



# Compliance Code & CVS Training

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Shaping the Industry, Keeping Patients First

# Who We Are

**Mecomed** is the trade association representing the medical devices, imaging, & diagnostics industries in the **Middle East and Africa**.





## Our Mission



Bring together all stakeholders in healthcare to improve people's health through the timely introduction of meaningful medical technology innovations that benefit the MEA region.

## Foster Good Citizenship



Collaborate with governments, regional organizations, and healthcare providers to deliver high-value solutions that improve patient outcomes.

## Our Association



Mecomed is a member of Global Medical Technology Alliance, which includes other associations, like AdvaMed, MedTech Europe, Samed, ApacMed and others.

## Mecomod Geographic

### Scope:

- Middle East
- Africa – Excluding South Africa
- Iran
- Pakistan





## Code of Ethical Business Practice

Mecomed Guidelines on Interactions with Healthcare Professionals & Healthcare Organizations  
Executive Committee Approved December 2024.



The code has been reviewed and updated in 2024, with the new version taking effect on January 1, 2025



English



French

# Why Mecomed Code?

 **Collaboration and partnership between hospitals, clinicians, nurses and other HCPs: driver of innovation & patient safety:**

- » Education and training is key to ensure safe delivery of services to patients.
- » We Value the Role of industry support to continuous medical education.

 **There is a need for the industry to adhere to high ethical standards and to comply with all applicable International, Regional & Local rules, laws and regulations.**

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

 **MedTech industry seeks to support HCPs education without jeopardizing its own reputation or that of individual HCPs.**

- » Mecomed Code is a safeguard for the industry reputation and ensures the right perceptions regarding the relationship between the industry and HCPs/HCOs

# Introducing 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 Party Intermediaries (TPIs).

# Principles of the Code

## IMAGE & PERCEPTION

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

## EQUIVALENCE

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

## SEPARATION

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



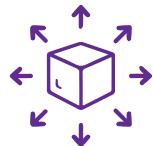
## TRANSPARENCY

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

## DOCUMENTATION

Interaction between a Member Company and a Healthcare Professional, must be documented in detail 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).



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)



# Mecomed Code – Part 1

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## Guidelines On The Interactions With HCPs & HCOs

# Chapter 1. General Criteria For Events:



The principles set out in this chapter shall apply to all events supported in any way by Member companies irrespective of who organizes the event



EVENT PROGRAM

TRAVEL



EVENT LOCATION  
& VENUE

REASONABLE  
HOSPITALITY



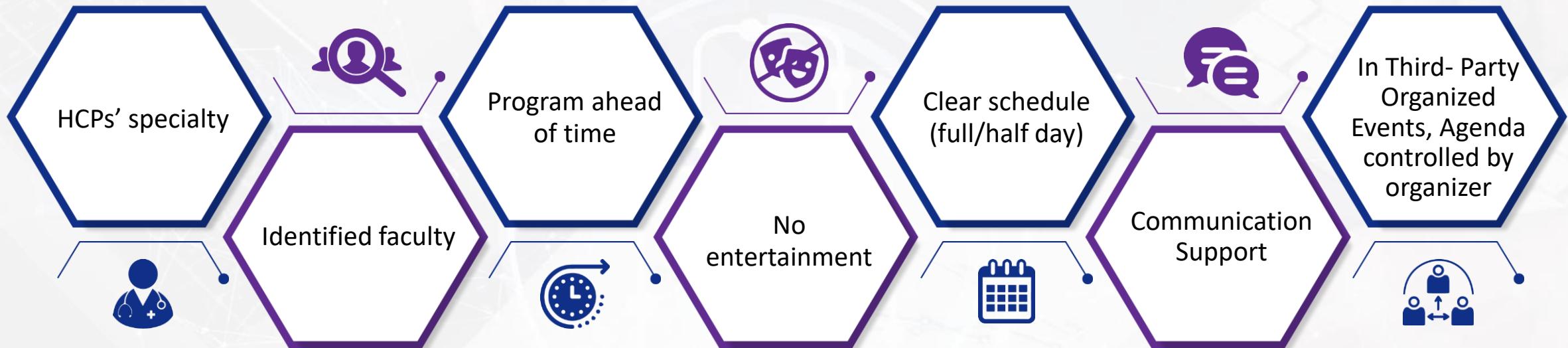
GUESTS

TRANSPARENCY



# Chapter 1. General Criteria For Events:

## EVENT PROGRAM



# Chapter 1. General criteria for events:



## EVENT PROGRAM

The Event Program should:



Directly relate to the specialty of medical practice of the Healthcare Professional who will attend the Event or be sufficiently relevant to justify the attendance of Healthcare Professionals;



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/ meals breaks).

