover their travel and accommodation (in compliance with chapter 5).

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 event days).

2.3.2. ENGAGEMENT WITH CONSULTANTS AT COMPANY-ORGANIZED EVENTS DURING THIRD PARTY ORGANIZED EDUCATIONAL CONFERENCES:

Company-Organized Events, including fee-for-service arrangements like Advisory Boards and Clinical Investigator meetings, may be organized at or around a Third-Party Organized Educational Conference for reasons of convenience and efficiency. The Healthcare Professionals must have an active role at such a Company-Organized Event, rather than being mere delegates (passive attendees). Member Companies shall ensure the compliance of the Company-Organized Events with the principles mentioned in Part 1, Chapter 1.

IT IS PERMISSIBLE FOR MEMBER COMPANIES TO:

» Pay the contractual remuneration and expenses agreed for the provision of the services by the Healthcare Professional, whether they are attending the Third-Party Organized Educational event or not, provided that any hospitality offered is subordinate in time and focus to the event purpose.

» If an event overlap occurs, Member Companies may provide flexibility in the Healthcare Professionals' travel arrangements and the costs involved (i.e., hospitality, accommodation, or travel).

IT IS NOT PERMISSIBLE FOR MEMBER COMPANIES TO:

» Directly support travel and/or accommodation or other expenses of individual Healthcare Professionals participating (either as delegates or trainees) in Company Events that take place during, around, or at the same time and in the same approximate location as a Third-Party Organized Educational Event.

2.4. Third-Party Organized Procedure Training

01 2.4.1. 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).

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.

02 2.4.2. 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 standalone if the training is organized in connection with, adjacent to, or at the same time and location as part of a larger Third-Party Organized Educational Conference. In such cases, direct sponsorship to Healthcare Professionals 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 criteria in Chapter 1, CVS will assess the event in accordance with the additional criteria outlined below:

PROGRAM:

The program must include practical demonstrations (and/or actual live surgeries where allowed). To be considered a Third-Party Procedure Training (TPPT), the practical sessions must, in all cases, represent more than 50% of the full program with hands-on participation 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 doubt, the term "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 that 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.

2.5. THIRD-PARTY ORGANIZED PUBLIC AWARENESS CAMPAIGNS

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

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

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.

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 shallensure compliance of Company Events with the principles mentioned in Part 1, Chapter 1.

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

Member Companies shall not organize Entertainment activities during Company Organized Events.

3.2. Company Educational Events

Where appropriate, 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 payingfor 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, Procedure Training, and Educational Events have the appropriate expertise to conduct such training.

To be compliant with the Code, a Member Company must meet the following criteria when organizing such an event:

CRITERIA FOR ORGANIZING COMPANY EDUCATIONAL EVENTS

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

The program must be rigorous from a scientific and/or educational point of view. This means the content must include current scientific information appropriate for the Healthcare Professionals attending the event.

The program must be genuine and bona fide educational and cannot have a sales or marketing objective. The educational 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 to qualify as a Company Educational Event.

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 at the 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 sessions.

3.4. Company Promotional Event

Where appropriate, Member Companies may organize Company Promotional Events 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 Professionals.

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 purchases, leases, recommendations, prescriptions, 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 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 potential bribery and corruption risks arising in connection with the provision of a Grant or Charitable Donation to a specific prospective recipient. This process shall include a documented, prior evaluation of any such associated risks and 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 the member company's sales function does not decide upon and/or approve a decision to provide a Grant or Charitable Donation. For example, such a process could be led by a Member Company's 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 proposed Grant or Charitable Donation for the proposed recipient.

01 Such an evaluation shall consider all circumstances, including, but not limited to, the legal status and structure of the requesting (i.e. prospective recipient) organization, as well as 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 based on information available to the Member Company, such as information or documentation available from public sources.

02 For Educational Grants provided in relation to Third-Party Organized Educational Events, this may also include information on 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. No Grant or Charitable Donation shall be provided until a written agreement documenting the terms of the grant is signed by both parties.

The written request by a requesting organization should include, at a minimum, a detailed description of the scope and purpose of the program, activity, or other 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, but 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 on Member Companies providing direct financial support to identifiable Healthcare Professionals to attend Third-Party Organized Educational Conferences.

Examples of "in-kind support" that Member Companies may provide 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 Professional 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:

01 Directly to Healthcare Organizations and/or Professional Conference Organizers.

02 Indirectly to Healthcare Organizations and/or Professional Conference Organizers through Third-Party Travel Agents.

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 organizations or other non-profit entities that have charitable and/or philanthropic purposes as their main focus and which are objectively engaged in genuine charitable or philanthropic activities. For the sake of clarity, public or private hospitals or universities are not considered charitable organizations or other non-profit entities. Such charitable organizations and non-profit entities should be licensed to conduct the aforementioned activities.

Restricted Charitable Donations to non-profit hospitals may be permissible in cases of demonstrated financial hardship when Charitable Donations serve exclusively the benefit of the patient, are limited in value, or are 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 that go beyond general restrictions to ensure that the funds (or other support) are applied for charitable and/or philanthropic purposes. Member Companies may impose general restrictions concerning the final use, such as the relief of a specific disaster in a particular country (e.g., for use in aiding the reconstruction and/or re-equipping of healthcare facilities following an 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 purchasing decisions through undue or improper advantages, nor should such donations be contingent upon sales transactions or the use or recommendation of Member Companies' products.

It is not appropriate for a Member Company to support the favorite 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 sporting events, such as payment of the registration charge to participate in a charity run.

In case of crisis situations, Member Companies must follow their internal crisis management processes and may provide charitable contributions to bona fide charitable organizations and beneficiaries, as determined by local laws.

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 Companiesshall specify the intended purpose of the Educational Grant in the Grant agreement.

