EACCME® CRITERIA FOR THE ACCREDITATION OF E-LEARNING MATERIALS (ELM)

UEMS 2023.08



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I. Presentation of the UEMS-EACCME®

The **Union Européenne des Médecins Spécialistes (UEMS)** was founded in 1958 with the aim of representing the interests of specialist doctors at an international level. The UEMS is a non-governmental voluntary organisation whose members are the national medical organisations that represent medical specialists in the European Union and in associated countries.

In January 2000 the UEMS established the **European Accreditation Council for Continuing Medical Education (EACCME®)** with the aim of encouraging the highest standards in the development, delivery and harmonisation of continuing medical education (CME) and, later, of continuing professional development (CPD).

The purpose of the EACCME® was to provide accreditation of international CME in Europe and to facilitate the recognition of credits between the various countries in Europe. In order to reach this goal, the UEMS-EACCME® signed agreements of cooperation with countries in Europe, and also outside of Europe.

In order to support this recognition process, the UEMS-EACCME® introduced a common "CME currency": the **European CME Credit (ECMEC®)**.

In 2009, the EACCME® implemented criteria for the accreditation of e-learning materials.

In 2016, the EACCME® implemented EACCME® 2.0 including new forms of CME/CPD activities.

Note:

Both the EACCME® and the ECMEC® are registered trademarks of the UEMS and cannot be used without the prior authorization of the UEMS.

II. <u>Agreements with European and non-European accreditation</u> bodies

Europe

The EACCME® has signed agreements with the majority of European countries. For a full and updated list of signed agreements in Europe please visit https://eaccme.uems.eu.

The countries with which the EACCME® has signed agreements will recognise EACCME® credits.

All the other countries may recognise EACCME® credits on a voluntary basis. For these countries you will also need to apply to the central or relevant regional accreditation authority.

USA

The UEMS-EACCME® has had an agreement of mutual recognition of credits with the **American Medical Association (AMA)** for live educational events and for e-learning materials since the year 2000.

The issue of territoriality is very important; both organizations are fully responsible for the activities taking place or organized within their remit. The UEMS-EACCME® is the central body for accrediting events in Europe and the AMA is the central body for recognition of CME credits in the USA.

E-learning activities need to be certified for credit by the process in place where the CME provider is based, i.e. AMA PRA Category 1 Credit™ for U.S. CME providers and ECMEC® credit for organizations in countries that are represented by the UEMS.

Canada

The UEMS-EACCME® has an agreement of mutual recognition of credits with the **Royal College of Physicians and Surgeons of Canada (RCPSC)** for live educational events since the year 2011.

The issue of territoriality is very important; both organizations are fully responsible for the activities taking place or organized within their remit. The UEMS-EACCME® is the central body for accrediting events in Europe and the RCPSC is the central body for accrediting events in Canada through its accredited providers.

III. Definitions

E-learning material (ELM):

E-learning is learning utilizing electronic technologies to access an enduring educational content at a time convenient to a learner. In most cases, it refers to a course or programme delivered completely online. It should utilise modern available IT options.

The accreditation of ELM is only for the educational content of the ELM and not the e-media used to deliver it.

Individual module:

An individual module is the basic unit of an ELM. It lasts between 30 minutes and 3 hours. To be considered an individual module, the content of the ELM has to be under the scope of the same medical specialty. Individual modules are self-paced learning experiences that may include a combination of written content, audio, video, or other visual elements.

The content and format of an accredited module cannot change once accredited or for the period for which it is accredited. If the provider wishes to change the content or format, a new application needs to be submitted.

Individual modules lasting more than 3 hours must be split into smaller components with a maximum duration of 3 hours in order to be accredited. Individual modules lasting less than 30 minutes must be combined to create a new module with a minimum duration of 30 minutes to be accredited.

ELM Course:

A course is a set of related individual modules aimed at providing education on a specific field of knowledge. In order to claim CME credits from a course, it is mandatory for learners to complete the entirety of the course.

Educational e-platform:

A set of interactive and complementary online educational materials that provide learners with on-demand content to support the delivery and management of teaching and learning activities. An educational eplatform needs to have at least 10 individual modules that meet the EACCME® criteria for accreditation of ELM.

An e-platform is different from an ELM Course in which it is not mandatory for learners to go through all of the elements of the platform to claim credits. The learners may take any number of E-platform modules and in any order. The credits are awarded for each individual module completed.

Educational app:

The word "app" is the abbreviation for application. An app is an element of software that has to be downloaded and run on a computer, on a phone or any other electronic device. An educational app is a means of delivering educational material that meets the EACCME® criteria for accreditation of ELM.

Quality control of educational e-platforms and apps:

Due to the dynamic character of educational e-platforms and apps, providers are entitled to change/upgrade the educational content after the initial accreditation without submitting a new application. Providers need to make sure that the changed/upgraded content will stay within the scope and remit of the initial accreditation. Also, backend technologies and cosmetic changes may undergo updates as long as requirements for obtaining EACCME® accreditation are met.

For this reason, there is a mandatory quality control of educational e-platforms and apps by EACCME® reviewers to ensure that their content remains within the scope and remit of the initial accreditation. This quality control procedure takes place one year after accreditation has been granted. Providers need to inform the EACCME® of any changes/upgrades made to the content of the educational e-platform or app.

Failure to comply with the quality control procedure may lead to removal of the accreditation.

Live educational event (LEE):

A live physical / virtual / hybrid meeting or webinar, the primary purpose of which is the provision of educational material of a medical nature to medical specialists, with the aim that they will achieve educational benefit. It requires presence of a participant on the event's site or a tele-presence when an event takes place via live-streaming. Each form of presence/participation requires a robust mechanism allowing confirmation of participation. It is expected that, as a result of this educational process, patients also will benefit from the lessons, applied in practice, that their specialist doctors have learned.

A live educational event can therefore be:

- held at a physical venue/on site;
- streamed live (virtual events or live webinars);
- hybrid (on site and via live-streaming).

