#### **UEMS/EBNM**

### The new UEMS-EACCME criteria for accreditation of live educational events (LEEs): another step forward to improve the quality of continuing medical education (CME) in Europe

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#### Introduction

Continuing medical education (CME) in Europe is a complex, multilevel, multilingual and multi-regulatory, rapidly growing learning system. An increasing number of countries are adopting voluntary or compulsory systems of CME participation for physicians under the stimulus of growing evidence that CME good quality systems are likely to improve both clinical practice and patient outcomes [1, 2].

Requirements of educational programmes are also rapidly growing in the effort to enhance CME quality and to unify CME principles and standards with the shared goal of "improved patient outcomes" beyond country borders. As the Good CME Practice Group published in its document to drive European CME, quality should be based upon four core principles: (1) adequate education, (2) productive education, (3) transparency and (4) fair balance.

- 1. Adequate education: educational activities should have focused learning objectives derived from coherent and objective processes that have identified performance gaps and unmet educational needs.
- 2. Productive education: education must be designed to positively reinforce existing good practice and effect a sustained change in daily clinical practice as appropriate. Post-activity evaluation should assess satisfaction, knowledge uptake and intent to maintain or modify behaviour in line with learning objectives.

- 3. Transparency: all relevant information should be disclosed to learners in order to make them understand fully how the content has been developed and presented, including terms of financial support, relevant disclosures of faculty and organizations involved in the development of scientific content, and presentation of the programme.
- 4. Fair balance: the content has to be developed independently and reflect the full clinical picture within the framework of learning objectives [3].

In October 1999, the European Union of Medical Specialists (UEMS) set up the European Accreditation Council for Continuing Medical Education (EACCME), with the aim of harmonizing achievement and improving the quality of specialist medical care in Europe, promoting the goal of the highest quality standards of CME, at both individual and institutional levels. During these 12 years the accreditation activity of the EACCME has been constantly growing up, to become the most important pillar of UEMS activities.

In order to enhance the quality of its CME accreditation process, in October 2012 the UEMS-EACCME amended and produced new criteria for accreditation of live educational events (LEEs) (UEMS 2012/30) [4].

These criteria have become applicable for all applications made as from 1 January 2013 and replaced the previous accreditation criteria (UEMS D 9908 and subsequent revisions) as of that date.

The aim of this editorial is to outline and discuss the key elements of the new document, giving suggestions for the interpretations of the rules arising from the UEMS Reviewers' Meeting held in Brussels in July.

## The accreditation of LEEs by the EACCME (UEMS 2011/30)

The criteria set out in the UEMS document "The Accreditation of Live Educational Events by the EACCME" (UEMS

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2011/30) hold a significant change in the standards required for accreditation, as Edwin Borman, UEMS General Secretary, said in an interview about good CME practice: "I would describe the new criteria as a revolutionary change in accreditation of live educational events throughout Europe, largely because for Europe as a whole they introduce criteria that go well beyond what currently occurs in many countries" (http:// www.pharmaphorum.com/articles/good-cme-practice).

The document includes 26 essential criteria focusing on learners (educational needs assessment, target audience, feedback), educational activity (defined objectives, active learning methods, independence in terms of the development of the programme, transparency in terms of financial support, scientific validity and balance), providers (information, track record), disclosures of conflicts of interest for organizers and faculty, and outcomes. All criteria are listed in the Appendix.

#### Educational objectives and fulfilment of learning needs

Criterion 1. *The provider must structure the LEE to fulfil defined educational needs.* The application must demonstrate that a "needs assessment" process has been completed, how that process was performed, and what relevant educational needs have been identified from that process.

Note: A "needs assessment" is what the audience needs to learn about. In other words the people who are providing CME should identify gaps in practice between what learners know and do (present practice) and what learners should know and do (optimal practice). This should be an important part of any CME planning. Research has shown that educational activities based on learning needs are more effective in delivering sustainable educational outcomes to participants [5]. The gaps in knowledge can be identified using physician self-assessment methods (physician self-testing, quality assurance reports, testing, etc.) or published or collected data [health care statistics (national, state, specialty), pretest/post-test results, evidencebased journals, published quality assurance reports]. What the pharmaceutical companies are prepared to offer, CME events have been offering year after year without data to support the need, decisions made by the organizers alone. This is not a needs assessment!