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

01 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 under the conditions outlined in Part 1, Chapter 2, must have approval by CVS.

02 SUPPORT FOR HEALTHCARE PROFESSIONAL PARTICIPATION AT THIRD-PARTY ORGANIZED EDUCATIONAL EVENTS:

When an Educational Grant is provided to support Healthcare Professionals' attendance at Third-Party Organized Educational Events, the Healthcare Organization or Professional Conference Organizer receiving the Grant shall be solely responsible for the selection of participants, and this shall be explicitly reflected in the written Grant agreement. The names of selected HCPs should not be shown or disclosed in the Educational Grant request letter or agreement.

A MEMBER COMPANY MUST ENSURE THE FOLLOWING:

The Member Company should have an Educational Grant agreement with the recipient organization to include the purpose of the Educational Grant, with rights to enable verification that the Grant is used for the agreed intended purpose.

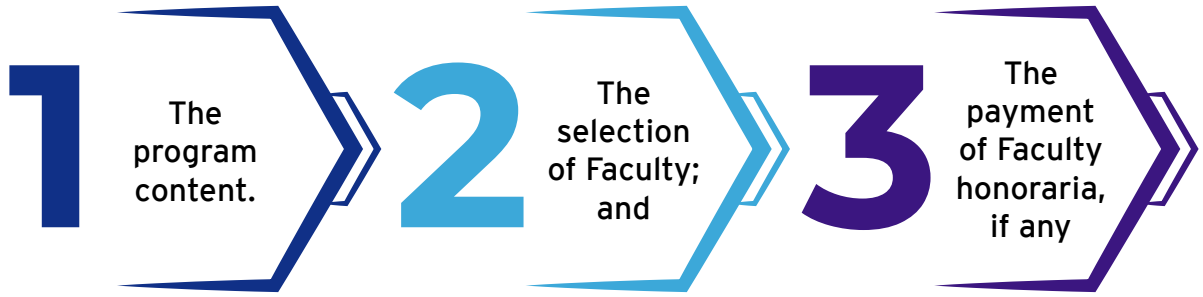
Member Companies may specify the participating Healthcare Professionals' specialty in accordance with the specified Grant. However, the Healthcare Organization or Professional Conference Organizer receiving the Grant shall be solely responsible for selecting participants, and this must be reflected in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

The 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.

03 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:



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

04 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, etc.).

Member Companies shall obtain the minimum required information and documents from 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 or receive résumés/CVs or other information leading to the identification of 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 Event 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.

05 SCHOLARSHIPS AND FELLOWSHIPS:

Member Companies may provide Educational Grants on a restricted basis in the form of Grants for Scholarships and Fellowships to support the 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 from 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.

06 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, 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 primary objective to promote the use of particular therapies or services or to 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.
- 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 has an interest or involvement. 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 products for the limited duration of the research.

Member Companies providing Research Grants must ensure that they do not influence the research. To maintain the "restricted" nature of the Research Grants, Member Companies shall document the intended research scope and purposes for which the Grant is requested and ensure that the written Grant agreement with the recipient organization includes the right for the Member Company to verify that the Grant is used solely for the agreed research purposes.

Such verification may include requests for study-related documentation, such as a copy of the research protocol, ethics committee and/or regulatory approvals, or a copy of the study report upon completion or early 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 practice and must 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 potential bribery and corruption risks arising from the use of consultants. This process shall include a documented, prior evaluation of any associated risks and relevant background information concerning each prospective consultant.

5.2. Criteria for Consulting Arrangements

In addition to the general principles above, the arrangements covering consultancy orother services must, to the extent relevant to the particular arrangement, fulfill all of the following criteria:

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

The number of consultants retained must not exceed the number reasonably necessary to achieve the identified need.

The 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 that 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.

Consulting arrangements with Healthcare Professionals must be documented in a written agreement, signed by the parties in advance of thecommencement of the services, which must specify the nature of the services to be provided and the basis for payment for those services.

The hiring of the consultant must not serve as an inducement to purchase, lease, recommend, prescribe, use, supply, or procure the Member Company's products or services.

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

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

The venue and other arrangements (e.g., hospitality, travel, etc.) for Member Company meetings with consultants must comply with the rules for Events set out in Part 1, Chapter 1.

CHAPTER 6:
REMUNERATION AND FAIR MARKET VALUE

The remuneration paid to Healthcare Professionals (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 that 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 Healthcare Organizations (HCOs) where they carry on their professional activities.

Fair-market-value, in this context, refers to the value of the specified consultancy services that would be paid by the Member Company to the consultant, with both parties dealing at arm's length in an open and unrestricted market, 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 an internal methodology to determine fair market value. Among other factors, this shall take into account 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 applicable tax, statutory, and other legal requirements. Member Companies may pay for expenses reasonably incurred by consultants in providing the services outlined in the consulting agreement, including reasonable travel, meal, and accommodation expenses incurred by consultants when 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 services and the basis for the 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, Member Companies may initiate, conduct, manage, and finance scientifically valid research to generate data, whether pre- or post-market. Legitimate business needs for data include medical needs, such as patient safety; research and development; scientific purposes (e.g., performance indicators, comparing objective scientific parameters); regulatory requirements, including post-market surveillance (PMS) and post-market clinical follow-up (PMCF), vigilance, safety, or reimbursement; and health economics, including clinical and cost-effectiveness and outcomes 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 fully comply 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 that references a written research protocol, a written schedule of work, and provides for all required consents, approvals, and authorizations to be obtained before the commencement of the study.

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

In line with the principles outlined in the Introduction: Aims and Principles of the Code, Member Companies shall also ensure appropriate clinical trial transparency regarding their research activities and results. As applicable, this includes the 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 organizations (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.

