EBAH
European Board for Accreditation in Hematology

EBAH Standards and Guidelines for CME-CPD providers

Table of Contents

1. The European Board for Accreditation in Hematology (EBAH) 2
1.1. Mission 2
1.2. Vision 2
2. General statements/definitions 2
3. Eligibility for accreditation 3
3.1. Eligibility of a CME-CPD provider 3
3.2. Eligibility of the educational activities of an accredited provider 4
4. Criteria (requirements) for provider accreditation 4
4.1. Provider's description 4
4.2. Adherence to "EBAH Standards and Guidelines for Accreditation of CME-CPD Activities" 5
4.3. Commercial interest 5
4.4. The allocation of EBAH CME-CPD credit points 5
5. Procedures 6
5.1. Pre-Application 6
5.2. Initial Accreditation Process 6
5.3. Accreditation Interview / Mentorship 7
5.4. Timeline 7
5.5. Granting of EBAH CME-CPD provider status 7
5.6. Obligations of the CME-CPD provider during and after the accreditation period 8
5.7. Evaluation and audit 8
6. Fees 9
6.1. Provider status application fee 9
6.2. Annual provider fee 9
7. Appendices 9
7.1. Appendix I. - EBAH Standards and Guidelines for Accreditation of CME-CPD Activities 9
7.2. Appendix II. - Checklist for the provider self-report 9
7.3. Appendix III. - Checklist for the reviewer for provider eligibility 10
7.4. Appendix IV. - Suggested data analysis for the annual provider report 10

EBAH
European Board for Accreditation in Hematology

1. The European Board for Accreditation in Hematology (EBAH)

1.1. Mission

EBAH stimulates and supports harmonized high-quality Continuing Medical Education in hematology, both for individuals and organizations, in order to provide the highest possible standard of patient and public health care within Europe.

1.2. Vision

EBAH aims to be the reference accreditation board in Europe for unbiased and transparent Continuing Medical Education in Hematology.

Continuing Medical Education - Continuing Professional Development (CME-CPD) is widely accepted as a means to encourage individual practitioners to maintain and develop professional knowledge and skills keeping up to date with latest developments within the field.

When spending valuable time on training activities, it is essential to ensure that one is attending a high-quality educational program. The European Board for Accreditation in Hematology (EBAH) has been established as an independent accreditation body in response to this need. In practice, EBAH applies a hybrid system:

- EBAH awards CME-CPD credit points as a sign of quality of CME-CPD activities irrespective of the format (live, on-line, blended) after strict reviewing by an independent review board considering the highest quality standards.
- EBAH awards accreditation of highly reputable scientific and medical associations and societies as education providers after strict reviewing and monitoring if they consistently show that they follow the standards and meet the requirements for delivering independent CME-CPD that accelerates learning, change, and improvement in healthcare.
- CME-CPD activities that benefit and develop hematology and related fields are within the scope of the present EBAH Standards and Guidelines document.

2. General statements/definitions

2.1. Definition of CME

Continuing Medical Education (CME) - The process by which healthcare professionals engage in activities designed to support their continuing professional development. Activities are derived from multiple instructional domains, are learner centered, and support the ability of those professionals to provide high-quality, comprehensive, and continuous patient care and service to the public or their profession. The content of CME can be focused not only on clinical care, but also on those attitudes/skills necessary for the individual to contribute as an effective administrator, teacher, researcher, and team member in the healthcare system.

2.2. Definition of CPD

Continuing Professional Development (CPD) –The learning journey of the healthcare professional as he/she seeks to improve her/his competence and expertise. This learning journey is supported by continuing medical education and other personal/professional activities by the learner with the intention of providing safe, legal, and high-quality services aiming at better health outcomes for the patients and the community.

2.3. Organizer: The institution or organization that has developed the CME-CPD activity. They may be an academic institution, a scientific society, a hospital or a medical education company. There cannot be a commercial interest.

2.4. CME-CPD provider: A CME-CPD organizer that produces CME-CPD activities and can award CME-CPD EBAH credits to them if they comply with the "Standards and Guidelines for Accreditation of CME-CPD Activities". The organizer itself must have successfully undergone a process of approval/accreditation/certification by a CME-CPD accreditation body.

