



MEDICAL TECHNOLOGY ASSOCIATION
MIDDLE EAST & AFRICA

Shaping the industry, while putting the patient first

Section 1:

Introducing Mecomed



WHO WE ARE

Established in 2009, Mecomed is the medical devices, imaging and diagnostics trade association serving as the voice of the Medical Technology industry across the Middle East & Africa.

Mecomed aim to:

- Bring all healthcare stakeholders together to improve the quality of people's health
- We foster Good Citizenship and promote ethical business behavior
- Working proactively with governments, regional bodies and healthcare professionals
- One voice in addressing issues facing the industry and healthcare in general

Visit Mecomed Website for more information:

[Mecomed – Medical devices, imaging and diagnostics trade association](#)

OUR INDUSTRY MEMBERS
2021



OUR ASSOCIATE MEMBERS
2021



Section 2:

Introducing Mecomed Code of Ethical Business Practices

ABOUT COMPLIANCE

Link to the Mecomed Code:
[code.pdf \(mecomed.com\)](https://www.mecomed.com/code.pdf)



Code of Ethical Business Practice

Mecomed Guidelines on Interactions with Healthcare Professionals
& Healthcare Organizations

Executive Committee Approved January 2021

HEALTHCARE INDUSTRY RELATIONSHIP WITH HCPs / HCO

Collaboration and partnerships between hospitals, clinicians, nurses and other HCPs is a driver of innovation & patient safety.

- ✓ Education and training is key to ensure safe delivery of services to patients.
- ✓ The role of the MedTech industry support to continuous medical education is crucial.

But there is a need for the industry to adhere to higher ethical standards and to comply with all applicable rules, laws and regulations.

All Healthcare industries are under scrutiny by media, government, public...

Healthcare industry should be able to support HCPs education without jeopardizing its own reputation or that of individual HCPs/ HCO.

INTRODUCING THE MECOMED CODE

Three Main Pillars of the Code

THE CODE

sets out the minimum standards when Member Companies (MCs) interact with Healthcare Professionals (HCPs) & Healthcare Organisation (HCOs)

THE CODE

is not intended to supersede national laws or regulations or professional codes (including company codes) that may impose more stringent requirements

THE CODE

must be followed by all Member Companies, and their Third Party Intermediaries (TPIs).

Aims of The Code



- Shaping The Industry, Keeping The Patient First
- Ensure that the industry's support and activities are based on the highest standards of integrity and transparency
- Safeguard the industry reputation and ensure the right perceptions regarding the relationship between the industry and HCPs/HCOs
- Alignment & Centralized system, a level playing field with the concept of equal chances to succeed and everyone plays with the same set of rules

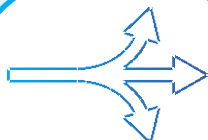
Introducing The Code

PRINCIPLES OF THE CODE



IMAGE & PERCEPTION

Member Companies should, always, consider the image and perception projected to the public when interacting with Healthcare Professionals and Healthcare Organizations.



SEPARATION

Interaction between industry and Healthcare Professionals with member companies should be independent from sales transactions, use or recommendations of members companies products.



TRANSPARENCY

Member Companies will disclose in advance to the Health Care organization administration the purpose and scope of the interaction. "Employer Notification"



EQUIVALENCE

Any remuneration paid by the Member Company to Health Care Professionals for the provision of services must be commensurate with, and represent a fair market value for, the services performed.



DOCUMENTATION

Interaction between a Member Company and a Healthcare Professional, must be documented in details on written agreements.



Obligations to Mecomed Members

- Mecomed Code applies to all Mecomed Member Companies as well as to all their Third-Party Intermediaries (Distributors) when interacting with Healthcare Professionals (HCPs) or Healthcare Organizations (HCOs).
- Mecomed Member Companies must comply with the Mecomed Code of Ethical Business Practices.
- Conference Vetting System (CVS) decision is a mandatory process for all Mecomed Members as well as to all their Third-Party Intermediaries (Distributors) before providing financial support for any Third-Party Educational Events in the form of:
 - Educational Grants.
 - Commercial Activities such as (booth, satellite symposia, advertising)

Section 3:

General Criteria of Events

Guidelines on the Interaction with HCPs/ HCOs

General Criteria of Events

There are Two Types of Events:

- ✓ Third Party Organized Events
- ✓ Company Organized Events



General Criteria for All Types of Events



Program

- Directly relate to the specialty of medical practice of the HCP* who will attend the Event.
- Be available (in detail) sufficient time prior to the Event.
- Present a clear schedule with no gaps during the sessions, (e.g., the minimum duration for a full day Event should be 6 hours or 3 hours for a half day Event including refreshments.
- For events lasting more than 1 day, a half day can be scheduled only on the afternoon of the first day or on the morning of the last day of the Event.
- For Third-Party Organized Educational Events, the agenda should be under the sole control and responsibility of the third-party organizer.
- For Third-Party Organized Educational Events, the Faculty must be identified.
- No Entertainment in the program.



Location & Venue

- should not be the main attraction of the Event.
- Member Companies must always consider 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.
- It is not appropriate for a Member Company to organize or support events at hotels or resorts renowned for their entertainment facilities or centered around recreational or sporting activities such as golf, casinos, private beach or ski/water sports.



Guests

- Member Companies are not permitted to facilitate or pay for meals, travel accommodation, registration or any other expenses for Guests of HCPs

General Criteria for All Types of Events



Reasonable Hospitality

- Hospitality must be reasonable and subordinate in time and focus.
- Must not induce Healthcare Professionals to purchase, prescribe or recommend Member Companies' products.
- The term "hospitality" includes but not limited to meals and accommodation.



Travel

- Member Companies may only pay or reimburse for reasonable and actual travel of HCPs.
- Travel provided to HCPs should not cover a period of stay beyond the official duration of the Event.
- Business class is considered only when flights are equal or above 5 hours. First class is never considered.
- For air travel, Member Companies can only pay or reimburse economy class ticket.
- Business class can be considered for a duration equal or greater than 5 hours Airtime,
- First class is never appropriate.



Transparency

- Employer Notification is required whenever a Member Company sponsors/engages
- Healthcare Professional in Company Event, Third-Party Organised Educational Event, Procedure Training, or as a Consultant.
- Incidental interactions as meals associated with educational or business meetings do not require Employer Notification.