7.1. Member Company Post-Market Product Evaluation

Where there is a legitimate business need, Member Companies may initiate post-market Third-Party evaluations of their products, therapies, and/or related services. They may, therefore, provide Evaluation Products under a written contract for services to obtain defined user evaluation by Healthcare Organizations in relation to the Evaluation Products. Evaluation Products may be provided at no charge 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 in compliance with all applicable local laws.

Where the Evaluation Products are multiple-use Evaluation Products, the defined period 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.

The 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.

7.2. 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 active participants, often make valuable contributions that improve products or medical technologies. They may develop intellectual property, such as 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 into 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 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 requirements to pay royalties, which may arise under the relevant 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.
- 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

01 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, and stationery items.

All Promotional Items should comply with the general principles in this section and can be provided either to HCOs or directly to HCPs.

02 EDUCATIONAL ITEMS:

Include, among others, medical textbooks, medical journal subscriptions, and medical utilities that are beneficial to enhancing the provision of medical services and patientcare.

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 or 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 an HCP's 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

01 PROMOTIONAL AND EDUCATIONAL ITEMS:

Should comply with national laws, regulations, and industry and professional codes of conduct.	Should relate to the HCP's practice, benefit patients, or serve a genuine educational function.	Should not be for the personal benefit of HCPs, such as items primarily used at home or 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 or 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., for life events, promotions, birthdays, etc.).		Do not require Employer Notification.

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

The 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 the Member Company's products or services. Any offer and/or supply of such products shall always comply with applicable national laws, regulations, and industry and professional codes of conduct.

Member Companies shall maintain appropriate records in relation to the provision of Demonstration Products and/or Samples to Healthcare Professionals and/or Healthcare Organizations. For example, they should record proof of delivery for any Demonstration Products and/or Samples provided and ensure receipt of returned multiple-use Demonstration Products and/or Samples. Member Companies shall clearly record in their records and disclose to Healthcare Professionals and/or Healthcare Organizations the no-charge basis and other conditions applicable to the supply of such Demonstration Products and/or Samples no later than the time of the supply. This 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. It does not apply to the provision of products or related services under other arrangements, such as within the framework of clinical trials, 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 Professional and patient awareness, education, and training. For example, a Healthcare Professional may use a Demonstration Product to show a patient the type of technology that will be implanted or 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 their books and records and disclose to Healthcare Professionals and/or Healthcare Organizations the no-charge basis and other conditions applicable to the supply of such Demonstration Products no later than the time of the supply. It is recommended that this disclosure 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 using them safely and effectively in clinical practice, and to determine whether or when to use, order, purchase, prescribe, or recommend the product and/or service in the future.

For single-use Samples, the quantity provided for familiarization purposes must not exceed the amount reasonably necessary for Healthcare Professionals and/or Healthcare Organizations to acquire adequate experience in using the products.

For multiple-use Samples, the specific length of time necessary for Healthcare Professionals to familiarize themselves with the product will depend on factors such as the frequency of anticipated use, the duration of required training, the number of Healthcare Professionals who need to acquire experience in using the product, and similar considerations.

Member Companies shall ensure that they retain title to multiple-use Samples and have a process in place to promptly remove 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 have been developed when providing Educational Grants, 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 events 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"), whether 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, they shall also include Professional Conference Organizers.

2.2 Applicability of these guidelines

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 thus committed to complying 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, are not within the scope of these Disclosure Guidelines for Aggregate Disclosure. The annual applicable geographic scope of disclosure shall be updated on the Mecomed Disclosure platform.

Applicability of these Disclosure Guidelines

Member Companies shall not be required to report the same information twice if they are 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, must be disclosed. In cases where reimbursement is for a partial contribution to a certain grant, the Member Company only needs to disclose the reimbursable part.

For the avoidance of doubt, Educational Grants paid by Third-Party Intermediaries that are not reimbursed by Member Companies are exempt from Mecomed disclosure requirements.

2.3. Disclosure Obligation

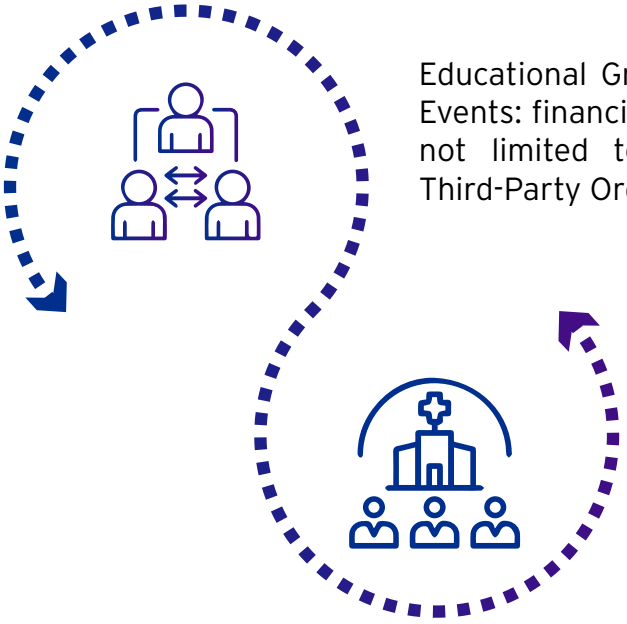
2.3.1 General Obligation

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 the Mecomed geographic area, without limitation of value.

To the best extent, 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 an 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: financial and/or in-kind support (including, but not limited to, support for HCP participation at Third-Party Organized Educational Events).

Other Educational Grants to Healthcare Organizations (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 the 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 the full calendar year. The calendar year of Mecomed starts on January 1st and ends on December 31st every year. The annual disclosure timeframe and mechanism shall follow 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 September 1st of the disclosure year.

