



November 8, 2023

Dr. João Grenho
Secretary General
European Union of Medical Specialists
24 Rue de l'Industrie – 1040
Brussels, Belgium

Dear Dr Grenho,

I am writing you on behalf of the [CME Coalition](#), a United States-based (Washington, DC) organization comprised of CE/CME providers, beneficiaries of CE/CME (including both educational institutions and professional societies) and supporters of CE/CME (such as pharmaceutical manufacturers and device makers).

We applaud EACCME's efforts to update their guidelines and appreciate the work that has gone into this release. Your goals are commendable.

With the release of the EACCME®'s updated guidelines (EACCME® 3.0), our membership wishes to weigh in and seek clarification on several concerns raised by our members. The following comments and opinions were developed by an all-volunteer working group comprised of members of the CME Coalition and is intended to convey the feedback and concerns of our 30+ organizations.

Thank you for this opportunity.

Recommendations

- 1. We are concerned that the EACCME will no longer consider for accreditation commercial/industry sponsored satellite symposium, even if it is stated that they are supported by an unrestricted educational sponsorship.**

By definition, accredited CME guarantees that education is objective, fair-balanced, free of commercial bias and meets rigorous high standards of quality and independence. Around the globe, independent industry-supported symposia at international congresses (both live and hybrid) provide a forum where health care providers (HCPs) receive quality accredited medical education that can improve their knowledge, competence and performance and ultimately impact patient care. Satellite symposia often allow case-based and practical opportunities to apply the data and knowledge from the congress and engage with, and learn from, national and international experts. Indeed, some of our US-based pharmaceutical company members will only support ex-US symposia that are accredited.

Oftentimes, symposia are supported by unrestricted educational sponsorships (previously grants) and they need to abide by the strict criteria outlined in the UEMS-EACCME's Requirements for the Accreditation of a CME/CPD Activity. The terms of awarding the unrestricted educational sponsorship is detailed in a Letter of Agreement (LOA), between the industry supporter and accredited provider, which must be signed before the activity (symposium) takes place. These criteria ensure that there is no opportunity for industry to influence the content, infuse marketing or promotional messages, or dictate/recommend how the grant should be managed, thus ensuring there is a clear separation between the industry supporter and the content of the CME activity. With all these safeguards in place when implementing industry supported satellite symposia, it is unclear to us as to why offering accreditation for this format is no longer available through the EACCME.

We are concerned, further, that EACCME's proposed criteria could have very negative implications for the future availability of, and access to, quality/fair balanced education at global ex-US conferences attended by both US and OUS HCPs. As the number of satellite symposia decreases, the reduced number of educational opportunities/choices for HCPs will likely hit hardest on the current and ever-increasing need to feature diverse perspectives from leaders in various fields. To the degree that symposia may still occur, they will no longer be accredited and may be more likely to be industry-led (thus lacking the independence and fair balance of accredited education).

Finally, we believe there is a real risk that the proposed changes could impact the collection of outcomes metrics and evaluations. As changes to EACCME live event accreditation reduce outcomes participation and evaluation completers, we will have less ability to evaluate the impact of education and provide meaningful metrics that are highly valued by both education providers and industry supporters.

2. Sponsorships Outside the Exhibit Hall

Societies and conference organizers utilize sponsorship from industry to help offset the cost of live educational events. In the United States, accredited providers of continuing education take rigorous steps to adhere to the ACCME *Standards for Integrity and Independence in Accredited Continued Education*. For live activities, these standards include ensuring that the educational space (rooms) where the accredited content is presented is free from any marketing/promotional presence or influence from industry/ineligible companies.

We agree with you that the Exhibit Hall serves as an appropriate space for learners to engage with industry and their representatives, but we would recommend that the "[o]n-site items that would be out of compliance" per the EACCME website, should be amended with appropriate guidance to allow for sponsorships outside the Exhibit Hall. This is compatible with safeguarding the integrity of the accredited education.