General Criteria for All Types of Events



Entertainment

- Entertainment if organized, must be outside of the educational programme schedule and paid for separately by the Healthcare Professionals.
 - Mecomed Member Companies or their TPIs, must not pay for any type of entertainment.
 - Entertainment must not be part of the sponsorship packages offered to the companies to support any type of events.
 - Entertainment should not dominate or interfere with the overall scientific content or the programme.
 - 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.
 - Entertainment should not be advertised on the website/brochure of the event.
 - The only acceptable entertainment during a gala dinner is background music.
-

General Criteria for Events Do's and Don'ts



DO

- Consider potential adverse public perceptions of the location and venue for the event.
- Select an event location and venue that is centrally located, when considering the place of residence of the majority of invited participants.
- Comply with the hospitality requirements in the country where the HCP carries on their profession, as well as the country where the event is being hosted.
- Only cover legitimate hospitality, i.e. pay or reimburse for legitimate travel, accommodation & meals.
- Ensure Employer Notification whenever a Member Company sponsors/engages an HCP in a Company Event as a Consultant.



DON'T

- Organise events which include social, sporting and/or leisure activities or other forms of entertainment
- Organize events in luxurious, or tourist/holiday oriented venue.
- Pay or facilitate for meals, travel, accommodation or other expenses for Guests of HCPs.
- Provide accommodation and/or other services to HCPs to cover a period of stay beyond the official duration of the event.
- Provide first class air travel in any circumstances.
- Provide business class air travel for flights below 5 hours.

Section 3:

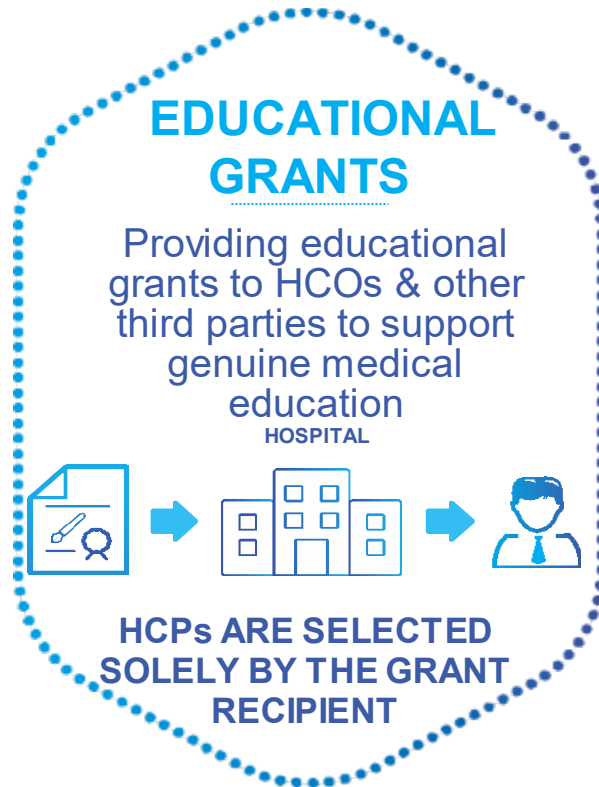
Third- Party Organized Events

THIRD PARTY ORGANIZED EVENTS



Educational Grants to Support Third - Party Organized Conferences

FROM DIRECT SPONSORSHIP TO EDUCATIONAL GRANTS



Member Companies can provide educational grants to Health Care Organizations, Professional Conference Organizers and other Third Parties to support a genuine Medical Education. Third Party Educational Conferences, must be assessed by Conference Vetting System (CVS).

The selection of Health Care Professionals is done solely by the grant recipient.

* Direct sponsorship of HCPs to Third-Party Educational Events is not allowed. Selecting HCPs and pay all expenses related to travel, accommodation and registration to attend Third-Party Events is banned, and it is replaced by providing Educational Grants.

Third Party Organized Events

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graph LR; A[Third Party Organized Events] --- B[Educational Conference]; A --- C[Procedural Training]
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Educational Conference

Procedural Training

THIRD PARTY EDUCATIONAL EVENTS

2 Types



THIRD PARTY EDUCATIONAL CONFERENCES

Conference organized by an independent third party to deliver or promote medical scientific knowledge



THIRD PARTY PROCEDURE TRAINING

Hands-on training, typically organized in a clinical environment

THIRD PARTY EDUCATIONAL EVENTS

THIRD PARTY EDUCATIONAL CONFERENCE

Member Company can specify HCP specialty but selection to be done by Healthcare organization/ Professional Conference Organizer HCO/PCO

Approved by CVS in advance

Support in form of:

- Educational Grant
- Satellite Symposia
- Promotional Activity



THIRD PARTY PROCEDURE TRAINING

When it is a stand-alone meeting direct HCP Sponsorship is permissible by Member Company

Approved by CVS in advance

Support in form of:

- Satellite Symposia
- Promotional Activity
- Educational Grant
- Direct Sponsorship for stand-alone procedure training



Third- Party Organized Educational Conferences

General Criteria:

- Member Companies may provide financial and/or in-kind support to Third-Party Organised Educational Conferences.
- CVS approval is a must.
- Types of support includes:
 - Educational Grants.
 - Promotional Activity for example, advertisement space and booth space for company displays.
 - Satellite Symposium.

Satellite Symposium in Third- Party Educational Conferences

It is permissible for Member Companies to:

- ✓ Select Speakers for their satellite symposia
- ✓ Speaker name at company sponsored Satellite Symposia can be shown on the agenda
- ✓ Directly sponsor (i.e., pay honorarium / hospitality expenses) Speakers to their satellite symposium (in compliance with the Mecomed Code).
- ✓ Where payment of a registration fee is required in order for the speaker to access the Satellite Symposium, Member Company may pay the registration fee related to the Satellite Symposium (most restricted package).
- ✓ Directly enter into contractual agreements with the Speakers.
- ✓ Member Companies can invite HCPs already attending the Third-Party Educational Event to the Company Organized Satellite Symposium provided that the Member Companies do not pay for directly cover any related cost (related to Registration, Travel & Accommodation).

It is not permissible for Member Companies to:

- × Cover additional hospitality expenses for the Speaker of the Member Company's Satellite Symposium to attend the Third-Party Educational Event (e.g. accommodation for all the event days).

Third-Party Organised Procedure Training

- **Definition:**

Primarily intended to provide HCPs 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 programme is delivered in a clinical environment.