For the avoidance of doubt, for events lasting more than 1 day, a half day can be scheduled only on the afternoon of the first day or on the morning of the last day of the Event;



# Chapter 1. General criteria for events:

## Location & Venue

The selection of event location and venue should consider the following factors:

**UPDATE**

### Compliance:

**01**

Ensure that the selected location and venue comply with local rules & regulations.

### Accessibility:

**02**

The location and venue should be easily accessible to attendees, whether it's near public transportation or major roadways & airports. Consideration should also be given to the distance and travel time required for participants.



### Capacity:

**03**

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

### Amenities and Facilities:

**04**

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

## Location & Venue



In principle it is not appropriate for a Member Company to organize or support Events at resorts renowned for their entertainment facilities or centered around recreational or sporting activities such as golf, casinos, private beach or ski/water sports.



Exceptions might be considered for venues well adapted to business meetings in an otherwise compliant geographic location where there is a compelling need to use the chosen venue, for example, a lack of alternative venues or genuine safety or security issues **or Out Of Season (vacation or holiday destinations)** which comply with the selection criteria mentioned in the previous slide.

# Chapter 1. General criteria for events

## Guests:

Sponsorship or facilitation of guests of HCPs are not allowed.

## Travel

Member Companies may only cover reasonable and actual travel of HCPs for the period of the official duration of the event. Business class is considered only when flights are of a duration equal or greater than 5 hours **Airtime**. First class is not considered.



## Reasonable Hospitality

Member Companies may provide reasonable hospitality to HCPs in the context of Company Events and Third Party Organized Educational Events. Such hospitality must be subordinate in time and focus.

**Provision of Alcohol: If Permitted by Local Laws & Regulations, Provision of Alcohol may include modest alcohol consumption with meals, and Companies may consider adopting controls including drink type, and spending limits or HCPs working hours. Alcohol may not be provided as a gift to Health Care Professionals.**

## Transparency

Member Companies shall nevertheless maintain appropriate transparency by sending the Employer Notification i.e. **“prior written notification within a reasonable time to the hospital administration, the Healthcare Professional’s superior or other locally designated competent authority”**.

Whenever the HCOs nominate, in a written communication, the HCPs who will participate in company organized events, employer notification is not required.

### Employer Notification:

Member Company shall ensure full compliance with local laws and regulations regarding the disclosures of consultancy engagement or financial support provided to a healthcare professionals.



Such Employer Notification is required whenever a Member Company sponsors/engages Healthcare Professional in Company Event, Standalone Third-Party Organized Procedure Training, or as a Consultant even if no consultancy fees will be involved.

## Transparency

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

[In case of self-employed HCPs, employer notification would not be required, however self-employment need to be properly documented by the member company.](#)

### Employer Notification:



[For Company Organized Virtual Events, invitations to HCPs to participate do not require Employer Notification.](#)

## Means of doing it:

Member Companies shall maintain appropriate transparency by requiring Employer Notification i.e. prior written notification.

### Employer Notification can be done by



EMAIL



COURIER



FAX



No acknowledgement  
or approval is required  
by the recipient



Every member company  
should be able to provide  
proof of notification

# Transparency for Virtual & Hybrid Events

## Employer Notification – (sponsorship of attendance only):



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



For Company Organized Face to Face Events, **Employer Notification is required** whenever a Member Company sponsors travel or accommodation for a Healthcare Professional.



For Third Party Organized Events, Employer notification is not applicable (Educational Grant no Direct interaction with HCPs !)



## Employer Notification – (arrangement with consultants):

Whenever a Member Company sponsors/engages Healthcare Professional in all types of Events including Procedure Training as a Consultant, **Employer Notification is required**.