Criterion 2. The provider must define the "target audience" for whom the LEE is most likely to be suitable. This must be explained in terms of the specialties and seniority of doctor(s) most likely to benefit. Note: The primary target audience for CME events accredited by UEMS/EACCME must be fully qualified medical specialists. Events directed at junior doctors specializing in... or general practitioners, technicians or nurses are not acceptable for accreditation.

Criterion 3. *The provider must identify and communicate the expected educational outcome(s) of the LEE.* These must be explained in terms of the expected educational impact in knowledge, skills, attitudes or behaviours, or ethical lessons, and where in a doctor's practice this will have an impact.

#### **Description of the LEE**

Criterion 4. *The provider must provide the title of the LEE, its venue, date(s) and a clear description of the nature of the event.* This must indicate whether the LEE will involve lectures, discussions, workshops and/or other educational methods, single or multiple sessions, and whether these will be sequential or in parallel.

Note: Satellite symposia sponsored by industries cannot be accredited.

Criterion 5. *The LEE must be presented in a manner suitable for an international audience.* The LEE will need to demonstrate that it can accommodate the educational needs of an international audience with the primary language determined by the composition of the audience and facilities available for interpretation as required. International terminology for procedures and therapeutic agents must be used.

Note: The application must be submitted in English (criterion 25).

Criterion 6. *The LEE must include methods to promote active learning*. Examples include: multimedia presentations, protected time for question and answer sessions, opportunities for audience participation, keypad votes and discussion.

> Note: Numerous articles have been published on the merits of active learning, and collectively they present a body of compelling evidence that these methods do enhance learning [6, 7].

Criterion 7. *The provider must provide detailed information on the duration of the LEE.* This is particularly important in order to determine the maximum number of European CME credits (ECMECs) that may be claimed by a learner who has attended the LEE. This must be a minimum of one educational hour, with each hour of educational time expected to count as one ECMEC, up to a maximum of three ECMECs for a half day and six ECMECs for a full day.

Note: This solution of a time-based model to grant credits is far from being the most satisfactory of quality criteria; nevertheless, it has been considered by the EACCME Task Force as the simplest method to be applied widely. It is important to note that coffee break, lunch sessions and opening ceremony cannot be included in the duration of the event. Should all criteria be satisfactorily met, full credits will be granted; if not only 75 % will be allocated.

Criterion 8. *The provider must indicate the mechanism(s) by which it will be verified that the learner has engaged with the LEE in order to fulfil the educational objective(s).* As a minimum this must involve a mechanism for confirmation of attendance at the LEE. The UEMS encourages the use of more sophisticated methods, such as smart cards confirming attendance at specific sessions, requiring the learner(s) to complete questions based on the LEE material, requiring the learner(s) to complete feedback forms, etc. An online evaluation system linked with the provision of a CME certificate also will be acceptable.

> Note: This could be an example of good practice of learners' engagement. "Learners will go online at the end of the event to complete a comprehensive evaluation (including whether objectives were achieved), log in with their unique ID, claim credit (a breakdown of max. credit daily is provided), and receive the customized CME/CPD certificate with hours actually attended".

Criterion 9. The LEE must be conducted in compliance with all relevant ethical, medico-legal, regulatory, industry-based and legal requirements. For example, this should include: confirmation of confidentiality for patients and other participants, or consent to inclusion of nonidentifiable details within LEE presentations, compliance with research ethics requirements, compliance with data protection legislation and copyright arrangements. It is essential to ensure that patients are not and cannot be identified in any of the presented materials. Relevant legal, regulatory and industry-based standards will be those valid for the country in which the LEE is being held.

#### Details of the provider, responsible for organization and application, the Scientific and/or Organizing Committee

- Criterion 10. *The provider must provide a short description of the provider organization(s).* The provider must submit a short description of their organization, and any other(s) with which they are working, with regard to this specific LEE, specifying, in each case, the organization's contribution to the LEE. Where the provider is a CME company producing a programme on behalf of another organization (e.g. pharmaceutical or device manufacturer) their relationship must be fully disclosed.
- Criterion 11. The provider must state the names and job titles of the individual(s) responsible for preparing the LEE. The name and contact address of the person/organization primarily responsible for the delivery of the LEE must be provided. In addition, if these are from different organizations, the names and contact addresses of the persons/organizations responsible for the planning of the LEE, the administration of the LEE and the scientific programme content of the LEE must be provided, and for billing purposes.
- Criterion 12. The provider must provide the name, title and contact details of a medical practitioner who will take responsibility for the application for accreditation of the LEE. This doctor must be registered with a Medical Regulatory Authority, and his/her registration details must be provided. Normally this will be a senior member of the Organizing Committee for the LEE. In all circumstances, this doctor will be expected by the UEMS to have verified the information submitted on behalf of the provider in the application for accreditation.
- Criterion 13. The provider must provide the name(s), job title(s) and contact details of the head and all other members of the Scientific and/or Organizing Committee. The person responsible for, or in charge of the committee responsible for, the planning of the scientific content of the LEE must be clearly identified.

