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

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I. <u>Presentation of the UEMS-EACCME®</u>

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</u> <u>accreditation bodies</u>

<u>Europe</u>

The EACCME[®] has signed agreements with the majority of European countries. For a full and updated list of signed agreements in Europe please visit <u>www.eaccme.eu</u>

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.

<u>USA</u>

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 agreement was renewed in 2014 for another 4 years.

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.

<u>Canada</u>

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 emedia used to deliver it.

Live educational event (LEE):

A meeting/event, 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. 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.

By extension, live webinars are considered LEEs. A webinar is a live online educational presentation during which participation by viewers can be confirmed and they can submit questions and answers.

The recording of a live educational event made available online after the event has taken place is not considered as a LEE. It is therefore not permissible to transfer the credits granted to a LEE to a viewer of an online recording of the LEE.

The recording however may be considered as an e-learning material if it complies with the criteria for the accreditation of e-learning materials.

Blended learning:

An educational programme that combines obligatory participation in a LEE and completion of an associated e-learning component. To apply for the accreditation of a blended learning module, you will need to apply for the live educational component and also for the elearning component of the module separately.

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.

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 <u>not</u> 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 <u>not</u> include the non-medical staff responsible for the logistical part of the organisation of the ELM, nor does it include the event faculty who have not been involved in the preparation of the ELM.

Unrestricted educational grant:

An unrestricted educational grant, is financial sponsorship offered to a provider by the sponsor through a transparent contract. 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.

E-learning module:

A complete unit of e-learning material that meets on its own right the EACCME[®] criteria for accreditation of an ELM. 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.

Educational e-platform:

An integrated set of interactive online services that provide a community of learners and facilitators with information, tools and resources to support the delivery and management of teaching and learning activities. An educational e-platform needs to have at least 10 e-learning modules that meet the EACCME[®] criteria for accreditation of ELM.

Educational app:

The word "app" is an abbreviation for *application*. An app is an element of software that can be run on the internet, on a computer, or on a phone or any other electronic device. While the word "app" has gained popularity in the context of mobile devices, it still applies more broadly to programs in general. An educational app is an app that is used as a medium for the delivery of educational material modules that meet the EACCME[®] criteria for accreditation of ELM.

Educational e-library (or digital library):

An organised collection of selected digital resources created to support learning, scholarship, research and teaching. Through the use of appropriate technological standards, a digital library is created to facilitate permanent access to and resource discovery of selected digital resources.

Content of educational e-platforms, apps and e-libraries and relevant quality control:

Due to the dynamic character of educational e-platforms, apps and e-libraries, providers are entitled to change/upgrade the educational content of an accredited ELM after the initial accreditation without submitting a new application, but they have to make sure that the content will stay within the scope and remit of the initial accreditation. Also, access technologies (platforms, apps etc.) may undergo changes as long as requirements for obtaining EACCME[®] accreditation for a given ELM format are met.

For this reason, there is periodical quality control of the educational e-platforms, apps and e-libraries by EACCME[®] reviewers to ensure that their content remains within the scope and remit of the initial accreditation.

IV. <u>Who is eligible to apply for EACCME® accreditation?</u>

The EACCME® considers for accreditation e-learning materials submitted by:

- an individual medical specialist
- a university or hospital department
- a scientific medical society
- a national medical association
- a medical communication agency
- a medical publisher
- 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 who will take responsibility for the application. This person must be registered with his/her National Regulatory Authority.

The EACCME[®] will **NOT** consider for accreditation e-learning materials (ELMs) where the content, format or faculty is influenced by industry.

V. <u>EACCME[®] general principles</u>

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;
- sponsorship must be under the form of an unrestricted educational grant.

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 material 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 randomly perform on-site quality controls of accredited ELMs.

Other healthcare professionals

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

VI. <u>Requirements for the accreditation of an e-learning</u> 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.

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.

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

The target audience must fall within the remit of the UEMS-EACCME[®] (fully qualified medical specialists). The target audience must therefore be explained in terms of specialty and seniority of the learner.

EACCME[®] certificates may be distributed to any other healthcare professional completing an e-learning module (i.e. nurses, pharmacists, clinical scientists...) who wishes to benefit from EACCME[®] credits. It is up to the healthcare professional's association to 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.
- 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.

This is particularly relevant in the case of interactive ELM (such as online websites). 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 one educational hour (60 mins of actual educational activity excluding introductions etc.), with each hour of educational time expected to count as one ECMEC[®].