- **Type of Support:**

- ☐ Educational Grants
- ☐ Financial support directly to individual HCPs to cover the cost of attendance at **standalone Third-Party Organised Procedure Training**.
- ☐ Third Party Organised Procedure Training will not qualify as a Stand Alone if the Training is organized in connection, adjacent to, or at the same time and location as part of a larger Third-Party Organised Educational Conference. **In such case, direct sponsorship to Healthcare Professional will not be permitted.**

Third-Party Organised Procedure Training & CVS (Conference Vetting System)

- Third-Party Organised Procedure Training must be vetted by CVS
- General criteria of events (Chapter 1) applies.
- In addition, CVS will assess the Event in accordance with the below additional criteria:

☐ **Programme:**

- ✓ must include practical demonstrations (and/or actual live surgeries where allowed).
- ✓ the practical sessions must in all cases represent more than 50% of the full programme with hands-on by the attendees. This requirement must be clearly indicated in the programme of the TPPT.

☐ **Venue:**

- ✓ Typically organized in a clinical environment, e.g., a classroom setting.
- ✓ Examples of simulation settings include conference or meeting rooms which are appropriately equipped with relevant simulation devices/systems or experimental laboratories suitable for training on cadavers, skin models, synthetic bones, live animals.

Third Party Educational Conference Do's and Don'ts



DO

- Provide educational grants to HCOs & PCO to support genuine medical education.
- Specify HCP specialty but selection must be done by PCO/HCO.
- Implement an independent (not primarily sales-driven) decision-making prior to the provision of any Educational Grant.
- Define a proper mechanism to ensure that the Educational Grant is used for the documented purpose.
- Document and timely disclose all Educational Grants.

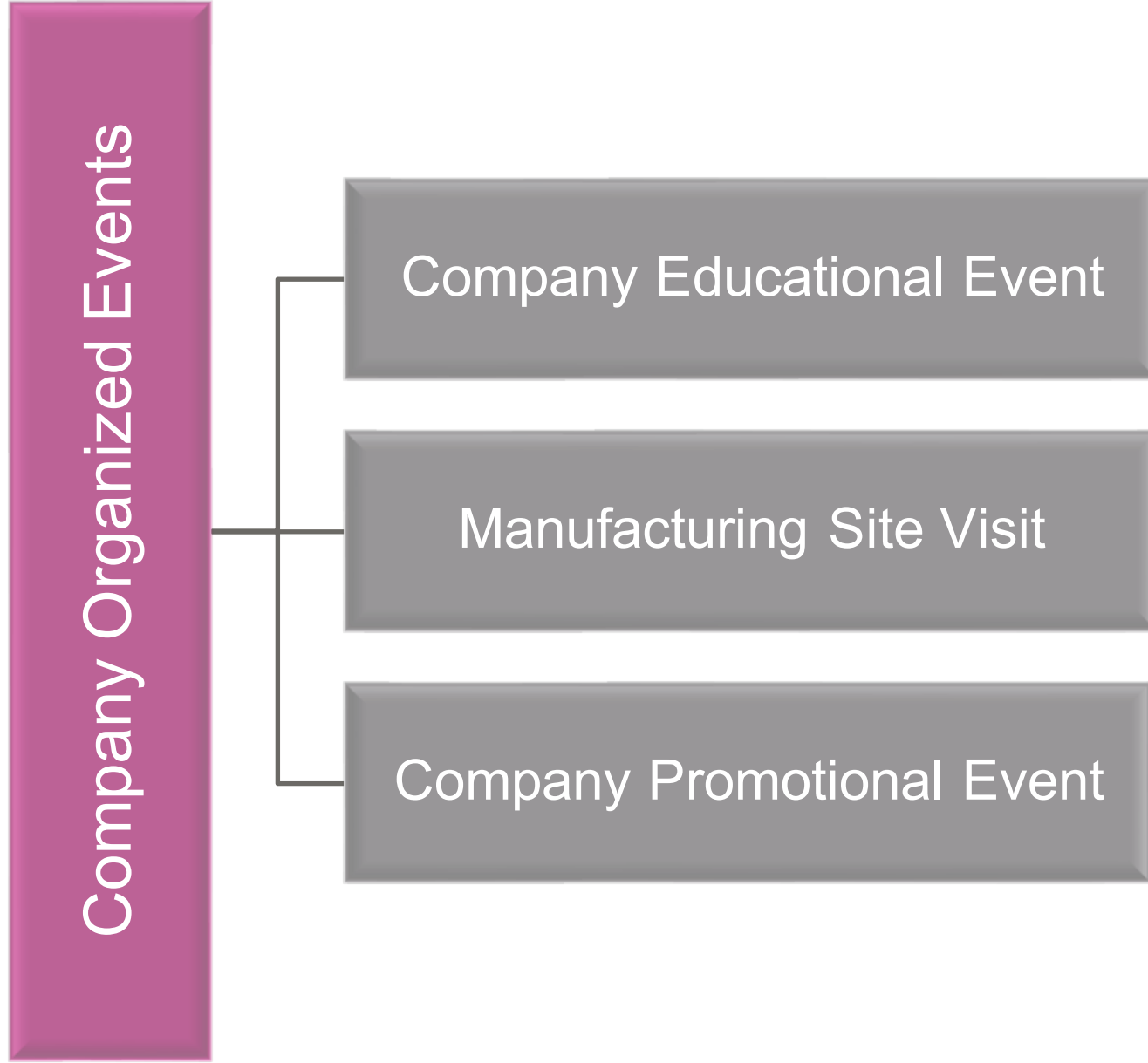


DON'T

- Select individual HCPs and financially supporting their participation to Third Party Educational Events.
- Proceed without getting CVS approval.
- Provide Educational Grants to individual HCPs.
- Provide Educational Grants which are contingent in any way on past, present or potential future purchase, lease, recommendation, prescription, use, supply or procurement of the Member Company's products/services.
- Sponsor travel and accommodation to HCPs to attend your company's event if it is organized along with a Third Party Educational Event.

Section 4:

Company Organized Events



COMPANY EVENTS GENERAL PRINCIPLES:

- ❑ General Criteria of Events (Chapter 1) is applicable on all types of Company Organized Events.
- ❑ Company events are not subject to CVS approval.
- ❑ Member Companies cannot directly support travel and/or accommodation or other expenses of individual HCPs passively participating at Company Events happening during, around, in connection with or at the same time and location as a Third-Party Organised Event.

COMPANY EDUCATIONAL EVENT

Definition:

- A Company Organised Event that is primarily intended to provide Healthcare Professionals with genuine education, including information and/or training on:
 - The safe and effective use of medical technologies, therapies and/or related services,
 - The safe and effective performance of clinical procedures, and/or
 - Related disease areas.
- The objective is to train HCPs on the safe and effective use of Member Company's product, to enhance the professional skills of HCPs.
- Product launches do not fall under this category.
- Company Product training & Procedure training falls under this category.
- It is appropriate for Member Companies to invite HCPs directly, meaning paying for their travel and accommodation.
- Majority of the program must be with an **Educational objective** and not with the sales and marketing objective .