2.4.4. Template and Language of Disclosure

For consistency purposes, disclosures made pursuant to these Disclosure Guidelines shall be made in English, using the template set forth on the 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, or deleting the published data, nor (ii) for the storage of data after the three-year period of disclosure on 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 on 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 on theMecomed domain as stated in 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 the currency in which they wish to disclose the aggregate amount and keep appropriate records 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 objective of which is to ensure compliance with the present Code by Member Companies and any Third-Party Intermediaries. It is based on the 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 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 within the Mecomed geographic scope.

Any activity or interaction within the 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:

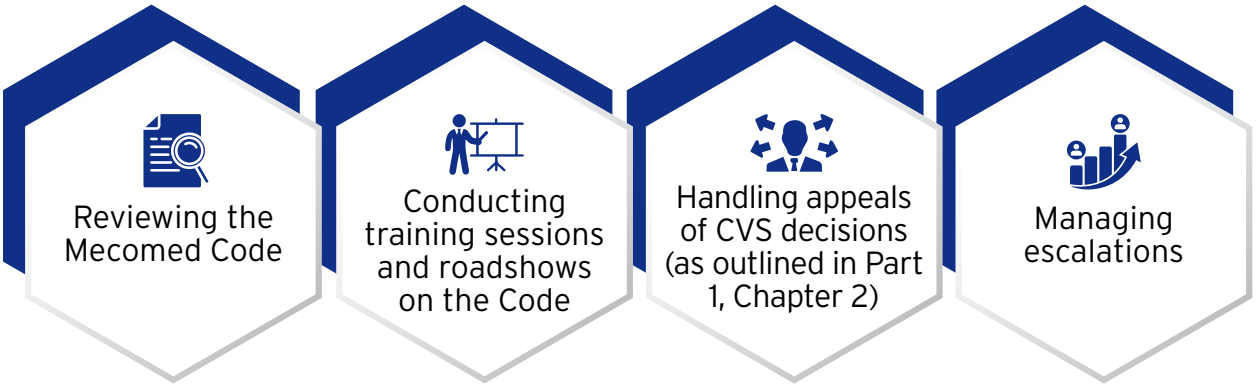
Chair of the Compliance Steering Committee

Compliance Officer of Mecomed

Vice Chairs of the Compliance Steering Committee

Appointed members from the Mecomed Compliance Committee

The Mecomed Compliance Core Committee is responsible for the:



Ad Hoc Members:

Compliance Officers from the Compliance Steering Committee may participate in ad hoc projects and initiatives.

3.5. Mecomed Escalation Procedure

3.5.1. Introduction

This escalation procedure provides guiding information for addressing incidents or events that violate the present Code, with the aim to:

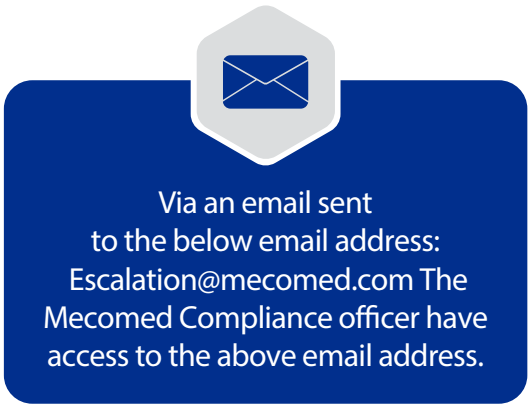
1. Create a venue for addressing violations, issues, and concerns among members freely (and anonymously if requested by the involved parties).
2. Improve communication among Member Companies regarding addressing any issues.
3. Provide necessary support to both the Reporter and Respondents when needed.
4. Follow up on escalated issues until they are resolved.
5. Raise awareness of certain issues among Member Companies.
6. Share best practices, 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 any of their Third-Party Intermediaries.

3.5.3. Reporting of Incidents

Any incident shall be reported via the following two options:



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

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

If the allegation is shared through the aforementioned email address, the Mecomed Compliance Officer will contact the Compliance Officer of the Member Company allegedly involved in the violation (the "Respondent").

The Respondent should investigate the alleged violation according to his/her company's internal procedures.

In case of direct reporting (option a.1), the Respondent should provide 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 that raised the alleged violation accordingly.

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

In the case of repeated incidents, the Chair of the Mecomed Compliance Steering Committee has the right to contact the Chief Compliance Officer or equivalent of the Respondent Company's headquarters.

The aforementioned procedure should not be initiated or should be suspended in the event of a formal investigation by law enforcement authorities or the commencement of legal proceedings in ordinary courts regarding 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 an anonymous basis.

The Reporter should not share the reported/alleged incident with any third parties without written consent from the Respondent.

PART 4: Third-Party Intermediaries Compliance & Due Diligence

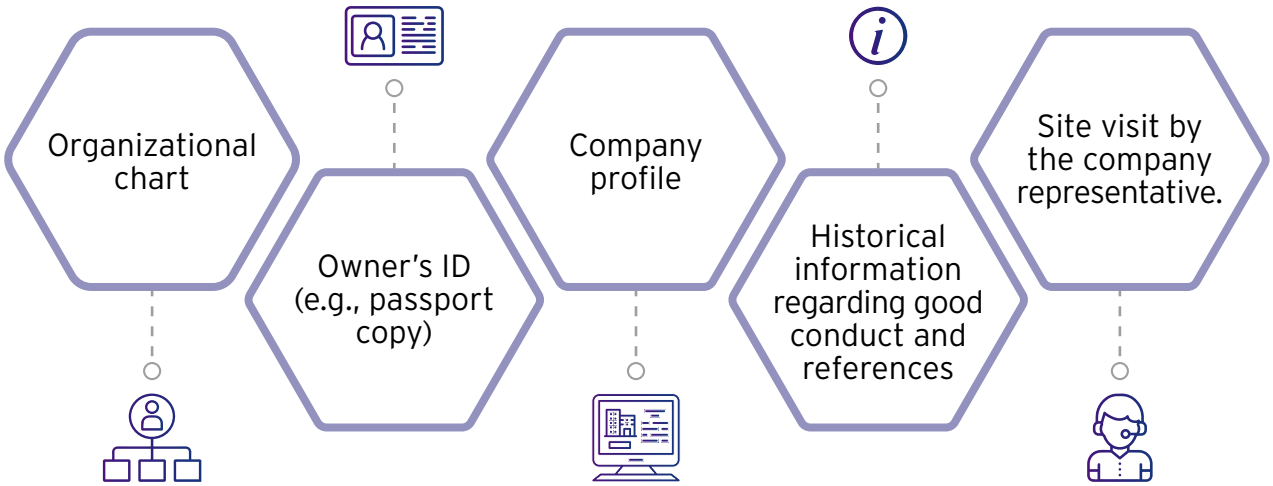
As a member of MECOMED, Member Companies are required to have an appropriate, effective, and efficient compliance program covering the member's business partners, i.e., intermediaries, distributors, suppliers, etc. The selection and hiring of business partners should be based on the results of a risk-based due diligence process.