All these formats must allow participants to submit questions and answers

For further information, see UEMS 2023.07 "EACCME® Criteria for the Accreditation of Live Educational Events (LEE)".

Blended learning:

An educational programme that combines obligatory participation in a LEE and completion of an associated e-learning component.

Continuing Professional Development (CPD) and Continuing Medical Education (CME):

Continuing Professional Development for physicians designates all the professional development activities that occur after specialist qualification has been obtained. It includes many forms of education and training that allow individual doctors to maintain and improve standards of medical practice through the development of knowledge, skill, attitude and behaviour.

CME provider:

Individual / organisation responsible for developing the scientific content of a CME activity.

Professional Congress Organiser (PCO):

Individual / organisation who has been contracted out by a CME provider to organise the logistics of the event.

Bias:

Bias is a term used to describe 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.

Faculty:

Faculty includes: invited speakers, session chairs, workshop trainers, round-table moderators, discussion facilitators, developers and presenters of educational content and format of e-learning material etc. This does not include abstract/open paper/slide/poster presenters, speakers in non-CME sessions, speakers in industry symposia and other non-accredited sessions.

Organising/Scientific Committee:

The people responsible for or who have contributed to the design of the ELM, selection and preparation of the format and the content of the programme, selection of the faculty etc. This does not include the non-medical staff responsible for the logistical part of the organisation of the ELM, nor does it include the ELM faculty who have not been involved in the preparation of the ELM.

Medical Regulatory Authority:

By Medical Regulatory Authority we mean the authority in a country that delivers to doctors the license to practice medicine in that country.

Unrestricted educational sponsorship:

An unrestricted educational sponsorship is financial sponsorship offered to a provider by the sponsor through a transparent contract. It is the CME provider's responsibility to use the funding to the ends it sees fit without any constraints from the sponsor. All funding must be provided free of any attempt of the sponsor to influence the programme, individual sessions, subjects for discussion, content or choice of faculty members.

Principal intended recipients:

Specific group or groups of specialist doctors identified as the intended recipients of a CME/CPD activity.

Sponsor:

An individual, group, corporation or organization (for-profit and not for-profit) who provides financial (unrestricted educational sponsorship, exhibition booth, industry-sponsored satellite symposium among others) or in-kind support (loan of equipment) in support of educational activities. For further details on the type of sponsorship, see Chapter VII, criterion 20.

Micro-learning:

A CME activity (LEE or ELM) lasting between 30 minutes and an hour.

Conflict of Interest (COI):

A set of conditions in which judgment or decisions concerning a primary interest (for example a patients' welfare, the validity of research and/or quality of medical education) is unduly influenced by a secondary interest (personal or organizational benefit including financial gain, academic or career advancement, or other benefits to family, friends, or colleagues).

Perceived conflict of interest:

A perceived conflict of interest occurs when an individual or institution may reasonably be understood by a third party as having two competing interests, one of which is likely to interfere with or undermine a researcher's/institution's ability to fulfil its responsibilities as a researcher or research institution.

Actual conflict of interest:

A real conflict of interest occurs when an individual or institution has two competing interests, one of which is likely to interfere with or undermine a researcher's/institution's ability to fulfil its responsibilities as a researcher or research institution.

IV. Who is eligible to apply for CME accreditation?

The EACCME® considers for accreditation events submitted by a physician organisation such as:

- an individual medical specialist;
- a university or hospital department;
- a scientific medical society;
- a national medical association;
- applications by other types of providers will be considered on a case by case basis.

As long as the application is supported by an appropriate medical specialist in activity who will take responsibility for the application. This person must be registered with his/her National Regulatory Authority.

Other types of providers must co-develop an event: co-development is when two or more organizations, at least one of which must be a physician organisation, work together to develop a CME/CPD activity to be accredited.

Examples of organisations that must co-develop a CME/CPD activity with a physician organisation:

- a medical communication agency;
- a professional congress organiser (PCO).

The EACCME® will **NOT** consider for accreditation events where the content, format or faculty is influenced by industry, submitted by industry or where the industry is the CME Provider.

Types of organizations that are not considered for accreditation:

- Pharmaceutical companies or their advisory groups;
- Medical/surgical supply companies;
- Other industry.

V. <u>Types of E-Learning materials</u>

	The module - must last minimum 30 minutes	One application per module
	- maximum 3 hours	Accreditation valid for two
	The content and format of an accredited module cannot change once	years
	accredited or for the period for which it is accredited. If the provider	Jeans
	wishes to change the content or format, a new application needs to	0.5 ECMEC® per 30 min (30
	be submitted.	min of education)
Series of	Each module	One application per
individual modules	must last minimum 30 minutesmaximum 3 hours	<u>module</u>
inodules	- maximum 5 nours	Accreditation valid for two
	The content and format of an accredited module cannot change once	years
	accredited or for the period for which it is accredited. If the provider	
	wishes to change the content or format, a new application needs to	0.5 ECMEC® per 30 min (30
	be submitted.	min of education)
E-platform	 must have a minimum of 10 modules available from the start 	One application for the whole platform
	the start	whole platform
	- modules must last	Accreditation valid for two
	minimum 30 minutes	years
	maximum 3 hours	
		Quality control review
	modules must be complementary	after 1 year (250 €)
	be part of the same educational scope	0.5 ECMEC® per 30 min (30
	be part of the same caucational scope	min of education)
	- the educational content of an accredited ELM can be	
	· · · · · · · · · · · · · · · · · · ·	
Арр		One application per
**	submission.	individual app
	• •	whole e-platform app
		Accreditation valid for two
	available from the start)	years
	and format of an accredited module cannot change once accredited or for the period for which it is accredited. If	platform app (250 €)
		plation in app (250 €)
	the provider wishes to change the content or format, a new application needs to be submitted.	0.5 ECMEC® per 30 min (30
	the provider wishes to change the content or format, a new application needs to be submitted.	
	the provider wishes to change the content or format, a new application needs to be submitted.e-platform app: the educational content of an accredited	0.5 ECMEC® per 30 min (30
	 the provider wishes to change the content or format, a new application needs to be submitted. e-platform app: the educational content of an accredited ELM can be changed/upgraded after the initial 	0.5 ECMEC® per 30 min (30
	the provider wishes to change the content or format, a new application needs to be submitted.e-platform app: the educational content of an accredited	0.5 ECMEC® per 30 min (30
Арр	changed/upgraded after the initial accreditation without submitting a new application, but providers have to make sure that the content will stay within the scope and remit of the initial accreditation. - the app must be already available at the time of the submission. - possibility to apply for	One application poindividual app One application for the whole e-platform app Accreditation valid for two years Quality control revie after 1 year for the