#### Transparency I: conflicts of interest (COI)

Criterion 14. The provider must ensure that all members of the Scientific and/or Organizing Committee provide written declarations of potential or actual COI. All declarations of potential or actual COI, whether due to a financial or other relationship, must be provided to the EACCME upon submission of the application. Declarations also must be made readily available, either in printed form, with the programme of the LEE, or on the website of the organizer of the LEE. Declarations must include whether any fee, honorarium or arrangement for reimbursement of expenses in relation to the LEE has been provided.

Note: The COI forms should cover interests going back 3 years.

Additional research can be made by the EACCME reviewer or EACCME office using online search engines (e.g. Google) to check the truth of the declarations both for Organizing/Scientific Committee and faculty members.

- Criterion 15. *The provider must confirm that any actual COI have been resolved.* Where there has been an actual COI involving a member of the Scientific and/or Organizing Committee, the EACCME must be informed of how this has been resolved. The EACCME considers it a responsibility of the head of the Scientific and/ or Organizing Committee to ensure that actual COI are addressed.
- Criterion 16. The Scientific and/or Organizing Committee must ensure that the LEE will provide a programme that presents a scientifically balanced perspective of the subjects included.

This must include impartiality in the scheduling of subjects, lecturers and opportunity for discussion. Challenge through peer review by participants during discussion sessions within the LEE can provide an effective safeguard.

Criterion 17. The provider must ensure that all members of the faculty provide written declarations of potential or actual COI. These declarations must be made publicly available, either in printed form, with the programme of the LEE, or in electronic form, on the website of the organizer of the LEE. The EACCME considers it a responsibility of the head of the Scientific and/or Organizing Committee to ensure that actual COI are resolved. These declarations must be retained for at least 1 year after the event for potential review by the EACCME.

Note: To better deal with the COI, on-site visits will be set by the EACCME on a more regular basis, in order to have at least 20 % of

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events controlled. In addition UEMS/ EACCME reserves the right to request doctors, attending the event, to provide independent reports.

# Transparency II: funding of the LEE. Compliance with sponsors

The EACCME will only consider for accreditation LEEs fulfilling specific requirements related to their funding. Accordingly, events provided by pharmaceutical and medical equipment industries will not be considered for accreditation.

- Criterion 19. *The source(s) of all funding for the LEE must be declared and be made available to learners in a readily accessible manner.* Failure by a provider to disclose the means of funding of an LEE will lead to rejection of its application. The provider must provide documentation confirming the basis of the funding for the LEE, whether this is by sponsorship, educational grant or any other means. While all sources of funding must be declared, the actual amounts provided do not need to be.
- Criterion 20. The Scientific and/or Organizing Committee must confirm that it has determined the content of all aspects of the LEE to be free of any attempt by sponsors to influence the Committee's decisions. All funding must be provided free of any attempt to influence the programme, individual sessions, subjects for discussion, content or choice of faculty members.

Note: Mono-sponsored events are not an exclusion criterion as such, but should raise the level of suspicion. In this case the reviewers are instructed to write back to the provider in order to request assurance that there is no undue influence from the sponsor.

Criterion 22,

All educational material must be free of any form of advertising and any form of bias.

The EACCME will reject any application that, in its opinion, includes advertising of any product or company directly related to any educational material. The EACCME defines "bias" as "a tendency or preference towards a particular perspective, ideology or result, especially when the tendency interferes with the ability to be impartial, unprejudiced or objective." "Bias may be scientific, political, economic and financial, religious, gender-related, ethnic, racial, cultural or geographical. Bias may occur in relation to a particular industry or commercial product such as a mechanical device or pharmaceutical agent, or in relation to a particular intellectual, political or other view, in situations where a range of products or views may be equally useful or valid."