# Chapter 1. General criteria for events

## Virtual & Hybrid Events:

**UPDATE**



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



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

## Chapter 2. Third Party organized Educational events

- Third Party Organized Educational Conference
- Third Party Organized Procedure Training
- Satellite Symposium
- Conference Vetting System (CVS)
  - » Scientific program
  - » Geographic Location
  - » Event Venue
  - » Hospitality
  - » Event Registration Packages and Benefits
  - » Communication Support
  - » Appeal



# Chapter 2. Third Party Organized Educational events

## General Guidelines

**UPDATE**

### 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.

### 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.

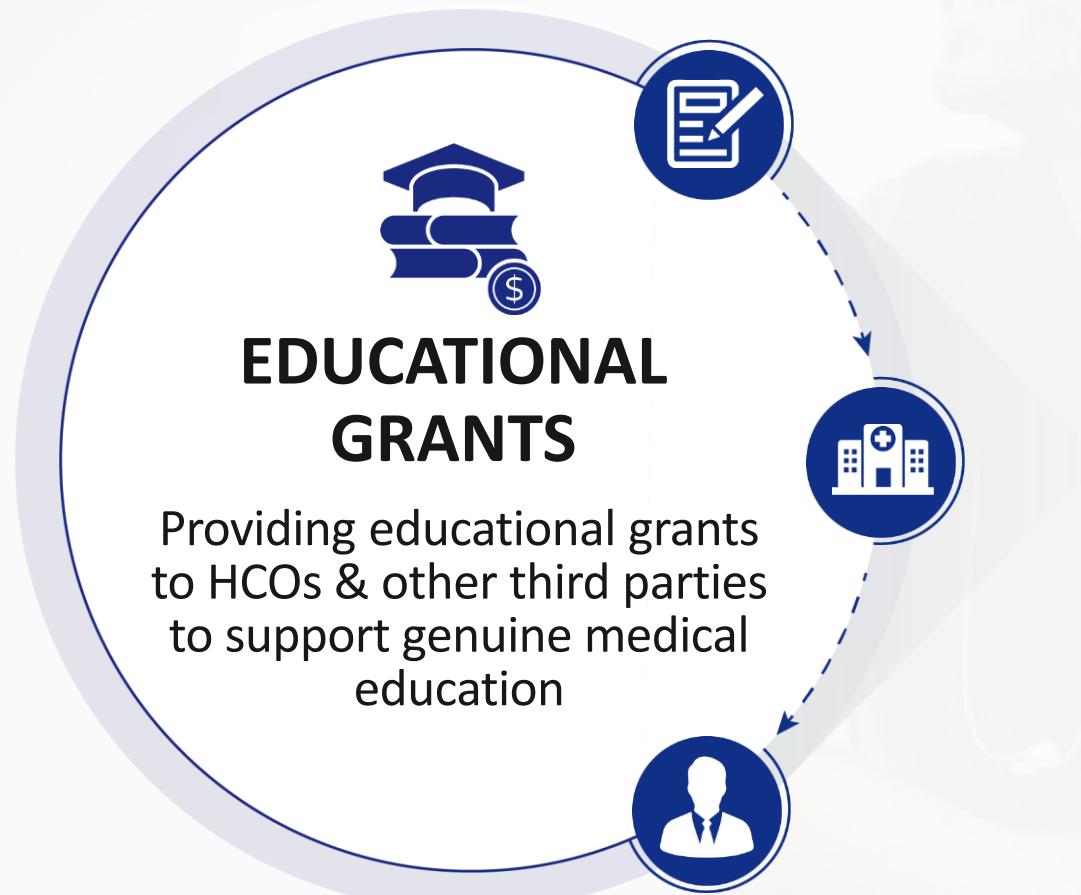
### Sponsorship packages

- » Member companies must ensure sponsorship packages are transparent, clearly detailing their value & associated benefits
- » Non-permissible benefits include gifts, business tickets for flights under 5 hours, first-class tickets, touristic tours, & other entertainment options; these must not be paid for, facilitated, or reimbursed by Member Companies.
- » Member Companies must ensure free delegate passes under sponsorship packages are not used for direct HCP sponsorship and comply with the Mecomed Code.
- » **If the PCO offers to select HCPs on behalf of the Member Company, the educational grant process must be followed, with the allocation recorded appropriately.**



# Educational Grants to support Third Party Organized Educational Events

From direct sponsorship to educational grants



## HCPs ARE SELECTED SOLELY BY THE GRANT RECIPIENT

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

## Chapter 2. Third Party Organized Educational Events



# Third-party organized educational events

## 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 organized educational events



## THIRD PARTY EDUCATIONAL CONFERENCES



## THIRD PARTY PROCEDURE TRAINING



Member Company can specify HCP specialty (not seniority), BUT selection to be done by **Healthcare organization HCO/ Professional Conference Organizer PCO.**

Approved by CVS in advance

### Support in form of:

- Educational Grant
- Satellite Symposia
- Promotional Activity

When it is a stand-alone meeting direct HCP Sponsorship is permissible by Member Company (With some conditions).