MANUFACTURING SITE VISIT:

Definition:

- A Company Organised Event which takes place in Member Company's manufacturing plant or Healthcare Organisations, used by the Member Company as reference centers.
- Must be based on a legitimate business purpose.
- Must be in the closest geographic location possible.
- The program during the visit must have at a minimum a full day agenda and must include educational/scientific session.

COMPANY PROMOTIONAL EVENT:

Definition:

- A Company Organised Event where the objective is to discuss product and related services features and benefits, conduct contract negotiations, or discuss sales terms with authorized and designated Healthcare Professional(s).
- Product launches fall under this category
- Member Companies may provide reasonable and modest meals as well as land transportation to HCPs.
- It is not appropriate for Member Companies to provide air travel or accommodation support to HCPs, except where demonstrations of **Non-Portable equipment** are necessary.

* Non portable device is a device which due its size, weight, installation, connectivity cannot be easily transported.

Company Organized Events Do's and Don'ts



DO

- Train HCPs on the safe and effective use of Member Company's products.
- Consider proximity when selecting the location of a product training.
- Pay travel and accommodation for speaker to your product launch, if needed.
- Organize Manufacturing/Reference site visits:
 - Based on legitimate business purpose.
 - Closest geographic location possible.



DON'T

- Submit Company organized events to CVS.
- Sponsor (travel and accommodation) for HCPs to passively attend a Member Company's product training unless:
 - Demonstration of non-portable devices.
 - Countries with political instability.
 - Countries in state of war.
 - Absence of training center in the HCP's country.
- Sponsor travel and accommodation for HCPs to attend company organized events which are taking place in a third party educational conferences.

Section 5:

Conference Vetting System - CVS

Conference Vetting System - CVS





CONFERENCE VETTING SYSTEM (CVS)

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

- Educational Grants
- Commercial activities (e.g. booths, advertising, satellite symposia etc.).

Applicable to all events

(International, Regional, National)

CVS is a mandatory process for all Members of Mecomed and their Third-Party Intermediaries (TPIs)..

Excluded from CVS Assessment

- Local in-institution activities:

Local events organized by a Health Care Organization (HCO) in its premises (in-institution activities) are exempt from the CVS assessment process only if **ALL** following conditions are met:

- The event is organized in the premises of the HCO (medical facility such as clinic, hospital, laboratory etc.)
- The event is of medical education content and is addressed to the Healthcare Professionals (HCPs) of the same HCO or HCPs from HCOs in the same city, where there will be **No registration fees, No accommodation and No transportation/ travel paid by Mecomed member companies.**

- Awareness Campaign:

Events organized by HCOs /Medical societies intended to provide information, promoting awareness and/or educating patients and the public about relevant healthcare topics or medical conditions or diseases in therapeutic areas. Such events are exempt from CVS submission.

CVS Time Frame for Submissions

Any submission to CVS for third-party educational event is **advised** to be done **75 days** prior to the event starting date or earlier.

Note:

CVS event submissions made less than **10 days** before the event starting date will not be reviewed and the related event will be marked as **“not assessed for late submission”** on the system.

Same principle applies to events submitted earlier and for which documentation or information is still missing 10 days before the Event starting date. And will be labeled as **“not assessed – insufficient information”**



CONFERENCE VETTING SYSTEM (CVS)

WHAT YOU NEED TO KNOW ABOUT CVS:

- Submissions must be made online via www.ethicalmedtech.eu
- For Further information on CVS in Mecomed region, please visit [Conference Vetting System – Mecomed](#)
- No charges apply when submitting an event on CVS
- Before submitting your event, you need to choose between:
 - ✓ Regular submission (events submitted less or more than 6 months)
 - ✓ Pre-Clearance (events submitted more than 6 months)
- Assessments are done as per first come, first served basis
- Compliant is the final decision.
- You can appeal CVS decision of Non - Compliant if you have justifications by sharing your justification with the Mecomed Compliance Officer @ arwa.asiri@mecomed.com
- Different stakeholders can do submissions in CVS:
 - Professional Conference Organizers (PCOs)
 - MedTech / Mecomed Members and their TPIs
 - Medical Societies and Healthcare Organizations (HCOs)

MECOMED COMPLIANCE
OFFICER CONTACTS:
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Required information and documents at minimum must be uploaded/submitted in CVS system:

- Name of event
- Date of event
- Name of Venue
- Location of event

Required information and documents to finalize the assessment:

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

In order to grant a compliant decision by CVS, Third party organized events should comply with the Mecomed general criteria of events and pass the assessment of the 7 criteria of assessments by CVS.

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

- Scientific Program
- Geographic Location
- Conference Venue
- Hospitality
- Registration Packages
- Communication Support
- Sponsorship packages

1. Scientific program

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

COMPLIANT

- Program content should be relevant to target audience.
- Detailed program with timetable format.
- No gaps during the conference scientific sessions.
- Session topics & faculty identified for each session.

NON- COMPLIANT

- Entertainment included in the main program.
- Sight seeing and tours as part of the program.
- Unjustified gap in the program.

2. Geographic Location

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

COMPLIANT

- Location is not the main attraction of the conference.
- Should be easily accessible near a city/town (airport, highways).

NON- COMPLIANT

- Location is touristic in nature or holiday destination.
- Location is in the desert, remote island or in remote areas in mountain.

3.Conference Venue

The event venue should be a business or commercial center with providing conference facilities conducive to the exchange of scientific and medical information and the transmission of knowledge. The image of the location among the public, media and authorities cannot be perceived as purely luxury, touristic/holiday and/or entertainment venue. CVS does not look into the financial advantage that a venue rental may present.

COMPLIANT

- Should be a business or commercial center.
- Not the main attraction of the conference.

NON- COMPLIANT

- Venue is perceived as over luxurious / touristic / holiday / beach resort by the public, media, authorities.
- Venue includes casino or on-site golf course, adventure parks etc.
- Cruise-ship is used as conference venue.

4. Hospitality

Hospitality includes Accommodation, meals/breaks and receptions (opening reception, gala dinner). It is important to differentiate hospitality which is permitted and entertainment which is not.

COMPLIANT

- Should be limited to reasonable hotel accommodation and meals.
- Background music during lunch/ dinner.