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) 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)* 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 within the duration expected for the accreditation of each educational hour (1 ECMEC[®]).

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

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.

14) All content must be free of any form of advertising.

The EACCME[®] will reject any application that, in its opinion, includes advertising of any product or company.

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.

15) 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

16) 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.

17) 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.

18) The ELM must provide the name and title of a medical practitioner who will take responsibility for its content. This doctor must be registered with a Medical Regulatory Authority, and his/her registration details must be provided.

19) There must be a full declaration of actual or potential conflict of interest of the individual(s) involved in preparing the content of the Material.

It is essential that the medical practitioner who will take responsibility for the material provides and the individual(s) involved in preparing the content of the material provide a full declaration of actual or potential conflict of interest. Earnings from the sale or marketing of the Material itself will not be considered a conflict of interest. Each ELM must contain authors' COI declaration provided as a slide or oral statement in the introductory part of the ELM.

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 grant is in the form of an "unrestricted educational grant" 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.

Quality Assurance by the Provider

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

As a minimum, 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 an evaluation form to be completed by learners after completion of the module.

In order to maintain accreditation, this feedback must be submitted to the EACCME[®] within 12 months of accreditation having been granted.

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

All the criteria below are <u>DESIRABLE</u> criteria.

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

Where these links are to commercial sites, this must be made clearly identifiable.

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

VII. <u>Submission/evaluation/accreditation/appeal processes</u>

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 www.eaccme.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;
- a fully completed EACCME[®] application form, confirmed by the medical practitioner who is taking responsibility for the material (see paragraph 18);
- full payment of the application fee.

In dealing with the application, the 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 material submitted;
- confirming for the applicant the following dates:
 - a) on which the material was received,
 - b) on which the application was complete,
 - c) on which the application fee was cleared,
 - d) 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;

- choosing, from a pool of suitably-trained specialists, two assessors who have expertise appropriate to the material submitted;
- providing, via the EACCME[®] part of the UEMS 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, when the process will take no longer than ten weeks;
- publishing on the EACCME[®] website the list of accredited modules.

Criteria and Decision-Making for Accreditation

- 1. The material and the application form will be reviewed by the two designated EACCME® assessors.
- 2. For a positive decision to be made by the EACCME[®] assessor, in favour of accreditation, <u>all</u> essential criteria, and at least one desirable criterion <u>must</u> be confirmed as 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

- 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.

<u>Appeal</u>

 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.

- 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. Mechanism of appeal in either case (automatic appeal, or appeal by applicant) the mechanism will be:
 - the Secretary-General of the UEMS (or his/her nominee) will review the material and the application form, and will discuss these with the two designated EACCME[®] assessors;
 - the three will vote on the Application, with a majority (2:1) decision being permitted to confirm accreditation;
 - the appeal decision will be final.

VIII. Fees for individual e-learning modules

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

-	€ 500	For 1 module
-	€ 1,000	for up to 10 accredited modules
-	€ 1,500	for up to 20 accredited modules
-	€ 2,000	for up to 30 accredited modules
-	€ 3,000	for up to 40 accredited modules
-	€ 5,000	for up to 50 accredited modules
-	€ 7,500	for up to 100 accredited modules
-	€ 10,000	for more than 100 accredited 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.

IX. 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 emedia 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. The e-platform must meet the criteria that apply to ELM (see pages 9-13).
- d. 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 (see pages 14-16) with two exceptions:

- Instead of completing the application form (see template pages 26-30) 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 elearning 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 a modification.

There is periodical quality control of the educational e-platforms, by EACCME[®] 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

-	€ 1,000	for up to 10 accredited modules
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- € 1,500 for up to 20 accredited modules
- € 2,000 for up to 30 accredited modules
- € 3,000 for up to 40 accredited modules
- € 5,000 for up to 50 accredited modules
- € 7,500 for up to 100 accredited modules
- € 10,000 for more than 100 accredited modules

In addition to the fees above, there will be a flat fee of \in 250 to be paid every year 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 1 credit for every hour (60 minutes of actual e-learning excluding introductions etc.) of use as evaluated by EACCME[®] assessors and stated in the EACCME[®] confirmation of accreditation, provided that the users have completed a module and have passed the relevant assessment.

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 re-accredited, a new application has to be submitted to EACCME[®].

X. <u>Accreditation of e-learning modules of apps</u>

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 eplatforms.