Approved by CVS in advance

### Support in form of:

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

# Third-party Procedure Training

## Third-Party Organized Procedure Training must be vetted by CVS:

- » In accordance with the general criteria for events provided in Chapter 1
- » In addition, CVS will assess the Event in accordance with the below additional criteria:

### Venue



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

### Program



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



# Satellite Symposium

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During Third- Party Organized  
Educational Conferences

# Satellite Symposium

## Definition:



A Company Organized Educational Event (as defined in the Mecomed Code) that takes place at a Third-Party Organized Educational Conference (as defined in the Mecomed Code). It should address educational topics that align with the Third-Party Organized Educational Conference Program's focus.

# Satellite Symposium

## It is permissible for member Companies to:



Select speakers for their Satellite Symposia



Add Company-sponsored Satellite Symposia speaker names to the website/brochure of the event/ agenda.



Directly sponsor and engage with speakers (i.e., pay honorarium / hospitality expenses) to their satellite symposium through a contractual agreement, in compliance with the Code related guidelines.



If required for the speaker to access the Satellite Symposium member companies should only pay the (most restricted package), the registration fee must where possible be prorated to the actual attendance required in order to deliver the agreed services, e.g., if the satellite symposium is held on a single day of the three-day event, and it is possible to choose a one-day registration, that option should be selected.



Invite HCPs already attending the Third-Party Educational Event to a Company Organized Satellite Symposium provided that member companies do not directly cover any cost related to registration, travel & accommodation of the participants at Third-Party Educational Event.



Provide participants at Satellite Symposia with reasonable and modest hospitality (i.e., snacks, etc.)



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 satellite symposium, however member companies must not cover their travel and accommodation (in compliance with chapter 5)

## Satellite Symposium

**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).

# Engagement with Consultants in Company Organized Events during Third-Party Conferences

**UPDATE**

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

## Permissible for member Companies to:

- Pay the contractual remuneration and legitimate expenses for the provision of the services by the Healthcare Professional, provided that any travel and/ or hospitality offered is subordinate in time and focus to the Event purpose.
- Member Companies may provide flexibility in the Healthcare Professionals' travel arrangements cost involved (i.e. hospitality, accommodation or travel).

## NOT permissible for Member Companies to:

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



# Conference Vetting System CVS

[www.mecomed.com](http://www.mecomed.com)

# 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 or commercial activities (e.g., booths, advertising, satellite symposia etc.).

# CVS Obligations

- Members of Mecomed and their Third-Party Intermediaries (TPIs), can provide support to any Third-Party Educational Event only if assessed compliant by CVS in advance. Furthermore, the decisions rendered by the CVS Officer is binding on Mecomed members & their TPIs.
- Member companies & their TPIs cannot support Third- Party Educational Events if the final outcome is one of the following:

Not Compliant

[Not assessed- Late submission](#)

[Not Assessed – Insufficient Information](#)

[Not submitted to CVS](#)



# Conference Vetting System (CVS)

## What you need to know about CVS

Submissions must be made online via the Ethical MedTech Conference Vetting System website: [www.ethicalmedtech.eu](http://www.ethicalmedtech.eu)

The final decision can only be rendered when all needed documents are complete and reviewed.

No charges apply when submitting an Event on CVS.



### Mecomed CVS Officer Contact:

 Ruba Khasati

 Email: [ruba.khasati@mecomed.com](mailto:ruba.khasati@mecomed.com)

Applicable to all types of Third-Party Educational events: (International, Regional, National/ Local).

You can check the events submitted to CVS using this link  
<https://cvs.solutions.iqvia.com/all-events>

### Different stakeholders can do submissions on CVS:

- » Professional Conference Organizers (PCOs)
- » MedTech / Mecomed Members & their TPIs / Distributors
- » Medical Societies & Healthcare Organizations (HCOs).

# Conference Vetting System (CVS)

## Excluded from CVS Assessment:



### Mecomed CVS Officer Contact:

 Ruba Khasati

 Email: ruba.khasati@mecomed.com

# How to Submit an Event to CVS



- Access <https://cvs.solutions.iqvia.com/login> and follow the steps outlined on the website to register and submit your event.
- Submission is done by logging in to your account or by creating an account if you are a new user.
- Once logged in, you can begin submitting your event. If you are the event organizer and submitting the event six months or more before its start date, you can submit a Pre-Clearance submission
- Always include the EMT ID / reference number of the event in any communication sent to the CVS officer.
- In the case additional information is requested you can add missing documents directly to the submission chat box on the platform.