4.1. Due Diligence Minimum Requirements

The minimum requirements for such a due diligence process should typically include a review of the following:

- Years of experience
- Owners' & shareholders' names as per passport copies and legal documents (IDs, CVs of key personnel)
- Screening against public databases
- Proof of status (TL/CR/etc.)
- Ties with government organizations (GO's) & healthcare professionals (HCP's)

4.2. Recommended Requirements



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 presentable condition and equipped to allow for conducting business in an orderly manner.

4.3. Screening

To gain a level of confidence in the business ethics of the potential business partner, the following should also be considered:

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

4.4. Training

All Member Companies that retain or oversee Third-Party Intermediary 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 and train such third parties on the requirements of the "Code." Such measures may include:

Development and communication of clear expectations and guidelines, including compliance with the "Code" and its requirements.

Appropriate contractual provisions and other necessary controls.

Development of training materials and the conduct of training programs as deemed appropriate and necessary. The training curriculum may be computer-based, interactive, or live.

4.5. Contractual Obligations

Acknowledgment & consent from the business partner to the member's compliance program.

Contractual protections in Third-Party Intermediary agreements & general terms and conditions (T&Cs).

Amending existing agreements to include references to the Code of Conduct.

4.6. Basic Steps for All Business Partners

Measures should take into account the results of the risk assessment.

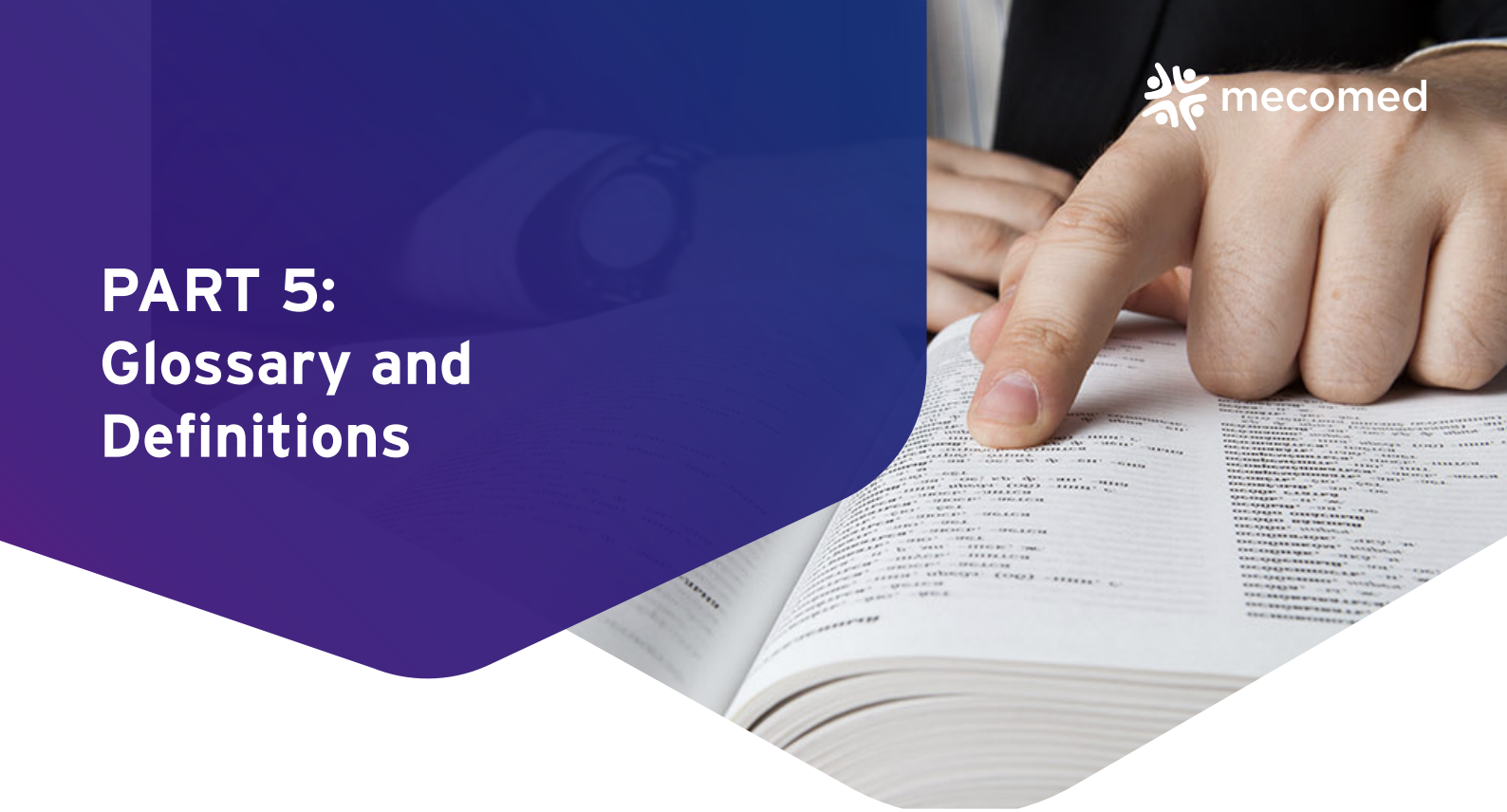
Enhanced due diligence, which may include several levels, e.g., Third-Party Intermediary questionnaires, and verification against watch lists.