VI. EACCME® general principles

The UEMS-EACCME® provides accreditation for medical education of the highest quality, thus supporting the need for the best and up-to-date patient care in Europe. In order to guarantee this high-level education, the EACCME® has set the following principles:

Commercial influence and bias

- The education provided must be free of any commercial influence or bias;
- The education provided must be free of any form of advertising;
- Educational sponsorship must be provided through an unrestricted educational sponsorship;
- As a general principle, all scientific content of an activity must be clearly separated from commercial component.

ELM provided entirely by a pharmaceutical or medical equipment industry will not be considered for accreditation.

Educational needs and learning objectives

- A needs assessment needs to be performed prior to design of the ELM;
- Learning needs and educational outcomes need to be defined.

Conflict of interest and resolution of conflict of interest

- Conflicts of interest will need to be disclosed by the Organising/Scientific Committee and the faculty;
- Any actual conflict of interest will need to be resolved prior to the ELM being accessible to learners.

Learners' engagement and feedback

- Learners' attendance will need to be monitored;
- Learners are expected to provide feedback on the ELM;
- The provider must submit an event report based on the learners' feedback.

Quality control

The UEMS-EACCME® will perform a mandatory periodical quality control of the educational e-platforms and apps by EACCME® reviewers to ensure that their content remains within the scope and remit of the initial accreditation. This quality control procedure takes place one year after accreditation has been granted. Failure to comply with the quality control procedure may lead to removal of the accreditation.

Other healthcare professionals

The EACCME® will consider supporting accreditation for other healthcare professionals (other than medical specialists) in collaboration with their relevant professional bodies.

VII. Requirements for the accreditation of an e-learning material (ELM)

All the criteria below are ESSENTIAL criteria.

Educational Objectives and Fulfilment of Learning Needs:

1. The provider must state, in a readily-accessible manner, that the ELM has been prepared in order to fulfil stated educational needs, and indicate how this will be achieved.

This confirmation must demonstrate that a "needs assessment" process has been performed, that these educational needs have been defined, and will be fulfilled.

A needs assessment must be carried out prior to the development of a CME/CPD activity. The process of a needs assessment is designed to identify the gap between a current situation and a desired situation.

There are different types of needs assessment:

- Evaluation results from a previous activity
- Surveys of potential participants
- Publication of a new clinical guideline or new research
- Legislative/regulatory/organizational changes affecting patient care...

The discrepancy between the current situation and desired situation must be measured to appropriately identify the need. The need can be a desire to improve current performance or to correct a deficiency.

A short description of this needs assessment process and derived educational needs must be provided.

2. The provider must state, in a readily-accessible manner, the expected educational outcome(s) of the ELM.

These must be explained in terms of the knowledge, skills, attitudinal or behavioural, or ethical lessons that can be learned, and whether these are clinical or non-clinical.

When defining an ELM's learning outcomes, action verbs must be used to express what participants will be able to do. eg. analyse, create, compare, evaluate.

Example: "After attending the ELM, participants will be able to + action verb + something."

A list of educational outcomes must be provided.

3. The provider must clearly define, and state in a readily-accessible manner, the "principal intended recipients" for whom the ELM is most likely to be suitable.

The principal intended recipients must fall within the remit of the UEMS-EACCME® (fully qualified medical specialist doctors). The principal intended recipients must therefore be explained in terms of medical specialty and seniority of the learner.

The UEMS (recognized) medical specialities can be found here https://www.uems.eu/about-us/medical-specialities.

In addition to fully qualified medical specialist doctors, an EACCME $^{\circledR}$ accredited activity is open to all interested medical and other healthcare professionals.

EACCME® certificates can therefore be distributed to any other healthcare professional attending the accredited ELM (i.e. nurses, pharmacists, clinical scientists ...) who wishes to benefit from EACCME®

credits. It is expected that the healthcare professional's association will recognise the EACCME® credits on a voluntary basis.

Description of Material

4. The provider must clearly explain, and state in a readily-accessible manner, in a brief summary, the content of the ELM.

The content of an ELM needs to be interactive and the use of voice-recording is encouraged. As such the content of an ELM can be a recording, a video, a practical case study, a clinical case or any other format or combination of formats provided that interactivity tools are implemented.

The EACCME does not accredit e-reading activities as e-learning material.

5. The provider must respect and confirm the privacy and confidentiality of the learner, and confirm that any information provided by the learner will only be utilised for the specific purposes of completing the ELM.

The only permitted exception to this will be with the valid consent of the learner

6. The provider must clearly state, in a readily-accessible manner, the likely duration that the learner will need to engage with the ELM in order to fulfil the educational objective(s).

This must be a minimum of 30 minutes (30 mins of actual educational activity excluding introductions etc.) and a maximum of three hours.

7. The Provider must clearly state, in a readily-accessible manner, compliance of the ELM with all relevant ethical, medico-legal and legal requirements.

Where applicable, these must include: consent by patients and other participants to inclusion in the ELM, confirmation of confidentiality for patients and other participants, compliance with research ethics requirements, compliance with data-protection legislation, and copyright arrangements for the ELM. It is essential to ensure that patients are not, and cannot be identified in any of the materials presented.

- 8. Both in the application and in the e-learning material, the provider must clearly state, in a readily-accessible manner, the date of preparation of the ELM, any substantial revisions to its content, and expiry date.
- 9. Both in the application and in the e-learning material, the provider must clearly state, in a readily-accessible manner, the required format for use of the ELM, (e.g. Windows/MacOS), and must provide contact details for the provision of assistance.