Specific examples that will lead to automatic rejection of an application include: use of a sponsor's name in the title of the scientific programme, a scientific session or a scientific lecture and display of brand names and/or individual company logos in scientific lectures or in the scientific programme. The EACCME will accept a single page acknowledgement, in the scientific programme, where all sponsors are acknowledged for their support of LEE and programmes that include the names of satellite symposia only if they are clearly identified as industry sponsored. All advertising components (including the listing of exhibitors) must be clearly separated and distinguished from the scientific/educational components of the programme and identified as such.

Criterion 23. The provider must confirm that it will comply with the applicable national rules, regulations and industry standards regarding exhibition areas where companies are permitted to present their products.

#### **Review by learners**

Criterion 24. The provider must provide a reliable and effective means for the learners to provide feedback on the LEE, including the extent to which the educational objectives of the LEE were met. The provider must commit to make available to the EACCME a report on this feedback and on the provider's responses to this.

> These reports, and the responses to them by the provider, will inform the EACCME of the provider's track record for future applications for accreditation.

#### Conclusion

During the first semester of the new criteria implementation, as reported by the UEMS Secretary General, Edwin Borman, 807 applications of LEEs have been received, 473 of which were accredited, 7 rejected, 32 suspended (late application) and 295 are still in review or in amendment. The quality of the accredited programmes is slightly improving; an increased number of providers are now working to meet these criteria

and positive feedback has been received from the pharmaceutical industry and the European Commission.

Conflicts of interest None.

#### Appendix

- 1. The provider must structure the LEE to fulfil defined educational needs.
- 2. The provider must define the "target audience" for whom the LEE is most likely to be suitable.
- 3. The provider must identify and communicate the expected educational outcome(s) of the LEE.
- 4. The provider must provide the title of the LEE, its venue, date(s) and a clear description of the nature of the event.
- 5. The LEE must be presented in a manner suitable for an international audience.
- 6. The LEE must include methods to promote active learning.
- 7. The provider must provide detailed information on the duration of the LEE.
- 8. The provider must indicate the mechanism(s) by which it will be verified that the learner has engaged with the LEE in order to fulfil the educational objective(s).
- 9. The LEE must be conducted in compliance with all relevant ethical, medico-legal, regulatory, industry-based and legal requirements.
- 10. The provider must provide a short description of the provider organization(s).
- 11. The provider must state the names and job titles of the individual(s) responsible for preparing the LEE.
- 12. The provider must provide the name, title and contact details of a medical practitioner who will take responsibility for the application for accreditation of the LEE. This doctor must be registered with a Medical Regulatory Authority, and his/her registration details must be provided.
- 13. The provider must provide the name(s), job title(s) and contact details of the head and all other members of the Scientific and/or Organizing Committee.
- 14. The provider must ensure that all members of the Scientific and/or Organizing Committee provide written declarations of potential or actual COI.
- 15. The provider must confirm that any actual COI have been resolved.
- 16. The Scientific and/or Organizing Committee must ensure that the LEE will provide a programme that presents a scientifically balanced perspective of the subjects included.
- 17. The provider must ensure that all members of the faculty provide written declarations of potential or actual COI.

- 18. The provider must provide the latest version of the programme of the LEE at the time of application.
- 19. The source(s) of all funding for the LEE must be declared and be made available to learners in a readily accessible manner.
- 20. The Scientific and/or Organizing Committee must confirm that it has determined the content of all aspects of the LEE to be free of any attempt by sponsors to influence the Committee's decisions.
- 21. The provider must submit information regarding the expected total number of learners attending the LEE and the schedule of fees for these learners.
- 22. All educational material must be free of any form of advertising and any form of bias.
- 23. The provider must confirm that it will comply with the applicable national rules, regulations and industry standards regarding exhibition areas where companies are permitted to present their products.
- 24. The provider must provide a reliable and effective means for the learners to provide feedback on the LEE, including the extent to which the educational objectives of the LEE were met. The provider must commit to make available to the EACCME<sup>®</sup> a report on this feedback and on the provider's responses to this.
- 25. In order to have an application for accreditation considered by the EACCME<sup>®</sup>, the provider must:
  - (a) Submit a fully completed application, in English, using the specific EACCME<sup>®</sup> application form
  - (b) Provide this completed application form, with all relevant attachments and full payment for the

application, no less than 14 weeks from the planned start date of the LEE

- (c) Ensure that suitable responses have been provided for each of the essential criteria
- (d) Provide confirmation by the medical practitioner who is taking responsibility for the application
- 26. The applicant must not attempt to influence the decision of the EACCME<sup>®</sup>.

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