# Time Frame for Submission & Assessment



Any submission to CVS for third-party educational event must **be 50 days** prior to the event starting date or earlier with NO EXCEPTION.



It will take up to 35 days to do assessment for events , depending on the starting date of the event and availability of full documentation.

# CVS Submissions

**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 or flyer)
-  Registration Fees and benefits for delegates

# Conference vetting System (CVS)



All criteria have the same weight in the assessment process.

Any criteria will be marked as Non – Compliant, will result of a Non – Compliant decision on CVS and a Non – Compliant Event.



# Scientific program

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



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



Entertainment included in the main program.



Sight seeing and tours as part of the program.



Unjustified gap in the program.

# 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 & the transmission of knowledge.



Location is not the main attraction of the conference



Should be easily accessible near a city/town (airport, highways)



Location is touristic in nature or holiday destination



Location is in the desert, remote island or in remote areas in mountain

The event venue should be a business or commercial center providing conference facilities conducive to the exchange of scientific & 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 &/or entertainment venue.



# 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.**



Should be limited to reasonable hotel accommodation & meals



Background music during lunch/ dinner



Entertainment, such as but not limited to live music, dancing, sight-seeing trips, sporting events



Hospitality is offered to spouses, partners, family, guests.

# Event Registration Packages

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

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



Entertainment included in the registration packages



Registration fees cover attendance of spouses, family members, partners.

# 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.



# Appeal



- An appeal may be filed by a Member Company or an Event Organizer (PCOs) or HCO on the CVS platform
- Legitimate justifications must be shared.
- The CVS Officer will forward the appeal request to the Mecomed Compliance Core Committee.
- The Core Committee will assess the appeal and the relevant documents/ justification.
- The decision will be taken within 10 working days from the receipt of the appeal request.

## Key Dates



CVS 2.0 Launched – February 1<sup>st</sup> 2025



CVS 1.0 (old platform) – Discontinued after February 28<sup>th</sup> 2025

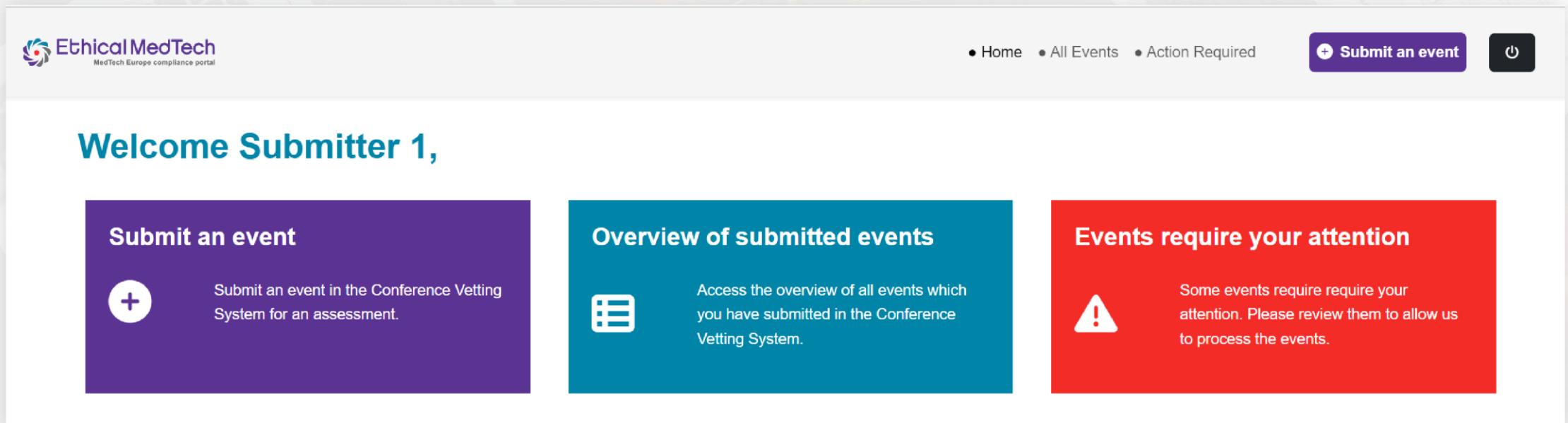
- Any event submitted on the old platform after February 28<sup>th</sup> 2025 will not be assessed.



