

WHEN DOES THE MEDTECH EUROPE AND MECOMED CVS SYSTEM APPLY TO EVENTS HOSTED IN SOUTH AFRICA?

To clarify which third-party organized educational events taking place in South Africa are eligible for submission to the <u>Ethical MedTech</u> and Mecomed CVS System and to assist industry, professional congress organisers and healthcare professional societies in their planning and decision making thereon, SAMED together with Ethical MedTech and Mecomed prepared the following explanatory note.

ABOUT CVS

The <u>Conference Vetting System (CVS)</u> is a unique initiative in the healthcare industry. It is a centralised decision-making system that encourages transparency and consistency in medical education events and alleviates the complex administrative burden previously faced by MedTech Europe and Mecomed members, who were constrained to make their own determinations on whether or not a third-party educational event they wished to provide support to was compliant with the associations' respective Codes.

CVS is an independently managed system which reviews the compliance of third-party educational events with the <u>MedTech Europe Code of Ethical Business Practice</u> and the <u>Mecomed Code of Business Practice</u> (the "Codes") to determine the appropriateness for companies which are members of MedTech Europe and Mecomed to provide financial support to such events in the form of educational grants or commercial activities (i.e. consultancy agreements for speakers, satellite symposium) in support of HCP attendance or to defray the costs of the event.

The review process is based on a set of fixed criteria:

- Scientific programme.
- Geographic location.
- Conference venue.
- Hospitality offered and registration package benefits.
- Communication of the event.

ELIGIBILITY & SCOPE

The following categories of stakeholders may submit an event for CVS review:

- MedTech Europe members and their distributors.
- Mecomed members and their distributors.
- SAMED members and their distributors.
- Healthcare Organisations (HCOs), including hospitals.
- Professional Conference Organisers (PCOs).
- Individuals or organisations not mentioned above, who host third-party organised events for the medtech industry in South Africa.

GUIDANCE TO DETERMINE WHICH EVENTS HOSTED IN SOUTH AFRICA ARE IN SCOPE FOR CVS REVIEW:

- **Note 1:** It is the **passive participants** (i.e. delegates) that determine the international nature of an event and not the active participants (i.e. faculty).
- **Note 2:** Veterinary events do not fall in scope of CVS review.
- **Note 3:** Tradeshows generally do not fall in scope of CVS review when such events offer only promotional exhibitions, with no educational sessions.
- Note 4: In the event that CVS review is not required, all the provisions of the South African Medical Technology Code of Ethical Marketing and Business Practice will still apply and SAMED members should perform internal review of such events against the criteria for compliant events.
- Principle 1: <u>CVS review does NOT apply</u> if the event organizer/host anticipates that <u>only South African</u> <u>HCPs</u> will attend the event as delegates. However, Note 4 still applies.
- Principle 2: CVS review DOES apply if the event organizer anticipates that HCPs from the MedTech Europe or Mecomed geographic areas may attend the event as indirectly sponsored delegates.
- → Refer to Annex I for countries that fall within the MedTech Europe geographic area.
- → Refer to *Annex II* for countries that fall within the Mecomed geographic area.

FREQUENTLY ASKED QUESTIONS

- 1. My company is a member of both SAMED and MedTech Europe. If CVS reviews and rejects an event may my company still support the event commercially (i.e., can we take a stand and / or pay for other forms of advertising)?
 - A Yes, provided the requirements around events as per the <u>Medical Technology Code of Ethical Marketing and Business Practice</u> are met. It is incumbent upon SAMED Members and the professional congress organisers to heed these even if CVS is not applicable. In instances where these requirements are not adhered to, for example the location of the event is a casino or primarily tourist attraction, then it would not be appropriate for the member to support the event commercially.
- 2. A European or African (non-South African) HCP is attending a third-party organized event in South Africa as a passive delegate at his/her own expense. Is CVS approval required?
 - A No, CVS approval is not required **but** all the provisions of the <u>South African Medical Technology</u> <u>Code of Ethical Marketing and Business Practice</u> will still apply and SAMED members should perform internal review of such events against the criteria for compliant events.
- 3. A European or African (non-South African) HCP is attending a third-party organized event in South Africa as **faculty**, however only South African HCPs are attending as passive participants (i.e., delegates. Is CVS approval required)?
 - A No, CVS approval is not required **but** all the provisions of the <u>South African Medical Technology</u> <u>Code of Ethical Marketing and Business Practice</u> will still apply and SAMED members should perform internal review of such events against the criteria for compliant events.
- 4. What if a European HCP is a speaker at a South African third-party organized event and I agree to provide an educational grant to indirectly support the costs of that speaker? Is CVS approval required? In this instance no European or African (non-South African) HCPs are attending as passive delegates.
 - A No, CVS approval is not required **but** all the provisions of the <u>South African Medical Technology</u> <u>Code of Ethical Marketing and Business Practice</u> will still apply and SAMED members should perform internal review of such events against the criteria for compliant events.
- 5. What if CVS does not apply? Does the <u>MedTech Europe</u>, <u>Mecomed</u>, <u>SAMED</u> or other code, still apply in terms of events?
 - A If CVS does not apply, all the provisions of the <u>South African Medical Technology Code of Ethical Marketing and Business Practice</u> will still apply and SAMED members should perform internal review of such events against the criteria for compliant events.
- 6. Can a medtech company (MedTech Europe/Mecomed/SAMED member and non-member companies) request CVS approval for an event?
 - **A** Yes, if the event is in scope for CVS review.
- 7. What is the timeframe for applications made to Ethical MedTech vs Mecomed CVS?
 - A All applications made to for MedTech Europe and Mecomed CVS review must be made no later than 50 days prior to the event starting date, via the online platform. Submissions made after the 50-day deadline will be attributed automatically the final status "not assessed/late submission". No exceptions are permitted.