Basic, medium, and high-level diligence reports.

The Third-Party Intermediary due diligence process should be auditable.

4.7. Due Diligence Renewal

Members should monitor all interactions with their business partners and maintain a due diligence renewal process as circumstances change. Each Member Company should set the frequency of due diligence renewals based on risk assessment.



PART 5: Glossary and Definitions

AIRTIME:

Refers to the time the aircraft spends in flight, excluding ground time, connection time, and transportation time from the location to the airport.

CHARITABLE DONATIONS:

Refers to the provision of monetary funds, equipment, company products, or relevant third-party products, exclusively for charitable or philanthropic purposes and/or to benefit a charitable or philanthropic cause. Charitable donations may be made only to charitable organizations or other non-profit entities that have charitable and/or philanthropic purposes as their main objective and are objectively engaged in genuine charitable or philanthropic activities.

COMPANY EDUCATIONAL EVENT:

A company-organized event primarily intended to provide Healthcare Professionals with genuine education, including information and/or training on:

The objective is to provide genuine, bona fide medical education and enhance professional skills. "Educational" refers to communicating information directly concerning or associated with the use of Member Companies' medical technologies, such as information about disease states and the benefits of medical technologies for 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:

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

COMPANY PROMOTIONAL EVENT:

A company-organized event where the objective is to discuss product and related service features and benefits, conduct contract negotiations, or discuss sales terms with authorized and designated Healthcare Professional(s).

CONFERENCE VETTING SYSTEM (CVS):

Refers to the centralized decision-making process that reviews the compliance of third-party organized educational events with the Mecomed Code of Ethical Business Practice. This system is managed independently by Mecomed and operates under the supervision of the Mecomed Compliance Core Committee. For more information, visit: http://www.ethicalmedtech.eu.

CODE:

Refers to the Mecomed Code of Ethical Business Practice, including its annexes.

DELEGATE:

A Healthcare Professional who is attending passively at a Company Event or a Third-Party Organized Educational Event (TPOE) and cannot be considered "Faculty." For avoidance of doubt, poster and abstract presenters are considered to be Delegates.

DEMONSTRATION PRODUCTS (DEMOS):

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

- Samples
- Products provided at no charge as part of a Charitable Donation or as part of a Research or Educational Grant
- Evaluation products
- 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 under a warranty agreement

EDUCATIONAL GRANTS:

Refers to the 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. Educational Grants are solely for the support and advancement of genuine medical education for 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 involved.

EMPLOYER NOTIFICATION:

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

ENTERTAINMENT:

Includes, but is not limited to, dancing or arrangements where live music is the main attraction, sightseeing trips, theater excursions, sporting events (e.g., skiing, golf, or football matches), and other leisure activities. For avoidance of doubt, incidental background music shall not constitute entertainment.

EVALUATION PRODUCTS:

Refers to 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 the purpose of obtaining defined evaluative user feedback over a defined period 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
- Products provided at no charge as part of a Charitable Donation or as part of a Research or Educational Grant.
- Evaluation products.
- 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 under a warranty agreement.

FACULTY:

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

FINANCIAL HARDSHIP:

Refers to extreme and unavoidable financial distress faced by a Healthcare Organization resulting from matters beyond its control, where the organization is unable to operate and patient care is consequently jeopardized. Financial distress resulting from mismanagement of funds or other matters within the Healthcare Organization's control is not considered financial hardship. Financial hardship must be documented and objectively substantiated.

GOOD CLINICAL PRACTICE (GCP):

An international ethical and scientific standard for the design, conduct, performance, monitoring, auditing, recording, analysis, and reporting of clinical trials. It assures that the data and reported results are credible and accurate, and that the rights, integrity, and confidentiality of trial subjects are protected.

GUESTS:

Refers to spouses, partners, family members, or other individuals who do not have a bona fide professional interest in the information being shared at an event.

HYBRID EVENTS:

Events that consist of exhibitions, presentations, panel discussions, or live clinical procedures (e.g., hands-on sessions, surgery simulations, live surgeries) where the attendance is a mix of speakers and Healthcare Professionals attending either physically or virtually.

HEALTHCARE ORGANIZATION (HCO):

Refers to any legal entity or body (irrespective of its legal or organizational form) that is a healthcare, medical, or scientific association or organization. These organizations may have a direct or indirect influence on the rescription, recommendation, purchase, order, supply, utilization, sale, or lease of medical technologies or related services. Examples include hospitals, group purchasing organizations, clinics, laboratories, pharmacies, research institutions, foundations, universities, or other teaching institutions.

HEALTHCARE PROFESSIONAL (HCP):

Refers to any individual (with a clinical or non-clinical role; whether a government official, employee, or representative of a government agency or other public or private sector organization) 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 may prescribe, medical technologies or related services.

MANUFACTURING SITE VISIT:

A company-organized event that takes place at a Member Company's manufacturing plant or healthcare organization, used by the member company as a reference center.