# Click on “Submit an event”.



The information to be provided is similar to what you used to provide in the previous system.



The screenshot shows the Ethical MedTech portal interface. At the top, there is a navigation bar with the logo 'Ethical MedTech' (MedTech Europe compliance portal), a search bar, and a 'Submit an event' button. Below the navigation bar, a welcome message 'Welcome Submitter 1,' is displayed. The page is divided into three main sections: 'Submit an event' (purple background), 'Overview of submitted events' (teal background), and 'Events require your attention' (red background). Each section contains an icon and a brief description.

- Submit an event**  
Submit an event in the Conference Vetting System for an assessment.
- Overview of submitted events**  
Access the overview of all events which you have submitted in the Conference Vetting System.
- Events require your attention**  
Some events require your attention. Please review them to allow us to process the events.

# Create the event:



Enter the event identification details and Event organizer information

## Submit an event

Follow the below procedure to submit an event

Event identification > Location > Venue > Audience & Scope 1 > Audience & Scope 2 > Scientific Programme > Catering > Social programme > Registration package > Additional information

### Event identification

Event name \*

Event acronym

Event therapeutic area \*

Event format \*

Event type \*

Event website

Event website exists, if not, please explain, else provide url

Explain why there is no website \*

Start date \*

End date \*

First Edition \*

Notification emails

*(List comma separated email address which (next to yourself) need to receive event updates)*

### Event organizer

This event is organized by another organization than my organization **Emard-Dare**

Save & Next

# Key Changes

Save a draft option



CO cannot change the submissions in the backend (dates, ...)



Appeal process in the system (no separate email)



No Calendar of events / Follow event feature

<https://cvs.solutions.qvia.com/all-events>



Request for information – Check Messaging system

You can access the events from someone from your organization

Can change the submission until CVS Officer (CO) starts the review

Claim ownership of an Event (when already existing Event)



Terminology Changes



No provisionally compliant



New terms: Precleared, under review, waiting for information

# Appeal via CVS 2.0

Status	Action Required	Event Name	Therapeutic area	City	Start date	End date	Actions
Not Compliant	⚠	Test EMT-24-00050	Diabetes	Brussels	18/09/2024	24/09/2024	   

Appeal Event! Confirmation Required X

Are you sure you want to appeal this event? Please note that this action is irreversible. Please fill the details below.

Appeal Reason \*

Please specify why you are appealing this event

Supporting Document

Close Submit appeal

# Duplicates & Claim ownership

A similar event exists in the system X

Event Exists X

The event you are trying to submit already exists in our system. The combination of the event start date and event venue matches an existing entry.

The event you are trying to submit matched an event with the following details:

- Event Name:Test
- Event Therapeutic Area:Diabetes
- Event Type:In-Person
- Event Start Date:2024-09-18
- Event End Date:2024-09-24
- Event Organizer Name:Emard-Dare
- Event Organizer Address:
- Event Organizer Country:Mauritius

Discard Adapt Claim Ownership

Claim Ownership X

You chose to claim ownership of the event. Do you want to proceed?

Close Claim now

 **Avoid duplicates!** Always check upfront in the search if the event was already submitted

 Automated control based on several Event details.

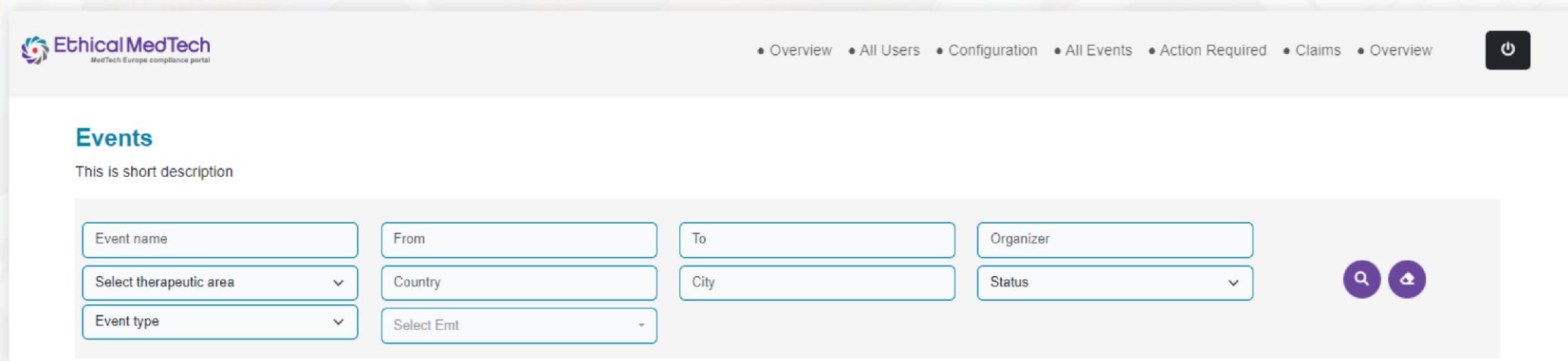
 If you're the organizer, you can claim ownership, so that you can adapt the Event