2.5. Learner: A participant in a CME-CPD activity.

2.6. (Healthcare) Professional: A professional in the field of hematology. Those include but are not limited to: physicians, nurses, laboratory technicians, and any other professionals that work in hematology or related fields.

2.7. Course director: A professional individual in charge of the program and who can ensure that procedures have been followed for quality control. Also, the course director will be asked to inform and educate the faculty on the criteria and guidelines of CME-CPD accredited activities.

2.8. Unbiased / independent CME-CPD: A CME-CPD activity, all elements of which, development, design and execution are free of any control of commercial interest and / or any other undesirable influence.

2.9. Commercial interest: Any interest in profit, especially associated with the production, sale, resale or distribution of healthcare products or services consumed by or used by patients.

2.10. Disclosure: Anyone in control of CME content must disclose relevant financial relationships. Individuals must also include in their disclosure the relevant financial relationships of a spouse or partner. Relevant financial relationships are financial relationships in any amount that may create a conflict of interest and that occurred in the previous twelve months. Financial relationships are those relationships in which the individual benefits by receiving a salary, royalty, intellectual property rights, consulting fee, honoraria for promotional speakers' bureau, ownership interest (e.g., stocks, stock options or other ownership interest, excluding diversified mutual funds), or other financial benefit. Financial benefits are usually associated with roles such as employment, management position, independent contractor (including contracted research), consulting, speaking and teaching, membership on advisory committees or review panels, board membership, and other activities from which remuneration is received, or expected.

3. Eligibility for accreditation

3.1. Eligibility of a CME-CPD provider

The EBAH has specific criteria for determining an organization's eligibility to receive EBAH accreditation as a CME-CPD provider.

Only certain organizations are eligible to receive EBAH accreditation as providers. The following criteria must be met before an organization willissidered for EBAH provider accreditation.

The organization must:

- Be developing and/or presenting CME-CPD programs in the hematology field on a regular and recurring basis.
- Have 3 previous high-quality applications for accreditation of CME-CPD activities with positive final EBAH decisions.
- Have in place **a peer-review system** for all their CME-CPD materials and activities.
- **Have been acquainted with "EBAH Standards and Guidelines for Accreditation of CME-CPD Activities",** understand their content, and agree to implement them for the time of accreditation.
- At the end of the accreditation period, **apply for renewal of its status of official EBAH CME-CPD provider.**
- Not have a commercial interest.

EBAH accredits the following institutions, if they choose to seek accreditation:

- Academic or scientific or educational organizations are eligible to apply for accreditation.
- The pharmaceutical and medical device industries are not eligible to apply for accreditation. The refusal to allow the pharmaceutical or medical device industries does not imply that their programs lack quality, as EBAH acknowledges their merits, but merely that in such cases bias cannot be excluded.
- Applications for accreditation coming from Medical Education Companies as Organizers are also accepted, in case they comply with all the rest of the criteria for accreditation.

When there is a question regarding eligibility, the EBAH reserves the right to make decisions on the issue, and has a formal process in place to do so.

3.2. Eligibility of the educational activities of an accredited provider

An EBAH accredited CME-CPD provider may accredit only educational activities that are eligible according to "EBAH Standards and Guidelines for Accreditation of CME-CPD Activities" which should be regarded as an integral part of the present document.

4. Criteria (requirements) for provider accreditation

4.1. Provider's description

The CME-CPD provider should give a clear description of the type of organization, its mission and vision, the exact name, address, contact person, web site, link to the statutes (ìf applicable).

The provider generates educational activities that are designed to change competence, performance, or patient outcomes as described in its mission statement. The applicant for provider's status should explain how it defines continuing professional development (CPD) or continuing medical education (CME) and describe how the organization will ensure that the activities in regard to this application conform to its definition of CME-CPD.

The applicant for provider's status has a solid track record of organizing educational activities (minimum 3 previously accredited CME-CPD activities) that have been successfully CME-CPD accredited. Description of its past and current practice in regard to CME-CPD accreditation of organized activities is desirable.

The CME-CPD activities organized by the applicant for provider's status within the scope of the current application should exclusively benefit hematology.