NON- COMPLIANT

- Entertainment is included, such as but not limited to live music, dancing, sight-seeing trips, sporting events.
- Hospitality is offered to spouses, partners, family, guests.

5. Event registration packages

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

COMPLIANT

- Registration fees covers attendance to scientific program and / or exhibition and reasonable hospitality.

NON- COMPLIANT

- Entertainment included in the registration packages.
- Registration fees cover attendance of spouses, family members, partners.

6. Sponsorship Packages / Prospectus

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

COMPLIANT

- Transparent with clear value of each package and clear benefits for each package.
- Inexpensive brand reminders are permissible.

NON- COMPLIANT

- Gifts for attendees and / or speakers.
- Obligation to offer business class tickets for all speakers , irrespective of actual flight time.
- First class tickets.

7. Communication Support (materials promoting the Event such as website, brochure)

Advertising support (brochures, website and other materials) should highlight the scientific nature of the programme content.

COMPLIANT

- Should highlight the scientific program content.

NON- COMPLIANT

- Excessive images or references of non-scientific activities.
- Promoting the location/venue instead of the event content.

Section 6:

Virtual & Hybrid Events

Mecomed Guidance on Virtual & Hybrid Third Party Organised Educational Events

Definitions:

Virtual Events:

Event consists of virtual exhibitions, presentations, panel discussions or live clinical procedures (e.g., hands-on sessions, surgery simulations, live surgeries, etc.) and their broadcasting to an audience which is not physically in attendance.

Hybrid Events:

Event consists of exhibitions, presentations, panel discussions or live clinical procedures (e.g., hands-on sessions, surgery simulations, live surgeries, etc.) where the attendance is a mix of speakers and HCPs attending either physically or virtually.

Transparency for Virtual & Hybrid Events at Third-Party Organized Educational Events

- **Employer Notification (arrangement with consultants):**

Whenever a Member Company sponsors/engages Healthcare Professionals in Third-Party Organized Educational Events or Procedure Training as a Consultant, Employer Notification is required.

- **Educational Grant Disclosure:**

Member Companies shall document and disclose all Educational Grants provided for Virtual and Hybrid events in accordance with the disclosure guidelines outlined in Part 2 of the Mecomed Code. The disclosure guidelines are therefore an integral part of the Code and need to be interpreted as such.

CVS Scope at Third-Party Organized Educational Virtual & Hybrid Events:

- **Third-Party Educational Virtual Events:**

For the moment, virtual events are out of scope of the CVS approval. But they still need to comply with the Mecomed Code.

But it is still recommended to submit virtual events into CVS. **Not for approval**, but for publication of the event in the official calendar, Virtual Events will show in **yellow colour** on the calendar..

To submit a virtual event for publication, submit it as a Regular Event (but notify it is a virtual event). There should be **NO** face-to-face component at all (faculty/attendance) otherwise it is considered a “hybrid event” .

- **Third-Party Educational Hybrid Events:**

CVS approval is REQUIRED, Member Companies must not support any Third-Party Educational Hybrid Events without CVS approval.

Section 6:

Grants & Charitable Donations

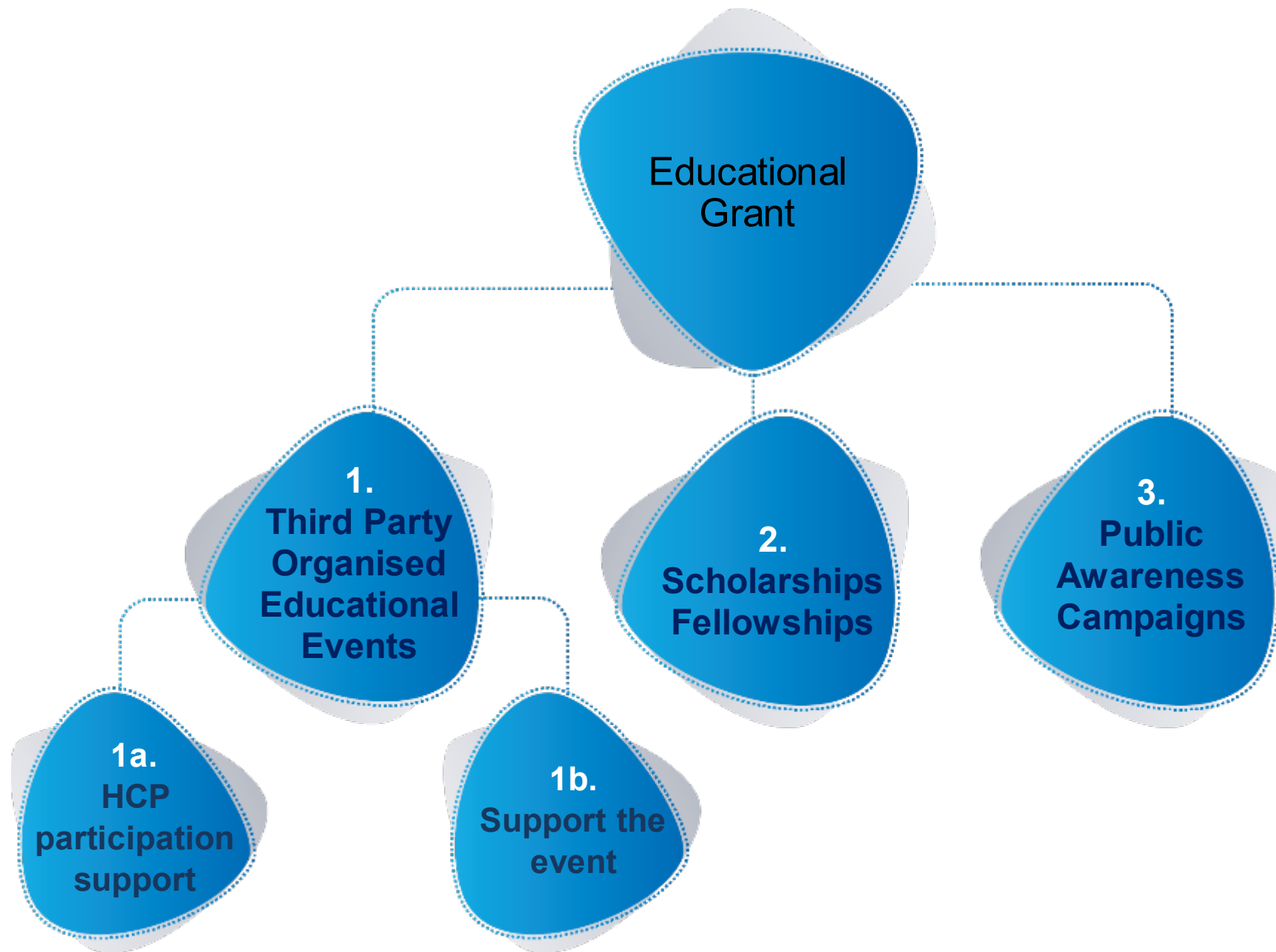
GRANTS & CHARITABLE DONATIONS

DEFINITION

Educational Grant:

A provision of funding, Member Company or Third-Party **products** or other **in-kind support** to a Healthcare Organisation by or on behalf of a Member Company **on a restricted basis** to use solely for the support and the advancement of **genuine medical education** of Healthcare Professionals, patients and/or the public on clinical, scientific and/or healthcare topics relevant to the therapeutic areas in which the Member Company is interested and/or involved.