Adapt is to change the Event details. Discard will delete the record you just created.

# Search Function



Search for Events (<https://cvs.solutions.iqvia.com/all-events>)



Ethical MedTech  
MedTech Europe compliance portal

Events

This is short description

Event name      From      To      Organizer

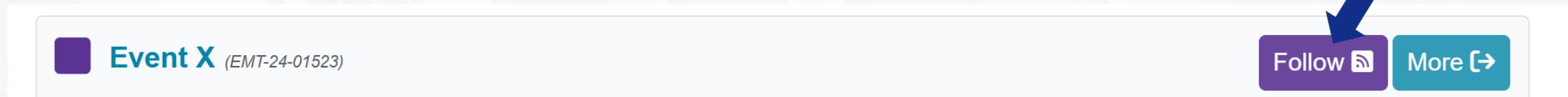
Select therapeutic area      Country      City

Event type      Status

Search      Refresh



No Calendar anymore



Event X (EMT-24-01523)

Follow  More 

# Request for Information



You will receive a  
notification by email



Visible in the  
messaging (red bubble)

Status	Action Required	Event Name	Therapeutic area	City	Start date	End date	Actions
Waiting for information	⚠	cheat sheet 2 EMT-24-00042	Other	Brussels	01/11/2024	02/11/2024	 



# Chapter 3

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## Company Organized Events

Member Companies may organize and directly invite Healthcare Professionals to Company Events

## CHAPTER 3. COMPANY ORGANIZED EVENTS



# 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 & 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 & accommodation.



Majority of the program must be with an **Educational objective** & not with the sales & 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 to its size, weight, installation, connectivity cannot be easily transported.



## Chapter 4

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# Grants & Charitable Donations

## Definition

### **Educational Grant:**

A provision of funding, by means of **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

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.

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

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

- 01
- 02
- 03
- 04
- 05

Must be provided directly to the qualifying organization or entity.

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.



## Educational Grants

**1**

Third party Organized  
Educational Event

**2**

Scholarships  
Fellowships

**3**

Public Awareness  
Campaign

**1a**

HCP Participation  
Support

**2b**

Support the event

# 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
- **Disclosure:**  
Member Companies shall document and timely disclose all Educational Grants
- **Verification:**  
Member Company shall define a proper mechanism to ensure that the Educational Grant is used for the documented purpose
- **CVS**  
Need to be approved by Conference Vetting System.