Nature of Material

10. All content within the ELM must be evidence-based, with notes on the level of evidence (where applicable), and suitable references.

This must be to the standard required for a publication in a scientific journal

11. The ELM must encourage the learner to employ methods of active, adult learning to achieve the educational objective(s).

These may include: problem-orientated learning, task-based learning, case-based learning, reflective learning, and performance improvement CME. The EACCME® also strongly recommends feedback be provided on the learner's engagement with the material, such as an explanation of why a response to the self-assessment component was incorrect.

12. The ELM must include a means of confirming learner engagement and achievement of the educational objective(s)

This must be of quality, duration and content appropriate to the ELM and the educational objective(s), and it must be integral to the ELM. It may be based on multiple-choice questionnaire or other self-assessment methodologies, but must have clearly stated assessment criteria (e.g. pass mark). This should be set by the provider of the educational content (as distinct from the provider of the product).

This self-assessment component must comprise a minimum of 10 minutes per educational hour.

13. All content must be free from any form of advertising and any commercial or other forms of bias (see "definitions").

The EACCME® will reject any application that, in its opinion, includes advertising of any product or company directly related to any educational material.

Where there is a valid evidence base for a specific therapy or agent, this may be stated, but must be referenced in a manner that is appropriate for a scientific journal. The EACCME® will reject any application that, in its opinion, includes biased information.

Specific examples that will lead to automatic rejection of an application include:

- The use of a sponsor's name, brand name or product name in the title of the ELM;
- The display of brand names and/or individual company logos in any component of the ELM;
- The presence of a speaker from industry in any component of the ELM.

The material can therefore not be hosted on the sponsor's website, nor contain the sponsor's logo on any page of the material. The EACCME® will allow one single page acknowledgement at the end where the sponsor is recognised for their support.

Regarding the communication about the ELM from external parties, the EACCME® accepts that when a commercial company supports an ELM, they can announce the ELM via their website or social media but not via mailing.

Should medical devices/software/equipment appear in the ELM, it is mandatory to use the following statement at the beginning and at the end of the ELM:

"Commercial names of medical devices/software/equipment may appear in this content because they are linked to specific medical procedures, which are the focus of this training material. Other products in the market can be used to perform the aforementioned medical procedures. The educational provider does not endorse any particular product."

14. All content should be suitable for an international audience.

This refers to the use of international terminology for procedures and therapeutic agents.

Details of the Provider

15. The provider must provide, in a readily-accessible manner, a short description of the provider organisation.

While the use of the provider's logo(s) will be permitted (and not the use of the sponsor's logo), there must not be any attempt at using this description for advertisement.

16. The ELM must state, in a readily-accessible manner, the names and qualifications of the individual(s) involved in preparing the content.

The EACCME® requires that all individuals who have contributed to the preparation and presentation of the material(s) are identified.

As a general rule, it is not permissible for a member employed by, in contractual relationship with or otherwise representing the industry to be involved in the ELM. In specific situations (ground-breaking scientific investigation, exceptional scientific merit, etc.), dependent on the approval of the EACCME®, a member employed by, in contractual relationship with or otherwise representing the industry may be exceptionally allowed to be involved.

The EACCME® encourages programmes using a number of speakers adequate to the size of the educational material. The EACCME® strongly encourages providers to promote diversity and inclusion when choosing the faculty of the educational material in order to adequately represent society. The name and affiliation of these individuals must also be provided in the application in the designated field.

17. The ELM must provide the name and title of a medical practitioner who will take responsibility for its content.

This person must be a specialist doctor and his/her registration number with a Medical Regulatory Authority must be provided as well as the name of that authority.

By Medical Regulatory Authority we mean the authority in a country that delivers to doctors the license to practice medicine in that country.

The medical officer (MO) taking responsibility for the application may be involved in the preparation of the content or may be any specialist doctor willing to take responsibility for the application.

From the EACCME®'s point of view, this person is responsible for the ELM.

18. There must be a full declaration of actual or perceived conflict of interest of the individual(s) involved in preparing the content of the material.

Conflict of interest: A set of conditions in which judgment or decisions concerning a primary interest (for example a patients' welfare, the validity of research and/or quality of medical education) is unduly influenced by a secondary interest (personal or organizational benefit including financial gain, academic or career advancement, or other benefits to family, friends, or colleagues).

A perceived conflict of interest: A perceived conflict of interest occurs when an individual or institution may reasonably be understood by a third party as having two competing interests, one of which is likely to interfere with or undermine a researcher's/institution's ability to fulfil its responsibilities as a researcher or research institution. Whereas **an actual conflict of interest** occurs when an individual or institution has two competing interests, one of which is likely to interfere with or undermine a researcher's/institution's ability to fulfil its responsibilities as a researcher or research institution.

The medical practitioner who will take responsibility for the material and the individual(s) involved in preparing the content of the material must provide a full declaration of actual or perceived conflict of interest for the last three years. The COI forms must be dated and signed by hand or using an authenticated or certificate-based electronic signature. The COI forms must be provided at the time of the application.

The list of perceived or actual conflicts of interest of the individuals involved in preparing the content must be made available online on the ELM page. Reviewers may ask for the COIs of any of the known individual at the time of submission if needed.

The COI template is available on the EACCME® platform for download.

19. Confirm that all actual conflicts of interest have been resolved.

This criterion is applicable to all individuals involved in preparing the content and is the personal responsibility of the medical practitioner in charge of the application.

The provider must ensure that all actual conflicts of interest have been resolved. This can be done in several ways:

- > The feedback form completed by participants must include a question on possible bias on the content of the ELM.
- > The list of perceived or actual conflicts of interest of all the individuals involved in preparing the content must be made available on the ELM page.
- Individual involved in preparing the content is excluded from the preparation of the scientific content.

20. The source of all funding provided for the preparation of the material must be declared, and stated in a readily-accessible manner.