XI. Accreditation of the use of educational e-libraries

1. Scope of accreditation

The EACCME[®] will not accredit the inclusion of an article in an e-library but the use of the e-library as a CPD/CME vehicle.

For example:

A medical specialist can use the time already spent researching clinical questions with the library toward continuing professional development requirements. In order to use the library for accreditation, a user logs into the database with their personal account. When a clinical question is researched in the database, the library tracks both the search activity and the time spent researching. In order to apply for accreditation, the user generates an activity assessment of topics researched. For each topic searched, the user ticks how the information found was applied to their clinical practice (for example, this modified my treatment plan, this reinforced my treatment plan or generated ideas for searching for new treatments in the future). Once completed the system awards the credits to the user.

2. Submission/ evaluation/ accreditation/ appeal processes

The submission, evaluation, accreditation and appeal processes will be identical to the ones described on pages 18-19 for the educational e-platforms

3. Fees

Flat fee of € 5,000

In addition to the fee above, there will be a flat fee of \in 250 to be paid every year for the quality control review by EACCME[®].

The above fee is 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.

4. Credits

The credits for the users of the library will be 1 credit for every hour (60 minutes of actual use of educational material excluding technical introductions etc.) of use of the accredited educational e-library provided that the users have completed a search and have passed the relevant assessment.

The provider will be responsible for ensuring that there is a mechanism in the e-library to ensure the hours of use and searches made, the assessments passed and subsequently award the relevant credits. Compliance of the provider with this process will be checked during the annual review of the educational e-library by the EACCME[®].

5. Validity of the accreditation

The accreditation will be valid for 2 years. After two years, if the provider wishes for the educational e-library to be re-accredited, a new application has to be submitted to EACCME[®].

XII. <u>Outcomes</u>

 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 one ECMEC[®] per hour of education) will be stated. Only after confirmation of accreditation has been made 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.

- 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. This extension of accreditation will be permitted at no extra charge.
- 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 cause for rejection of an application at the level of</u> <u>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. <u>Allocation of European CME Credits (ECMEC®s)</u>

1 hour (60 minutes of educational activity) = 1 ECMEC[®]

Each additional full hour will be granted 1 ECMEC[®].

The EACCME[®] does not award half credits.

XV. <u>Application form for the accreditation of e-learning</u> <u>materials: individual e-learning modules and educational e-</u> <u>platforms, apps and e-libraries</u>

Title of the material	
Nature of the material	 Recorded audio Recorded video Interactive module Other: (please specify) In the case of "hybrid" materials, please contact the UEMS-EACCME[*] Office before submitting your application.
Means by which the Material is made available	 Website: (please provide URL) Supported by Personal Digital Assistant (PDA) E-platform App <u>e-Library</u> Other: (please specify) Please provide the direct access to the educational material as well as the necessary log-in details (e.g. username and password) for at least 3 Reviewers and this, for the entire duration of the evaluation process (i.e. ca.3 months).
Overall description	
Provider	
Contact person e-Mail Telephone Address	
Start date	
End date	
Main language of the material Translations available into	

Written declarations can be added to this application form separately

CHECKLIST

In order to be validly submitted, all essential and desirable criteria must be completed.

ES	SENTIAL CRITERIA
1.	State how the Material has been prepared in order to <i>fulfil stated educational needs</i> , 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.
	Open response box
2.	What are the <i>expected educational outcome(s)</i> of the Material? 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.
	Open response box
3.	What is the <i>"target audience"</i> for whom the Material is most likely to be suitable? This must be explained in terms of the speciality/ies and seniority of doctor (henceforth referred to as the <i>"Learner"</i>) most likely to benefit.
	Open response box
4.	What is the <i>content</i> of the Material?
	Open response box
5.	Confirm how the <i>privacy and confidentiality</i> of the Learner will be respected, and how you will make sure that any information provided by the Learner will only be utilised for the specific purposes of completing the Material. This is particularly relevant in the case of interactive Material (such as online websites). The only
	permitted exception to this will be with the valid consent of the Learner.
	Open response box
6.	What is the likely duration that the Learner will need to engage with the Material in order to fulfil the educational objective(s)? This must be a minimum of one educational hour, with each hour of educational time expected to count as one ECMEC [®] .
	Open response box
7.	State how will compliance of the Materials with all relevant <i>ethical, medico-legal and legal requirements</i> be met. Where applicable, these must include: consent by patients and other participants to inclusion in the Material, confirmation of confidentiality for patients and other participants, compliance with research ethics requirements, compliance with data-protection legislation, and copyright

arrangements for the Material. It is essential to ensure that patients are not, and cannot be identified in any of the materials presented.