The CME-CPD provider should have in place a peer-review system for all their CME-CPD materials and activities. This system should be described to EBAH upon application to become a provider.

4.2. Adherence to "EBAH Standards and Guidelines for Accreditation of CME-CPD Activities"

The educational activities organized by the provider should be compliant with "EBAH Standards and Guidelines for Accreditation of CME-CPD Activities". The provider demonstrates understanding of their content and agrees to implement them for the time of provider's accreditation.

The applicant for provider's status must answer the following questions:

- Demonstrate that the educational needs (knowledge, competence, or performance) that underline the professional practice gaps of the learners are incorporated into CME-CPD activities. A description of the "needs assessment" process should be provided as well as how the provider will ensure that the intended target audience is described for each CME- CPD activity.
- Demonstrate that the educational activities are developed in the context of desirable physician attributes, e.g. taking into account the *European Hematology Curriculum*.
- Explain how overall learning objectives are developed and communicated to the target audience for each CME-CPD activity. Describe how the expected learning outcomes are assessed.
- Explain how the learning methodologies and educational formats are selected that are appropriate for the learning objectives and desired results of each activity and demonstrate how these are adapted to the needs of the potential users.
- Describe the process of planning CME-CPD activities in order to achieve scientific integrity, objectivity and balance.
- Demonstrate ways to analyze changes in learners (attitude, competence, performance, or patient outcomes) achieved as a result of the overall educational activities. The provider is asked to describe how the organization will ensure that each CME-CPD activity is assessed or evaluated to determine how well it met its learning objectives.
- Demonstrate that data are collected and analysis is performed on the degree to which the CME-CPD mission has been met through the conduct of educational activities. The provider is asked to describe how they identify, plan and implement the necessary or desired changes required to improve the execution of the CME mission.

4.3. Commercial interest

The provider actively promotes improvements in health care and NOT proprietary interests of a commercial interest. The provider develops activities/educational interventions independent of commercial interests. The provider maintains a separation of promotion from education. The provider appropriately manages commercial support.

4.4. The allocation of EBAH CME-CPD credit points

The provider must adhere to the EBAH approved practice of time-based allocation of CME-CPD credit points.

1 hour of CME-CPD activity = 1 EBAH CME-CPD credit point.
The provider defines the time a learner will need to complete the activity.

The provider must adhere to the EBAH approved practice of time-based allocation of CME-CPD credit points.

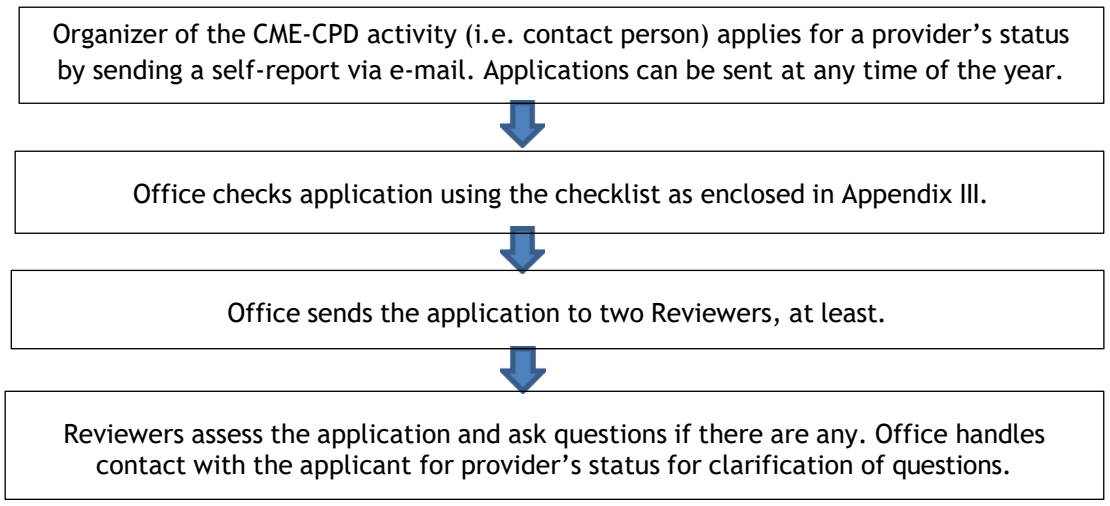
1 hour of CME-CPD activity = 1 EBAH CME-CPD credit point.
0.5 EBAH CME-CPD credit points can be allocated for e-learning activities.