The source of all funding must be declared.

Sponsorship (from one or more sponsors) of an ELM can only be considered as long as the funding is in the form of an "unrestricted educational sponsorship" and all other EACCME® ELM criteria are met.

The EACCME® reserves the right to ask for the contractual arrangement between the provider and the sponsor. Providers are entitled to redact any financial information.

Quality Assurance by the Provider

21. The provider must provide confirmation that it has had the ELM quality-assured against the EACCME criteria prior to application to the EACCME® for accreditation.

The EACCME® requires the provider to have assessed its material using the criteria set out in this document.

22. The provider must provide a reliable and effective means for the learner to provide feedback on the ELM, and must make available to the EACCME® a report on this feedback and on its responses to this.

Each ELM module must include a feedback form to be completed by learners after completion of the module. Providers must use the EACCME® template of feedback form as a minimum for their feedback forms. Additional feedback questions may be added by the provider if deemed necessary.

In order to maintain accreditation, this summary feedback must be submitted to the EACCME® within 12 months of accreditation having been granted, using the "Event report" template.

23. The provider's evaluation record for previous or on-going modules or programmes with EACCME must be satisfactory or, where not, reasons for unsatisfactory ratings must have been addressed.

All the criteria below are DESIRABLE criteria.

- 24. All content should be easy to use.
- 25. The ELM should provide links to further relevant information

Links to commercial sites are not allowed.

26. The provider should make available for the learner technical support related to the ELM.

VIII. Submission/evaluation/accreditation/appeal processes

If there is a fixed date when the e-learning material will go live and will be available for use to learners, the recommended time for submission of an application is at least 10 weeks from the planned launch of the online material.

The whole evaluation process should take **no more than 7 weeks** from the moment the application has been sent out for review. An application will be sent out for review when the EACCME® office considers the application to be complete and has received payment of the accreditation fee.

Every time there is a delay in the process for which the applicant is responsible (cf. amendment procedure), the clock stops and the delay is not included in the above 7 weeks' schedule.

Submission process

- ✓ The only application form that will be accepted is that made available at https://eaccme.uems.eu;
- ✓ No applications sent on paper or by email will be considered.
- ✓ The EACCME® will not accept late applications;
- ✓ As applications can only be received in English, applicants will be responsible for the translation of all submitted materials.

On application for accreditation by the EACCME®, the applicant will provide:

- ✓ A link to the complete material with three sets of logins for the reviewers to access the material;
- ✓ The final product of the material needs to be available online;
- ✓ A fully completed EACCME® application form, confirmed by the medical practitioner who is taking responsibility for the material (<u>criterion 17</u>);
- ✓ Full payment of the application fee.

In dealing with the application, EACCME® commits to:

- ✓ providing, on its website, an EACCME® application form, based on the criteria (essential and desirable) set out in this paper;
- ✓ ensuring confidentiality regarding the application submitted;
- ✓ confirming for the applicant the following dates:
 - o on which the material was received,
 - o n which the application was complete,
 - o on which the application fee was cleared,
 - \circ the "starting date" on which the EACCME® has begun its evaluation which will be determined by the above two criteria (b & c) having been met,
 - o choosing, from a pool of suitably-trained specialists, two assessors who have expertise appropriate to the material submitted;
- ✓ providing, on the EACCME® website, a progress record that is accessible by the applicant;
- ✓ ensuring that a decision is provided to the applicant within seven weeks of the starting date, except in the case of an appeal being lodged, then the process will take no longer than ten weeks;
- ✓ publishing, on the EACCME® website, the list of accredited ELMs.

Criteria and decision-making for Accreditation

- 1. The Material and the application form will be reviewed by the two designated EACCME® assessors.
- 2. <u>For a positive decision</u> by the EACCME® assessor, in favour of the accreditation, all essential criteria, and at least one desirable criterion must be confirmed and achieved by the submitted material. As a specific point, the assessor also will be required to confirm whether, according to their use of the material, the stated learning objectives have been fulfilled.

3. In order for the EACCME® to accredit the material, both assessors must support the application.

Amendment Procedure

- 1. The EACCME® recognises that some applications may fulfil almost all the criteria needed for accreditation but be lacking in a small number. In accordance with its remit to encourage the improvement of the quality of CME/CPD, the EACCME® will provide feedback and recommendations for amendments to the material submitted by the applicant.
- 2. The EACCME® will permit the applicant one opportunity, at no additional charge, to submit a revised version of the material for accreditation. This amended submission must be provided within three weeks of the EACCME®'s request for amendment or the EACCME® reserves the right to reject the application without further assessment.
- 3. The EACCME® commits to providing a decision within two weeks of receipt of the amended submission. Other than through the mechanism of appeal (see below), this decision by the EACCME® shall be final.

Appeal

- 1. Automatic appeal/automatic reconsideration should the two designated EACCME® assessors differ in their assessment, an automatic appeal will be triggered, and the applicant will be informed that this has occurred. This automatic appeal will be completed within the timescale applicable for any application and will be performed at no further cost to the applicant.
- 2. Appeal by the applicant should both designated EACCME® assessors reject the application, the applicant may appeal. This will require a further two weeks from the date that the appeal, and the clearance of the appeal fee, is confirmed as having been received by the EACCME®. The appeal fee will be € 375.
- 3. The mechanism of the Appeal will be:
 - the Secretary General of the UEMS (or his/her nominee) will review all the information provided on the application form, any supplementary permissible correspondence and may ask for additional information to all parties involved. The Secretary General will discuss the application with the two EACCME® designated evaluation bodies for the initial review, if needed;
 - the appeal decision of the EACCME® will be final.

IX. Fees for individual e-learning modules

The fee for application to the EACCME® for its accreditation of an e-Learning material will be:

- € 550 for 1 module
- € 1,100 for up to 10 modules
- € 1,650 for up to 20 modules
- € 2,200 for up to 30 modules
- € 3,300 for up to 40 modules
- € 5,500 for up to 50 modules
- € 8,250 for up to 100 modules
- € 11,000 for more than 100 modules

The above fees are VAT excluded.