Support for items should also be acknowledged *without* the use of logos. We suggest permitting industry sponsorship of items that would primarily be utilized by the healthcare professionals during the course of the CME event where there would be an imperceptible influence or bias toward the industry product. Sponsorship of awards and scholarships, for example, especially if multi-supported, demonstrates a collaborative effort on the part of industry to support continuing professional development, thus eliminating the appearance of bias. Thus, we would recommend allowing the following:

- Sponsoring of specific items such as lanyards, pens, notepads

- Sponsoring of specific facilities such as hand sanitizer stations, charging stations, rehydration station and water bottles
- Congress Wi-Fi and Wi-Fi access/username/password
- Sponsoring of awards
- Multi-sponsorship scholarship

3. Eligibility Criteria

The eligibility criteria on page 8 of the EACCME®’s updated guidelines require professional congress organizers and medical communications agencies to co-develop CME/CPD activities with a physician organization.

We consider this policy to be potentially discriminatory towards private firms who employ thousands of workers in the EU to help organize accredited educational activities. As a practical matter, all the medical communications companies and congress organizers work with physicians but should not be required to draw them into the EACCME accreditation process.

Furthermore, we believe this potentially could be considered going against the spirit of European Union treaties. Article 16 of the Charter of Fundamental Rights recognizes the freedom to conduct a business in accordance with Union law and national laws and practices. The ability to start and maintain private enterprise is a basic right for European Union Citizens.

4. Definitions

In addressing the EACCME®’s new guidelines, particularly regarding unrestricted educational sponsorships, we find ourselves at a crossroads of understanding. Our confusion lies in discerning the true distinction that EACCME® is drawing between the traditional concept of an unrestricted educational sponsorship and its application within the updated framework. If the control and direction of the funding rests firmly in the hands of the CME provider, with explicit accountability on the part of the medical director, and if the provision of transparency remains a steadfast requirement, how does this differ fundamentally from previous practices? Furthermore, there seems to be a lack of consistency in the acceptable sources of funding between various educational formats. We respectfully request a more detailed explanation of the reasoning behind these changes.

Regarding “unrestricted educational sponsorships,” our interpretation has been that such funding is granted to CME providers through a clearly defined and transparent contract, allowing the provider to use the funds as they deem appropriate for educational purposes. This use is to be without interference or direction from the sponsor, safeguarding the program, session topics, content, and faculty selection from any undue influence.

The concept of ‘Conflict of Interest’ (COI) in EACCME® 3.0 introduces three variants: COI, Perceived COI, and Actual COI. For the benefit of clarity and the application of best practices, we ask for the EACCME® to provide a more explicit hierarchy of these terms, accompanied by guiding examples for each definition. Concerning the term 'Perceived COI', we seek clarification on which third party is empowered to ascertain the presence or absence of a COI, and why there has been a shift from using the term “potential” to “perceived,” as “potentiality” does not inherently imply perception.

To reiterate these definitions for clarity:

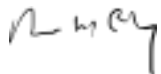
- Conflict of Interest (COI): This is a situation where a person's or organization's decision-making regarding a primary interest, such as patient care, research integrity, or educational quality, could be unduly swayed by a secondary interest, including financial gain, professional advancement, or benefits to associates.
- Perceived Conflict of Interest: This arises when it is reasonable for an observer to believe that an individual or organization has competing interests that may compromise their commitment to their primary responsibilities.
- Actual Conflict of Interest: This occurs when there is a direct conflict between one's duties and responsibilities and personal interests, likely affecting the individual's or organization's ability to honor their professional obligations.

Conclusion

We appreciate your consideration of the above comments and implore you to continue to solicit stakeholder feedback, including from United States based organizations, as to the potential implications of EACCME® 3.0. Our members share the EACCME's mission of providing independent, impactful continuing medical education to providers across the spectrum. We believe that there is an important role to be played by industry/commercial supporters and that sensible, consistent rules can ensure that this education is fair/balanced, absent of bias, and highly beneficial to achieving better patient outcomes.

We would welcome an opportunity to speak with you at your convenience should you have any interest in further discussing our comments.

Sincerely,



Andrew Rosenberg, JD, MP

Senior Advisor, CME Coalition

Washington, DC