“Restricted” in this context means that Member Companies shall specify the intended purpose of the Educational Grant in the Grant agreement.



GENERAL CRITERIA PRINCIPLES

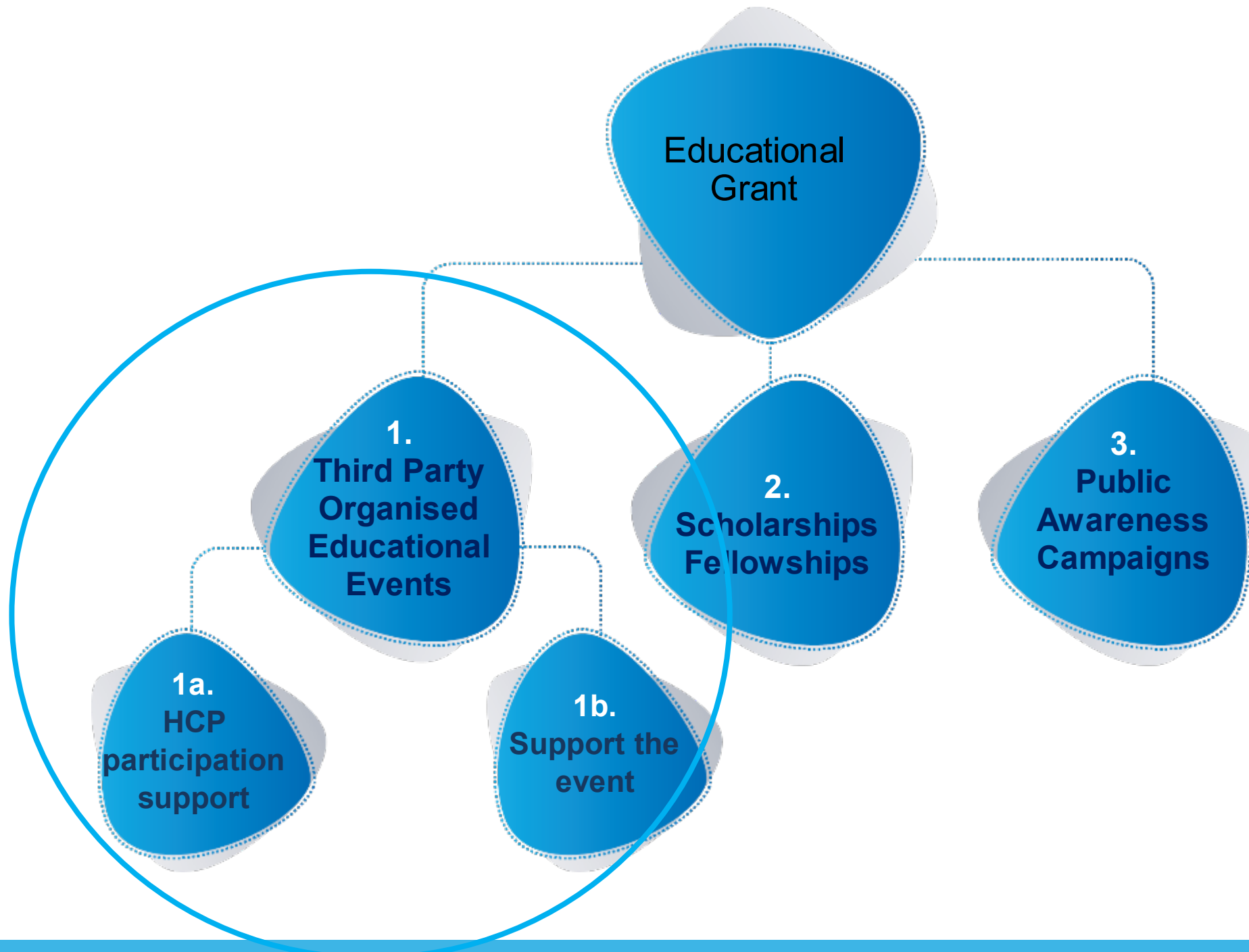
- 1 Shall not be contingent in any way on past, present or potential future purchase, lease, recommendation, prescription, use, supply or procurement of the Member Company's products/services.

- 2 Must be provided directly to the qualifying organization or entity.

- 3 Member Companies shall implement an independent decision-making process including a documented prior review. Such process should not be primarily sales-driven.

- 4 Grants and Charitable Donations shall only be provided:
 - a) in response to a written request by the requesting Organization
 - b) following a Member Company's comprehensive documented initiative which permits an objective evaluation of the request to be carried out.

- 5 Written agreement documenting the detailed terms should be signed by both parties in advance.



Educational Grants for Third Party Organized Educational Events General Principles



Purpose :

The purpose of the Educational Grant should be specified in the agreement with the recipient organization



Verification:

Member Company shall define a proper mechanism to ensure that the Educational Grant is used for the documented purpose



Disclosure:

Member Companies shall document and timely disclose all Educational Grants



CVS

Need to be approved by Conference Vetting System.

Third Party Organized Educational Events

1a. HCP PARTICIPATION SUPPORT

No HCP Selection

Member Companies may specify the specialty of the participating HCPs, however, the recipient HCO/PCO shall be solely responsible for selection of participants.

1b.SUPPORT GENERAL EVENT

The recipient HCO is solely responsible for:

- The program content
- The selection of Faculty
- The payment of Faculty honoraria, if any.

If expressly requested to do so, Member Companies may recommend speakers.


Definition:

Charitable Donations:


A provision of **monetary funds, equipment, company product or relevant Third-Party product**, for exclusive use for **charitable or philanthropic purposes** and/or to benefit a charitable or philanthropic cause.