Should an applicant appeal, in accordance with the procedure set out in this document, the EACCME® will charge an additional appeal fee of € 375.

The EACCME® reserves the right, in its sole discretion, to change its fees at any time. An application already submitted will be charged at the rate applicable at the time that it was made.

In some specialties, the UEMS-EACCME® has particular agreements with European Specialty Accreditation Boards (ESABs). Through mutual agreements with each of these, the UEMS-EACCME® will submit all eligible applications in these fields to the relevant ESAB for their specialist review. Accordingly, ESABs are entitled to issue an invoice to providers in order to cover for their specific administrative tasks and provisions for quality assurance in their CME events.

X. Accreditation of educational e-learning platforms

1. The EACCME® will accredit **educational e-learning platforms** and **not** websites. The accreditation is for the educational content of the platform and not the e-media used to access and use it.

2. For an educational e-platform to be accredited

- a. The educational material must be complementary and part of the same educational scope.
- b. The platform has to have different teaching e-learning modules addressing from different angles the same overarching topic of specialist practice.
- c. Please note that a single course even if composed of 10 educational modules or more is not an eplatform and must be submitted as separate individual modules.
- d. The e-platform must meet the criteria that apply to ELM (pages 11-15).
- e. It is up to the provider to ensure that the material submitted for accreditation is compatible with EACCME® criteria for ELM.

3. Submission/ evaluation/ accreditation/ appeal processes

- a. The submission/ evaluation/ accreditation/ appeal processes will be as described for EACCME® ELM (pages 16-17) with two exceptions:
 - Instead of completing the application form for the single ELM, the provider will need to complete it for the whole platform he/she wishes to have accredited.
 - The EACCME® review will not cover each and every single one of the e-learning modules of the platform but it will be a selective review of no less than 10% of the submitted modules.
- b. The list of accredited e-platforms will be published on the EACCME® website.

4. Modifications and quality control

Modifications of e-platforms are allowed according to principles stated in the definition of "Quality control of educational e-platforms and apps".

There is periodical quality control of the educational e-platforms by $EACCME^{\circledR}$ reviewers to ensure that their content remains within the scope and remit of the initial accreditation.

The reviewers will report to the EACCME® for any concerns raised by the quality control appraisal.

5. Fees

- € 1,350 for up to 10 modules
- € 1,900 for up to 20 modules
- € 2,450 for up to 30 modules
- € 3,550 for up to 40 modules
- € 5,750 for up to 50 modules
- € 8,500 for up to 100 modules

- € 11,250 for more than 100 modules

The above fees include a flat fee of €250 for the quality control review of the platform by EACCME®.

The above fees are VAT excluded.

The EACCME® reserves the right, in its sole discretion, to change its fees at any time. An application already submitted will be charged at the rate applicable at the time that it was made.

6. Credits

The credits for the users of the platform will be 0.5 credit for every half hour (30 minutes of actual elearning excluding introductions etc.) of use, provided that the users have completed a module and have passed the relevant assessment.

It is the provider's responsibility to assess the duration of the ELM and to determine the number of credits accordingly following the principle stated above.

The provider will be responsible for ensuring that there is a mechanism in the platform to ensure that a module has been completed, an assessment has been passed and for awarding the relevant number of credits. Compliance of the provider with this process will be checked during the annual review of the platform by the EACCME®.

7. Validity of the accreditation

The accreditation will be valid for 2 years. After two years, if the provider wishes for the platform to be reaccredited, a new application has to be submitted to EACCME®.

XI. Accreditation of e-learning modules for apps

Accreditation of the e-learning modules delivered through apps is possible as long as the apps don't serve for example as "tools" for attending a Congress or just means of communication. As long as the providers can prove that the app contains educational material in the modular form that meets the same criteria as the applications for educational e-platforms, the educational content of the app can be accredited following the same process, pricing and award of credits as for the educational e-platforms.

- €800 for one app
- € 1,350 for up to 10 apps
- € 1,900 for up to 20 apps
- € 2,450 for up to 30 apps
- € 3,550 for up to 40 apps
- € 5,750 for up to 50 apps
- € 8,500 for up to 100 apps
- € 11,250 for more than 100 apps

The above fees include a flat fee of €250 for the quality control review of the app by EACCME®.

The above fees are VAT excluded.

The EACCME® reserves the right, in its sole discretion, to change its fees at any time. An application already submitted will be charged at the rate applicable at the time that it was made.

XII. Outcomes

1. Confirmation of accreditation of the material by the EACCME® will permit the provider to use a statement to this effect (prepared by the EACCME®) on and within the material. This will be confirmed on the EACCME® website, and the number of ECMEC®s (as 0.5 ECMEC® per 30 minutes of education) will be stated. Only after confirmation of accreditation has been received can the provider use the UEMS- EACCME® logo on material related to the e-learning module(s).

The logo may only be used in conjunction with, and in proximity to, the EACCME® accreditation statement and must not be associated with any commercial logo.

The logo cannot be used in notices, advertising, or promotion of activities other than in association with the EACCME® accreditation statement.

- 2. EACCME® accreditation of e-CPD/CME materials will be time-limited for a period of two years from the date of confirmation of accreditation. This date, and the expiry date, will be displayed on the EACCME® website, and the confirmation of accreditation will be removed from the website after this period has elapsed.
- 3. The EACCME® will permit, on request by the provider, the accreditation of translated versions of the originally accredited material as long as this does not involve any alteration of the content.
- 4. Accreditation of the material will not be transferable, and will only be permitted for the defined material, in the particular format, by the specified provider. Any breach of this rule will lead to the withdrawal of accreditation.
- 5. An application shall be limited to a single process of assessment for accreditation. As indicated in this document, this process normally will incorporate the assessment by assessors, one opportunity for improvement if deemed appropriate (amendment procedure), and the potential for one appeal. Beyond these steps, and the timescales set out above, should the EACCME® reject the application, no further opportunity for re-assessment will be offered, other than by a new application.
- 6. Where a website, an electronic communication or a printed material lists EACCME®-accredited ELM along with non-accredited ELM, the provider must assure that learners can easily recognise the accreditation status. Listing an ELM not accredited by the EACCME® in a misleading way, suggesting that EACCME® has also accredited it, will lead to withdrawal of accreditation.