OUT OF SEASON (VACATION OR HOLIDAY DESTINATIONS):

Refers to geographic locations and venues renowned primarily as seasonal vacation or holiday destinations (e.g., ski resorts, islands, or beach resorts) that are not appropriate locations during the high season. For avoidance of doubt, the season is defined as the common time when the audience may benefit from access to recreational facilities, which may be perceived as a vacation or holiday destination.

PROFESSIONAL CONFERENCE ORGANIZER (PCO):

A for-profit company or organization specializing in managing 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, medical conditions, or diseases in therapeutic areas in which the Member Company is interested or involved.

REPORTER:

The Mecomed member that notices or becomes aware of a violation made by another Mecomed member.

RESPONDENT:

The Mecomed member that receives the information from the Reporter.

RESEARCH GRANT:

Refers to the provision by or on behalf of a Member Company of funding, products/equipment, and/or in-kind services to any organization conducting research. These grants are made solely to support the development or furtherance of bona fide, scientifically valid, and legitimate research by the recipient, aimed at advancing medical, scientific, and healthcare knowledge, medical technologies, and/or clinical techniques to improve patient outcomes.

SAMPLES:

Refers to single-use or multiple-use products provided free of charge by or on behalf of a Member Company to Healthcare Organizations (HCOs) or Healthcare Professionals (HCPs) who are equipped and qualified to use them. The purpose is to enable HCPs to familiarize themselves with the products in clinical use. Samples do not include:

- Demos
- Products provided at no charge as part of a Charitable Donation or as part of a Research or Educational Grant
- Evaluation products
- 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 under a warranty agreement

SATELLITE SYMPOSIUM:

A company-organized educational event that takes place at a Third-Party Organized Educational Conference. It should address educational topics that align with the focus of the Third-Party Organized Educational Conference Program.

SCHOLARSHIPS AND FELLOWSHIPS:

Refers to 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 refer to Educational Grants supporting a medical school undergraduate, while a Fellowship is an intensive training period for post-graduate physicians in a clinical sub-specialty. "Scholars" and "Fellows" shall be understood accordingly.

THIRD-PARTY INTERMEDIARIES:

Refers to any third-party entities that interact with Healthcare Professionals or Healthcare Organizations in connection with the sale, promotion, or other activities involving Member Companies' products or services, on behalf of the Member Companies.

THIRD-PARTY ORGANIZED EDUCATIONAL EVENTS:

Refers to 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 fulfill Healthcare Professional medical educational needs.

THIRD-PARTY ORGANIZED EDUCATIONAL CONFERENCES:

Refers to 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. These events are typically organized by national, regional, or international specialty medical associations/societies, hospitals, Professional Conference Organizers (PCOs), patient organizations, or accredited continuing medical education providers.

THIRD-PARTY ORGANIZED PROCEDURE TRAINING:

Refers to a type of Third-Party Organized Educational Event primarily intended to provide Healthcare Professionals with information and training on the safe and effective performance of one or more clinical procedures. This is relevant when the information and training concern:

1. Specific therapeutic, diagnostic, or rehabilitative procedures, i.e., clinical courses of action, methods, or techniques (rather than the use of medical technologies).

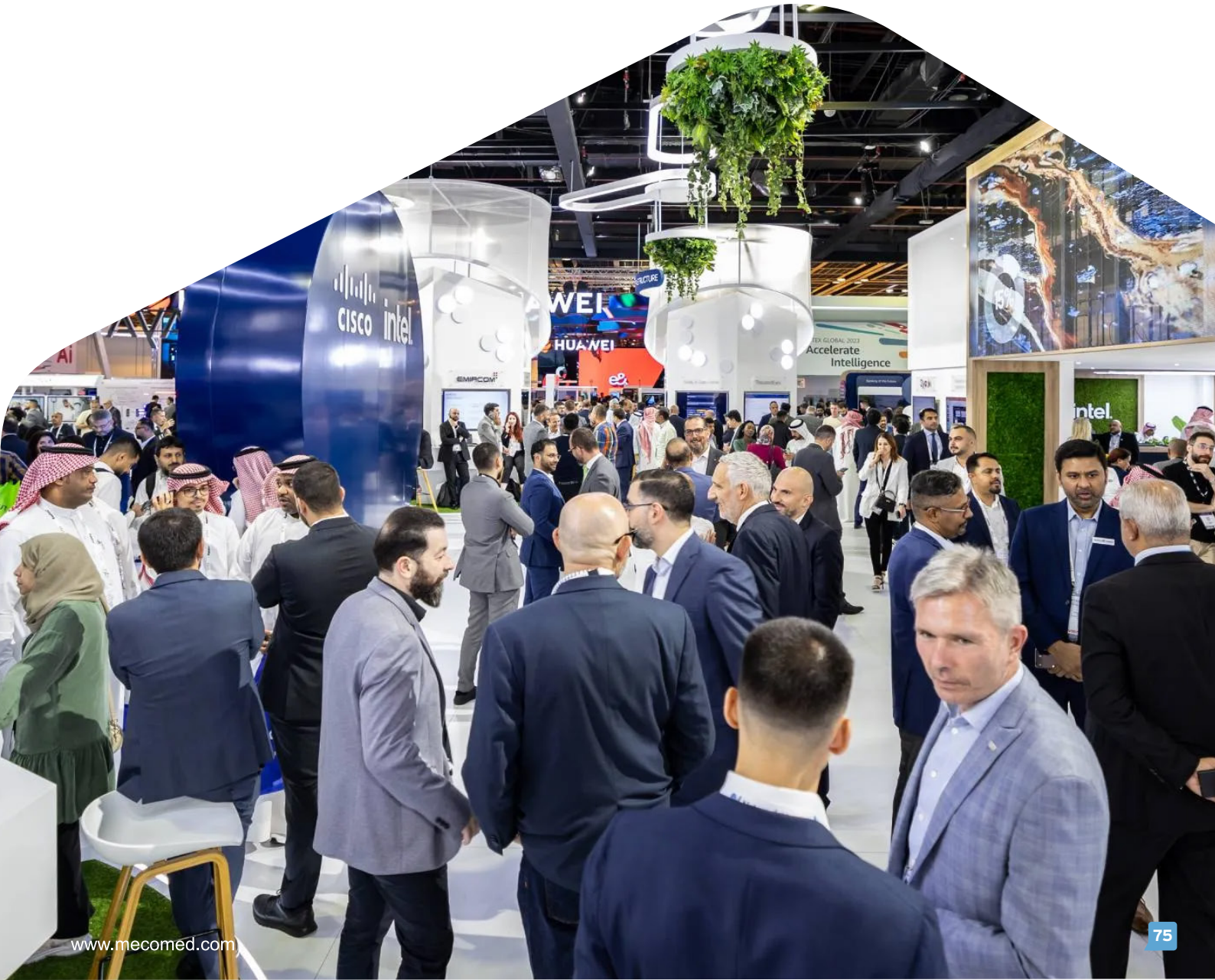
2. Practical demonstrations and/or training for HCPs, where the majority of the training program is delivered in a clinical environment.