Open response box

8. Please specify the *date of preparation* of the Material, any substantial revisions to its content, and *expiry date*.

Open response box

9. What is the required *format for use* of the Material, (eg. Windows/MacOS; DVD region)? *Provide contact details for the provision of assistance.*

Open response box

10. Please specify the *level of evidence* of the content. All content within the Material must be evidence-based, with notes on the level of evidence (where applicable), and suitable references, at the standard required for a publication in a

scientific journal. Open response box

11. Please specify how the Material 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 UEMS-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.

Open response box

12. Please specify the extent to which the Material includes a means of confirming Learner *engagement*, and *achievement of the educational objective(s)*.

This must be of quality, duration and content appropriate to the Material and the educational objective(s), and it must be integral to the Material. It may be based on multiple-choice questionnaire or other self-assessment methodologies, but must have clearly stated assessment criteria (eg. 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 within the duration expected for the accreditation of each educational hour (1 ECMEC[®]).

Open response box

13. Please specify the extent to which the content is *free from any commercial or other forms of bias*.

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 UEMS-EACCME[®] will reject any application that, in its opinion, includes biased information.

Open response box

14. Please specify the extent to which the content is *free of any form of advertising*.

	The UEMS-EACCME [*] will reject any application that, in its opinion, includes advertising of any product or company.
	Open response box
15.	Please specify the extent to which the content is suitable for an <i>international audience</i> .
	This refers to the use of international terminology for procedures and therapeutic agents.
	Open response box
16.	Please provide a <i>short description of the Provider organisation</i> .
	While the use of the Provider's logo(s) will be permitted, there must not be any attempt at using
	this description for advertisement.
	Open response box
17.	Please state, in a readily-accessible manner, the <i>names and qualifications of the individual(s)</i>
	involved in preparing the content.
	The UEMS-EACCME [®] requires that all individuals who have contributed to the preparation and presentation of the material(s) are identified.
	Open response box
18.	Please state, in a readily-accessible manner, the <i>name and title of the senior medical specialist</i> <i>who will take responsibility for its Scientific content (? And faculty).</i> <i>This doctor must be registered with a Medical Regulatory Authority, and his/her registration</i> <i>details must be provided.</i>
	Onen response hov
	Open response box
19.	Open response box Please provide a <i>full declaration of actual or potential conflict of interest</i> of the individual(s) involved in preparing the content of the Material. It is essential that the medical practitioner who will take responsibility for the material provides a full declaration of actual or potential conflict of interest. Earnings from the sale or marketing of the Material itself will not be considered a conflict of interest.
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In order to maintain accreditation, this feedback must be submitted to the UEMS-EACCME^{*} within 12 months of accreditation having been granted. Failure may affect future recognition.

Open response box

23. Please confirm that your *evaluation record* for previous or ongoing modules or programmes is satisfactory. Where not, please specify how the reasons for unsatisfactory ratings have been addressed.

Open response box

DESIRABLE CRITERIA

24. Please specify the extent to which the content is *easy to use*.

Open response box

25. Please specify whether and which *"hot-links" to further relevant information* are provided. *Where these links are to commercial sites, this must be made clearly identifiable.*

Open response box

26. Please specify the extent to which *technical support* related to the Material was made available.

Open response box

XVI. 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 http://www.eaccme.eu.

"The UEMS-EACCME[®]", "Ourselves", "We" and "Us" refer to the Belgian international nonfor-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 re-enacted, (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 (<u>http://www.eaccme.eu/</u>) 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[®] logos on material related to the ELM. Any unauthorized use of these logos will result in action being taken by the UEMS, including, but no 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 module, eplatform, app, e-library is determined in accordance with the principles set forth in the "EACCME[®] Criteria for the Accreditation of E-Learning Materials (ELM)" document which is available through this following weblink: www.eaccme.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.

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 five 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 fulfill 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/its 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 a processing fee amounting to 75 EUR 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.

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 postponement anymore, except in exceptional circumstances to be duly justified by the Applicant and upon written acceptance of the UEMS-EACCME[®].

INCOMPLETE APPLICATION POLICY

If the Applicant does not complete his/her/its 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/its 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, facsimile or mobile telephone numbers.

This 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[®] 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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