XIII. <u>Major causes for rejection of an application at the level of initial review</u>

The applicant must not attempt to influence the decision of the EACCME®. Specifically, any attempt to contact the reviewers of the application will result in automatic rejection of the application and forfeiture of the fee.

XIV. Allocation of European CME Credits (ECMEC[®]s)

The EACCME® awards ECMEC®s on the following basis:

30 minutes (30 minutes of educational activity) = $0.5 \ ECMEC^{\circledast}$

Each additional half hour will be granted 0.5 ECMEC $^{\circledR}$ with a maximum of 3 ECMEC $^{\circledR}$ per module.

XV. Terms and Conditions

By applying for an accreditation on this website, you are deemed to have read and agreed to the following Terms and Conditions (as defined hereafter):

TERMINOLOGY AND INTERPRETATION

Unless the context otherwise requires, each of the following words and expressions in these Terms and Conditions shall have the following meaning:

"**Terms and Conditions**" refers to the present terms and conditions with all schedules and annexes (if any).

"Applicant", "You" and "Your" refer to the natural person or legal entity accessing this website and applying for the UEMS-EACCME® accreditation system of e-learning materials pursuant to the online process provided on the website https://eaccme.uems.eu.

"The UEMS-EACCME® ", "Ourselves", "We" and "Us" refer to the Belgian international non-for-profit organization Union Européenne des Médecins Spécialistes AISBL, having its registered seat at B-1040 Brussels (Belgium), Rue de l'Industrie, 24 and registered under the legal entity register (RPR Brussels) of the Crossroads Bank for Enterprises under no. 0469.067.848.

"Party", "Parties", or "Us", refer to both the Applicant and Ourselves, or either the Applicant or Ourselves. Unless the context otherwise requires, (i) words importing the singular shall include the plural and vice versa, (ii) all references to a provision of law include a reference to that provision as amended or reenacted, (iii) all references to a "party" include references to its permitted assigns and transferees and its successors in title, and (iv) headings contained herein are for ease of reference only.

SCOPE

These Terms and Conditions shall apply to the accreditation application made by the Applicant through the UEMS-EACCME® website (https://eaccme.uems.eu) and shall govern any service or any product supplied by the UEMS-EACCME® to the Applicant in this framework, unless specifically agreed otherwise in writing by the Parties.

By making an application, the Applicant, to the fullest extent permitted by law, waives irrevocably and unconditionally the application of its own terms and conditions to the UEMS-EACCME® accreditation application launched by it.

INTELLECTUAL PROPERTY RIGHTS

Copyrights and other relevant intellectual property rights exist on all text relating to the UEMS-EACCME®'s services and the full content of this website. These rights shall always remain the exclusive and entire property of the UEMS-EACCME®.

The UEMS-EACCME®'s logo, brand names and specific services featured on this website are registered trademarks of the UEMS-EACCME® in the European Union.

Only after confirmation of accreditation has been made can the Applicant use the UEMS and EACCME $^{\circledR}$ logos on material related to the e-learning materials. Any unauthorized use of these logos will result in action being taken by the UEMS, including, but not limited thereto, legal proceedings.

CONFIDENTIALITY

The Applicant commits not to inform or disclose to third parties any confidential information regarding the UEMS-EACCME®, its contractors, employees, suppliers, representatives, advisors, agents and/or any related company, except in case of a prior express consent in writing by the UEMS-EACCME®. This

obligation shall apply throughout the duration of the contract between the UEMS-EACCME® and the Applicant as well as for a period of five years following the end of the contract.

Confidential information is all information and documents that are exchanged between the UEMS-EACCME® and the Applicant, either oral or spoken, regardless of their nature, and whether or not these are marked as confidential.

PRICES

The fee for a UEMS-EACCME® accreditation application relating to an e-learning material is determined in accordance with the principles set forth in the "Accreditation of E-Learning Materials by the EACCME®" document which is available through this following weblink: https://eaccme.uems.eu.

This document is an integral part of the present Terms and Conditions. The Applicant acknowledges that it has read such documents and undertakes to comply with their applicable terms.

The fee for a UEMS-EACCME® accreditation application relating to an e-learning material is determined in accordance with the number of modules. The Applicant shall submit in good faith the number of modules for the accredited e-learning material. When the Applicant submits a number of modules below the number of actual modules, the UEMS-EACCME® will send an additional invoice based on the actual number of modules.

Any tax of any kind on the fee payable to us shall be borne by the Applicant in accordance with any applicable regulation.

The Applicant shall provide correct billing information, and in case of a VAT exemption, the certifying documents proving such exemption.

The UEMS-EACCME® reserves the right, in its sole discretion, to change its fees at any time. A UEMS-EACCME® accreditation application submitted before a modification of the fee will be charged at the rate applicable at the time that it was made.

The Applicant acknowledges and agrees that the review by Us of an UEMS-EACCME® accreditation application shall only start if the fee has been entirely paid.

PAYMENT

Bank transfers and online payments are acceptable methods of payment. In the case of a bank transfer our terms are payment in full and free of bank charges within seven days of the date of receipt of the invoice. In the case of an online payment the service fee will be borne by the applicant. Provision of service by the UEMS-EACCME® will only be performed upon receipt of the full payment upon submission.

Any delay in payment shall give rise to interests on the account of late payment, at the statutory rate in accordance with Belgian law. We reserve the right to seek recovery of any monies remaining unpaid sixty days from the date of invoice via debt collection agencies and/or through court. In such circumstances, you shall be liable for any and all additional administrative and/or court costs.

If the Applicant fails to pay an invoice at its due date, the UEMS-EACCME® reserves the right to suspend the processing of any pending or future application until full payment.