TRADE SHOWS EVENTS:

Events where companies and professionals in the medical industry gather to showcase, demonstrate, and discuss the latest advancements, products, and services in medical technology. These exhibitions provide a platform for networking, collaboration, and staying updated on the latest trends and innovations within the healthcare and medical technology sectors. For avoidance of doubt, no educational agenda is organized during the Trade Show events.

VIRTUAL EVENTS:

Events consisting of virtual exhibitions, presentations, panel discussions, or live clinical procedures (e.g., hands-on sessions, surgery simulations, live surgeries) that are broadcasted to an audience that is not physically present.



PART 6: ANNEXES

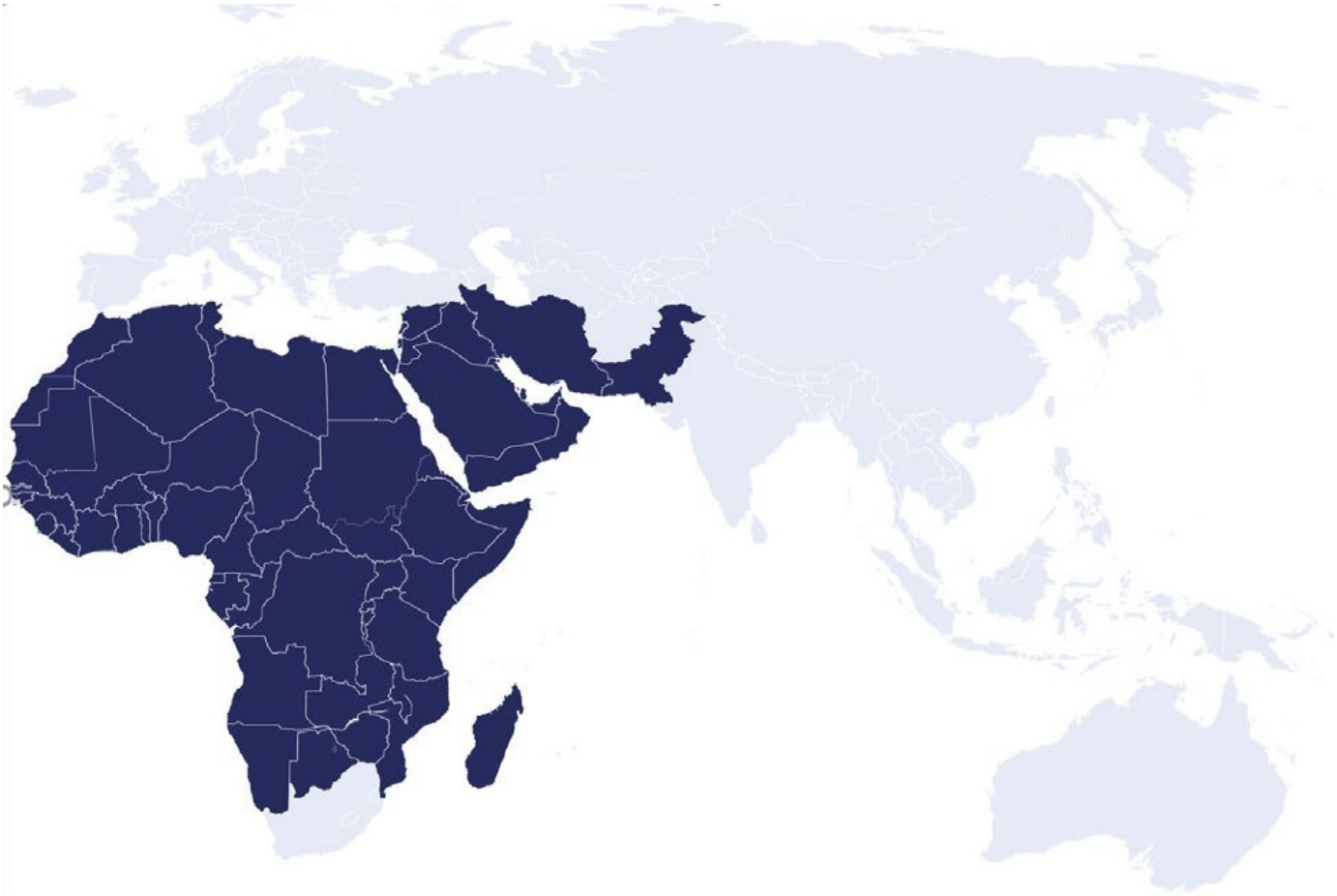
ANNEX I

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 include funds to support HCP attendance to the conference	Subject to CVS Decision	Subject to CVS Decision	Subject to CVS Decision
	Educational Grants that include 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



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