Charitable Donations may only be made on an **unrestricted basis** and to bona fide charities or other non-profit entities or bodies whose main objects are **genuine charitable or philanthropic purposes**.


GENERAL CRITERIA PRINCIPLES - 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.

- 


Charitable Donations may be made only to charitable organisation or other non-profit entities which have charitable and/or philanthropic purposes.

- 


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

- 

Under the Code it is not appropriate for a Member Company to apply conditions or restrictions to the final use of a Charitable Donation which go beyond general restrictions to ensure that the funds (or other support) are applied for charitable and/or philanthropic purposes.

- 

Shall not be contingent in any way on past, present or potential future purchase, lease, recommendation, prescription, use, supply or procurement of the Member Company’s products/services.

- 

It is not appropriate for a Member Company to support the favourite charity of a Healthcare Professional in response to a request by that Healthcare Professional irrespective of the underlying reasons.


Section 7:


Arrangements with Consultants


ARRANGEMENTS WITH CONSULTANTS





GENERAL PRINCIPLES FOR CONSULTANT ARRANGEMENTS

-  Healthcare Professionals may be engaged as consultant and advisors to provide *bona fide* consulting services, including but not limited to, research, participation on advisory boards, presentations at Company Events and product development

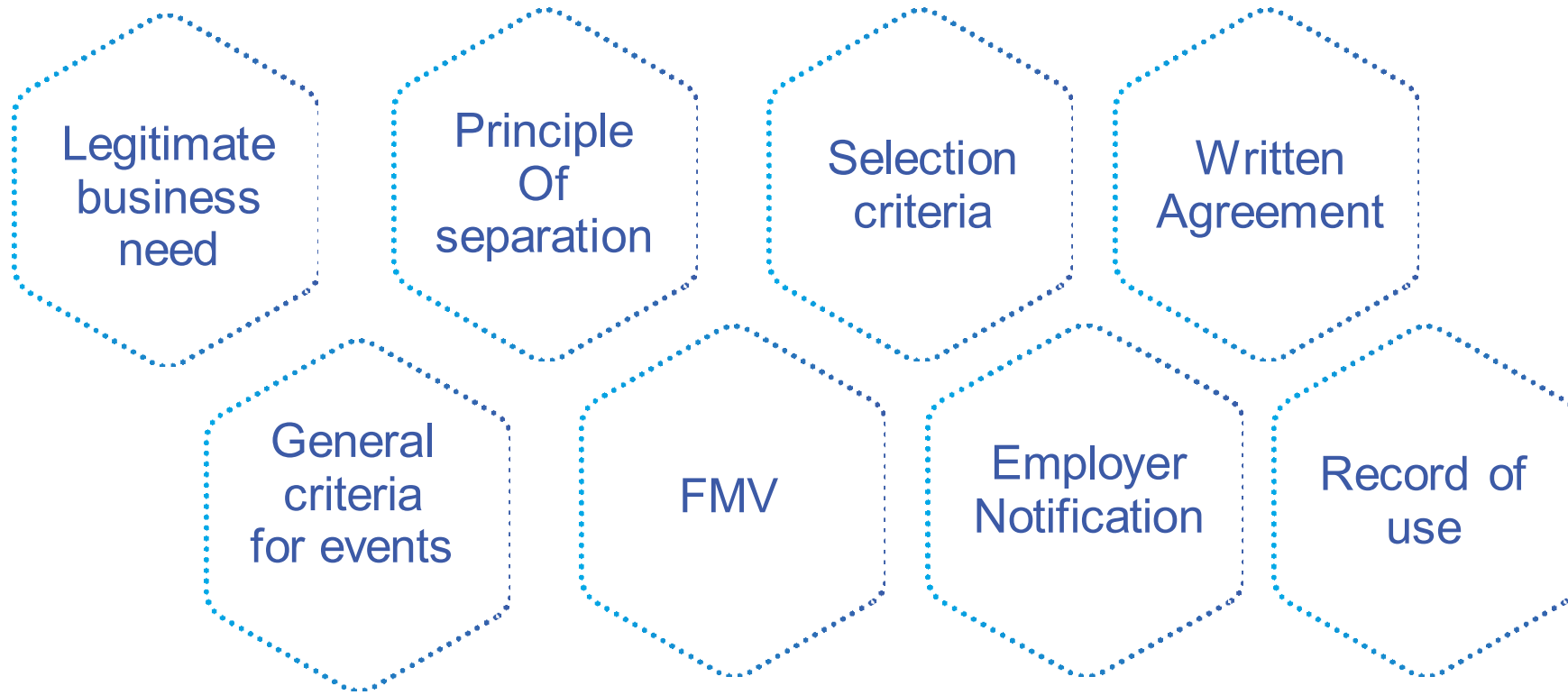
-  Healthcare Professionals may be paid reasonable remuneration for performing these services

-  Principles and criteria apply even if the consultant is paid no honorarium for providing services.

-  Consulting arrangements may never be contingent on past, present or future purchase, lease, recommendation, prescription, use, supply or procurement of any product or service.

-  The selection of Healthcare Professionals provide consulting services must be done via an independent decision-making/review process to identify, prevent and mitigate against potential bribery and corruption risks. Such a process must be undertaken in advance of each engagement and be properly documented.

CRITERIA FOR CONSULTING ARRANGEMENTS



CRITERIA FOR CONSULTING ARRANGEMENTS (CONT'D)

- **Legitimate Business Need:**

Consulting arrangements must be entered into only where a legitimate business need for the services is identified in advance. The hiring of the consultant must not be an inducement to purchase, lease, recommend, prescribe, use, supply or procure the Member Company's products or services.

- **Principle of Separation:**

This principle refers to the separation of commercial concerns from the process of selecting and engaging Healthcare Professionals. The volume or value of business generated by a prospective consultant, or their Healthcare Organization is not a relevant criterion.

- **Selection criteria:**

Clear selection criteria should be *established in advance of the selection* of the consultant and are subject to the *Principle of Separation*. The criteria must directly relate to the identified *Legitimate Business Need* and the relevance of the consultant's qualifications, expertise and experience to address the identified need. Furthermore, the number of consultants retained must not be greater than the number reasonably necessary to achieve the identified need.

- **Written Agreement:**

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

CRITERIA FOR CONSULTING ARRANGEMENTS (CONT'D)

- **Compliance with Chapter 1: General Criteria for Events:**

The venue and other arrangements (e.g., hospitality, travel, etc.) for activities with consultants shall follow the rules for Events set out in Chapter 1: General Criteria for Events.