## THIRD-PARTY ORGANIZED EDUCATIONAL EVENT



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



Directly to Healthcare Organizations and / or Professional Conference Organizers



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

### 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 the 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.

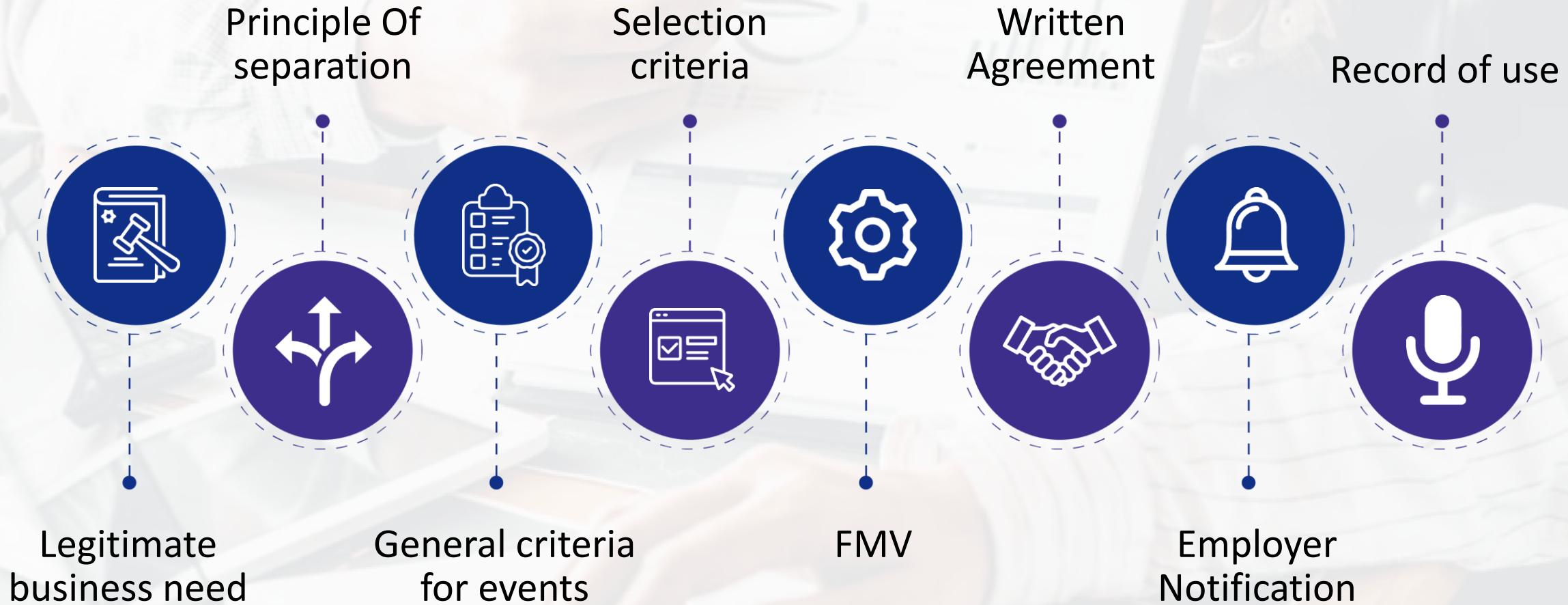


# Chapter 5

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## Arrangements With Consultants

# Criteria for Consulting Arrangements



# Criteria for Consulting Arrangements

**Legitimate  
Business Need:**

**Principle of  
Separation:**

**Selection  
criteria:**

**Written  
Agreement:**

- 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.
- 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.
- 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.
- 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

Compliance with Chapter 1:

Fair Market Value (FMV):

Employer Notification

Record of Use

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

# Chapter 9. Promotional & Educational Items Provided To HCOs/HCPs

## Promotional Items

### 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.



# Chapter 9. Promotional & Educational Items Provided To HCOs/HCPs

## 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 provided 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.

# Providing Promotional and Education Items

## General Principles

Promotional and educational items should:	Promotional and educational items should not:
<ul style="list-style-type: none"><li>✓ Comply with national laws, regulations and industry and professional codes of conduct</li><li>✓ Relate to the HCP's practice, or benefit patients, or serve a genuine educational function</li><li>✓ Do not require Employer Notification</li></ul>	<ul style="list-style-type: none"><li>✗ Be for the personal benefit of the HCPs such as items primarily used at home/in the car</li><li>✗ Be provided in response to requests initiated by HCPs</li><li>✗ Be given in the form of cash or cash equivalents (e.g. debit/gift cards/gift certificates)</li><li>✗ 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</li><li>✗ Be provided to HCPs engaged as consultants/speakers in lieu of a professional fee for their services</li><li>✗ Be offered on more than an occasional basis, even if each individual item is appropriate</li><li>✗ Be provided for personal benefit or out of cultural courtesy (e.g. life events, promotion, birthdays etc.)</li></ul>

# 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.

# Chapter 10. 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.



Demonstration Products and/or Samples may be either single or multiple-use products.



Appropriate records in relation to the provision of Demonstration Products and/or Samples need to be kept, e.g.



Products from another company in conjunction with the Member Company's own Demonstration Products &/or Samples may be provided on an exceptional basis if these products are required to properly and effectively demonstrate & evaluate. e.g. computer hardware & software produced by a company other than the Member Company.



Under no circumstances 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.



Recording proof of delivery for any products.

Receipt of return for multiple-use products.

# Chapter 10. Demonstration Products & Samples

## General Principles

Any supply of such products shall always be done in full compliance with applicable national laws, regulations and industry and 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



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 (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).

## 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



## 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.



THANK YOU

COMPLIANCE