- 8. How long does it take to get a response from Ethical MedTech and Mecomed CVS once you have made an application?
 - **A** For both the aim is 35 days however this may be more than 35 days dependent on the number of applications currently under review by the CVS teams.
- 9. What is the website address for MedTech Europe and Mecomed CVS? Note one platform services both MedTech Europe and Mecomed.
 - A https://cvs.solutions.igvia.com/
- 10. Who to reach out to at MedTech Europe and Mecomed CVS should you have queries.

A MedTech Europe: https://www.ethicalmedtech.eu/contact/

Mecomed: https://www.mecomed.com/focus-areas/compliance

Important note on communicating with the CVS teams:

- Emails about meeting review statuses will not be answered.
- The status of an event should be checked on the website: https://www.ethicalmedtech.eu/conference-vetting-system/search-events/
- 11. Are member company-arranged events subject to CVS approval?
 - A No, company-arranged events are not subject to CVS approval. However, all the provisions of the South African Medical Technology Code of Ethical Marketing and Business Practice will still apply and SAMED members should perform internal review of such events against the criteria for compliant events.
- 12. Does third-party arranged procedure training also require CVS approval?
 - → Yes, refer to https://www.ethicalmedtech.eu/.../third-party-procedure-training/

13. Important Links

CVS Website https://www.ethicalmedtech.eu/conference-vetting-system/objective/
Submit an event for https://www.ethicalmedtech.eu/conference-vetting-system/submit-a-conference-in-cvs-2-0/
Search CVS events https://www.ethicalmedtech.eu/conference-vetting-system/search-events/
CVS Training Decks https://www.ethicalmedtech.eu/conference-vetting-system/submit-a-conference-vetting-system/search-events/
CVS Training Decks https://www.ethicalmedtech.eu/conference-vetting-system/search-events/
CVS Training Decks 202409 Launch of CVS/e4ethics 2.0 and reviewed criteria Training Slides deck
202407 CVS Assessment Criteria - Overview of the changes

202501 CVS/e4ethics 2.0 training deck (including 2025 new features)

MedTech Europe Subscribe to the mailing list be informed of CVS training events

Mailing List https://forms.office.com/e/pu6w3DwSaM

ANNEX I

Luxembourg*

MEDTECH EUROPE GEOGRAPHICAL AREA Austria ■ Malta* Belgium Norway Bulgaria Poland Croatia Portugal Cyprus Romania Czech Republic Slovakia Denmark Slovenia Estonia Spain Sweden Finland France Switzerland Germany The Netherlands Greece The United Hungary Kingdom Iceland* Türkiye Ireland *Countries party to Israel the European Italy **Economic Area** Latvia agreement without a Liechtenstein* MedTech Europe Lithuania **National Association**

ANNEX II

MECOMED GEOGRAPHICAL AREA

- Algeria
- Angola
- Benin
- Botswana
- Burundi
- Cameroon
- Central African Rep.
- Chad
- Congo
- Cote D'Ivoire
- Dem. Rep of the Congo
- Egypt
- Equatorial Guinea
- Eritrea
- Ethiopia
- Faso
- Gabon
- Ghana
- Guinea
- Iran
- Iraq
- Israel
- Jordan Bahrain
- Kenya
- Kuwait
- Libya

- Madagascar
- Malawi
- Mali Burkina
- Mauritania
- Morocco
- Mozambique
- Namibia
- Niger
- Oman
- Pakistan
- Qatar
- Rwanda
- Saudi Arabia
- Senegal
- Sierra Leone
- Somalia
- South Sudan
- Sudan
- Syria
- Tanzania
- Tunisia
- U.A.E.
- Uganda
- Western Sahara
- Yemen
- Zambia
- Zimbabwe