- **Fair Market Value (FMV):**

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

- **Employer Notification:**

Member Companies must issue Employer Notification (*i.e.*, prior written notification to the Consultant Healthcare Professional's employer (e.g., hospital administration, Healthcare Professional's superior or other locally designated competent authority).

- **Record of Use:**

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

Arrangement with Consultants Do's and Don'ts



DO

- Enter into consulting arrangements only where a legitimate business need for the services is identified in advance. Such arrangements should be documented in a written agreement.
- Ensure the remuneration paid to HCPs engaged as consultants is consistent with the fair market value for the services provided.
- Maintain appropriate transparency by securing the relevant Employer Notification, disclosing the purpose and scope of the consultancy arrangement.
- Maintain records of the services and associated work products, provided by the consultant HCPs and of the use made of those services.
- Select consultants based on criteria directly related to the identified business need and the relevance of the consultant's qualifications, expertise and experience to address the identified need.



DON'T

- Enter into consulting arrangements which are in any way contingent 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.
- Select the consultant based on the volume or value of business generated by the prospective consultant or their HCO.
- Engage more consultants than reasonably necessary to achieve the identified need.
- Provide gifts to HCPs engaged as consultants instead of a professional fee for service.

Section 8:

PROMOTIONAL & EDUCATIONAL ITEMS PROVIDED TO HCOs/HCPs

PROMOTIONAL & EDUCATIONAL ITEMS PROVIDED TO HCOs/HCPs



Definitions: Promotional and Education Items

1. Promotional Items:

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

2. Educational Items:

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

- Be related to the therapeutic areas in which the Member Company is interested / involved.
- Be appropriately documented in the Member Company's books and records.
- Be provided to HCOs only.
- Not be provide to HCPs for their own personal use or benefit.

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

Providing Promotional and Education Items

General Principles

Promotional and educational items should:

- Comply with national laws, regulations and industry and professional codes of conduct
- Relate to the HCP's practice, or benefit patients, or serve a genuine educational function
- Do not require Employer Notification

Promotional and educational items should not:

- Be for the personal benefit of the HCPs such as items primarily used at home/in the car
- Be provided in response to requests initiated by HCPs
- Be given in the form of cash or cash equivalents (e.g. debit/gift cards/gift certificates)
- 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
- Be provided to HCPs engaged as consultants/speakers in lieu of a professional fee for their services
- Be offered on more than an occasional basis, even if each individual item is appropriate
- Be provided for personal benefit or out of cultural courtesy (e.g. life events, promotion, birthdays etc.)

Providing Promotional and Education Items

Brand Reminder



- Item of nominal value
- Company and/or product branding
- Promotional reminder
- include but not limited to: company branded or non-branded calendars, notepads, mouse-pads, post-it notes, USB memory sticks, stationary items

Item of Medical Utility



- Genuine educational function
- Intended to aid in medical care of Patients
- include but not limited to: Medical Textbooks, Medical journal subscriptions
- Should only be provided to HCOs.

Cultural Courtesy & Gifts



- Not allowed to be provided.
- Recognize a national or religious holiday or personal milestone is not allowed.

Prize Draws

General Principles

- Prize draws and other competitions at Events are permissible if the prize awarded complies with the general guidelines under “PROMOTIONAL & EDUCATIONAL ITEMS PROVIDED TO HCOs/HCPs”
- On an exceptional basis, prizes can be provided either to HCOs or directly to HCPs
- In all cases, prize draws must comply with national laws, regulations and industry and professional Codes of conduct.

In particular prize draws must not:

- ... be given in the form of cash or cash equivalents.
- ... improperly reward, incentivize and/or encourage Healthcare Professionals to purchase, lease, recommend, prescribe, use, supply or procure the Member Company's products or services.
- ... be excessive in value.

Section 9:

Demonstration Products & Samples

Demonstration Products & Samples



Demonstration Products & Samples

General Principles

- Member Companies may provide their own products as Demonstration Products and/or Samples at no charge to evaluate and/or familiarize HCPs/HCOs with the safe, effective and appropriate use and functionality of the product and/or related service.
- Under no circumstance's demonstration products/samples may improperly reward, induce and/or encourage HCPs/HCOs to purchase, lease, recommend, prescribe, use, supply or procure Member Companies' products or services.
- Demonstration Products and/or Samples may be either single or multiple-use products.
- Products from another company in conjunction with the Member Company's own Demonstration Products and/or Samples may be provided on an exceptional basis if these products are required to properly and effectively demonstrate and evaluate.
- Appropriate records in relation to the provision of Demonstration Products and/or Samples need to be kept, e.g.
 - Recording proof of delivery for any products
 - Receipt of return for multiple-use products

Demonstration Products & Samples

General Principles

- Any supply of such products shall always be done in full compliance with applicable national laws, regulations and industry professional codes of conduct.
- Provision of demonstration/sample products needs to be recorded.
- The no-charge basis and other conditions applicable for the supply of such demonstration products/samples needs to be clearly disclosed to HCPs/HCOs no later than the time of the supply.
- The disclosure shall be done in writing.

Limitations:

- This Chapter is not intended to apply to provision of products or related services under any other arrangements, for example (but not limited to):
 - provision within the framework for clinical trials and/or
 - other research or commercial supplies by way of rebates or pricing incentives in a public procurement context.

Demonstration Products & Samples

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).

Purpose:

Healthcare Professionals and patient **AWARENESS**, **EDUCATION** and **TRAINING**.

Example, a Healthcare Professional may use a Demonstration Product to show a patient the type of technology which will be implanted in the patient or may use the Demo to train other Healthcare Professionals in the use of the product

Controls:

- Not intended for clinical use
- Not for sale
- Disclose in writing the no-charge and any other conditions for supply
- Proper documentation to be archived

Demonstration Products & Samples

Samples

Member Companies may provide a reasonable number of Samples of their products at no charge to the Healthcare Professionals and/or Healthcare Organizations.

Purpose:

- Product familiarization
- Gain experience in dealing with the product safely and effectively in clinical use
- To help the customer determine whether and when to use, purchase, prescribe or recommend the use of the product

Controls:

- For single-use products, the quantity provided must not exceed the amount reasonably necessary to acquire adequate experience in dealing with the products
- For Multiple-use products,
 - length of sample availability at site depend on the frequency of anticipated use, duration of required training, number of HCPs,... etc.
 - Member companies shall have a process in place for promptly removing such multiple use Samples from the Healthcare Professional's location at the conclusion of the familiarization period