LIABILITY

To the fullest extent permitted by law, except in the case of intentional negligence or misconduct on its part, the UEMS-EACCME® excludes all liability for damages arising out of or in connection with your application and/or the use of this website. This includes, without limitation, direct loss, loss of business or profits (whether or not the loss of such profits was foreseeable, arose in the normal course of things or you have advised the UEMS-EACCME® of the possibility of such potential loss), damage caused to your computer,

computer software, systems and programs and the data thereon or any other direct or indirect, consequential and incidental damages.

To the fullest extent permitted by law, the Parties agree that the total liability of the UEMS-EACCME® for damages that are the consequence of its failure to fulfil the contract shall, in any case, be limited to DATA. The Applicant shall indemnify and hold harmless the UEMS-EACCME®, its employees and its contractors and agents from and against any and all liability to a third party, if exceeding or different from its liability to the Applicant.

TERMINATION OF AGREEMENTS AND REFUNDS POLICY

The Applicant has the right to terminate any service agreement for any reason, at any time, including the ending of services that are already underway in accordance with the rules contained in this section of the Terms and Conditions. No refund will be provided.

In case of serious breach of these Terms and Conditions which is not remedied within 5 days of notice by the UEMS-EACCME® by the Applicant, the UEMS-EACCME® shall have the right to terminate a service agreement without compensation. This termination shall be notified in writing to the Applicant. No refund shall be offered, and the UEMS-EACCME® reserves the right to claim an additional compensation from the Applicant by reason of any loss caused by his/her misconduct.

CANCELLATION POLICY

The UEMS-EACCME® will permit an application to be withdrawn within one week of submission for any reasonable reason provided by the Applicant and will return the application fee if it was already paid. The Applicant will be charged with the processing fee and any bank charges that are incurred.

After one week, it will not be possible to withdraw the application or receive reimbursement for cancellation except in exceptional circumstances to be duly justified by the Applicant and upon written acceptance of the UEMS-EACCME®. However, in accordance with the amendment procedure it will be permissible to make necessary and appropriate changes to the information submitted.

REJECTION POLICY

In the case of rejection of an application, the UEMS-EACCME® will not refund the fee paid at the time of application.

POSTPONEMENT POLICY

Before an application has been sent to review, whether it has already been paid or not, it is possible to postpone it upon written notice to the UEMS-EACCME® without any additional charge or fee.

Once the application has been sent to review, the UEMS-EACCME® will not accept any change except for one postponement. Any other change will be evaluated on a case-by-case basis and may require a new submission.

INCOMPLETE APPLICATION POLICY

If the Applicant does not complete his/her application within the deadlines set by the UEMS-EACCME®, the application will be automatically rejected without any reimbursement.

PERSONAL DATA PROCESSING

The Applicant shall obtain the consent of its members to the processing by the UEMS-EACCME® of their personal data, in accordance with the UEMS-EACCME® Privacy Policy and any applicable privacy regulation. The UEMS-EACCME® reserves the right to suspend the processing of any application until all necessary data has been provided. The UEMS-EACCME® excludes all liability for any damage arising from the delay in the processing of the application due to non-compliance with this provision.

FORCE MAJEURE

Neither party shall be liable to the other for any failure to perform any obligation under any agreement which is due to an event beyond the control of such party including but not limited to any terrorism, war, political insurgence, insurrection, riot, civil unrest, act of civil or military authority, uprising, earthquake, flood or any other natural or man-made eventuality outside of his/her control, which causes the failure to perform any obligation or the termination of an agreement or contract entered into, nor which could have been reasonably foreseen.

Any Party affected by such event shall forthwith inform the other Party of the same and shall use all reasonable endeavours to comply with the terms and conditions of any agreement contained herein. The obligations of the affected Party shall be reduced and deadlines shall be prolonged for the duration of the force majeure. Both Parties shall use all reasonable endeavours to limit the consequences of the force majeure on the contract or the agreement as much as possible.

WAIVER

Failure of either Party to insist upon strict performance of any provision of this or any agreement contained in these Terms and Conditions or the failure of either Party to exercise any right or remedy to which it is entitled hereunder shall not constitute a waiver thereof and shall not cause a diminution of the obligations under this or any agreement. No waiver of any of the provisions of these Terms and Conditions or any agreement shall be effective unless it is expressly stated to be such and signed by both Parties.

SEVERABILITY

If any of the present provisions are deemed invalid or unenforceable for any reason (including, but not limited to the exclusions and limitations set out above), then the invalid or unenforceable provision will be severed from these Terms and Conditions and the remaining provisions will continue to apply. The Applicant and the UEMS-EACCME® shall negotiate in good faith in order to replace the invalid or unenforceable provision by a valid and enforceable one, which should be as close to the purpose of the original one as possible.

Failure of the UEMS-EACCME® to enforce any of the provisions set out in these Terms and Conditions and any agreement, or failure to exercise any option to terminate, shall not affect the validity of these Terms and Conditions.

COMMUNICATION

We have several different e-mail addresses for different queries. These, and other contact information, can be found on our Contact Us link on our website or via UEMS-EACCME® literature or via the UEMS-EACCME® 's stated telephone number.

The UEMS-EACCME® is registered in Belgium under the registration number: 0469.067.848

The registered office is located at Rue de l'Industrie, 24, BE-1040 Brussels.

AMENDMENTS

These Terms and Conditions shall not be amended, modified, varied or supplemented except in writing and signed by duly authorized representatives of the UEMS-EACCME®.

The UEMS-EACCME® reserves the right to change these Terms and Conditions from time to time as it sees fit it being specified that an UEMS-EACCME® accreditation application submitted before a modification of the present Terms and Conditions shall remain governed by the Terms and Conditions applicable at the time that it was made.

CHOICE OF LAW AND JURISDICTION

The laws of Belgium govern exclusively these terms and conditions and all relationships between the UEMS-EACCME $^{\circledR}$ and the Applicant.

Any disputes arising from any agreement subject to these Terms and Conditions are under the exclusive jurisdiction of the courts and tribunals of Brussels.

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