The provider defines the time a learner will need to complete the activity.
Up to a maximum of 8 EBAH CME-CPD credit points can be allocated per day.

An activity can be accredited either by the cumulative number of hours of the activity or per section/module if the organizer wishes to monitor the attendance.

5. Procedures

5.1. Pre-Application



5.2. Initial Accreditation Process

If the organization is deemed eligible through the pre-application review process, it will be invited to continue with the initial accreditation process. The initial accreditation process is an opportunity for each applicant to demonstrate that its practice of CME-CPD is in compliance with EBAH's accreditation requirements through three primary sources of data.

The self-study report is an opportunity for the organizer to tell the "story" of the CME program to the EBAH and provide background and information on how the organization accomplishes its CME mission. Initial applicants are asked to provide descriptions, attachments, and examples to give the reader an understanding of CME practice(s) related to the EBAH Accreditation Criteria, Standards for Commercial Support, and policies. Descriptions are narrative explanations. Attachments are

specific documents. Examples are demonstrations of the implementation of the practices described that may include narrative and/or attachments.

Initial applicants are asked to verify that their CME activities are in compliance with EBAH accreditation requirements through the documentation review process. The initial applicant will present evidence to EBAH for documentation review from at least two recently completed educational activities.

5.3. Accreditation Interview / Mentorship

Initial applicants can further describe the practices presented in the self-study report and activity files, and provide clarification as needed, in conversation with a member of the EBAH.

Applicants will be required to submit the final version of the written self-study report and evidence of performance-in-practice, along with payment of the Initial Accreditation Fee. In case any issues could not be clarified in writing, then there will be an optional accreditation interview. Depending on the assessment of EBAH, mentorship and guidance may be provided in writing to the applicant, in case that is needed.

Once all required information and payment have been received, the EBAH will make its decision and, in case it is needed, schedule the accreditation interview. The organization must have a CME activity reviewed, which entails the assessment of one of the organization's CME activities by an EBAH member. These requirements must be fulfilled as a part of the organization's initial application process, or as part of the organization's subsequent reaccreditation review process.

5.4. Timeline

The process for initial accreditation may take up to 6 months.

5.5. Granting of EBAH CME-CPD provider status

The decisions of the two EBAH reviewers on the self-report (together with the report of the interviewing EBAH member if applicable) are presented to the entire EBAH for decision. The provider status is granted for a defined period of **3 years**.

Upon final decision, EBAH coordinator informs by e-mail the contact person if the organizer is accredited the provider's status and what is the period of accreditation. In case of rejection, the EBAH Office will provide the organizer the reason for the negative decision.

Accredited providers are listed in a prominent page on EBAH's website. In addition, the accredited providers can also present their status on their own websites.

If the EBAH's decision is negative the Applicant can submit a written reasoned appeal to the chair of EBAH within 2 weeks of receiving the Board's decision. The chair of EBAH can ask the Board for reconsideration of the application or confirm the decision in which case the decision becomes final. The decision taken by EBAH after reconsideration of the application is final.

A reaccreditation application can be submitted after the expiry of the accreditation period. An update of the procedures or any other relevant changes, which may affect the adherence to the standards and guidelines, must be communicated to EBAH.

5.6. Obligations of the CME-CPD provider during and after the accreditation period

The provider must peer-review all accredited educational activities for compliance with "EBAH Standards and Guidelines for Accreditation of CME-CPD Activities". The provider must keep a track of the reviewing process.

The provider must collect and keep a track on disclosure forms of potential COI for all meeting and session chairs, speakers, authors of educational materials.

The provider must inform all potential learners about the EBAH accreditation by including the following statement in the final program of educational events or materials: *" [insert title of the organizer] is an accredited CME-CPD provider by the European Board for Accreditation in Hematology (EBAH). This educational activity has been accredited for a maximum number of [insert the allocated number] EBAH CME-CPD credits. Each participant should only collect credits for time that she/he actually spent in the educational activity."*

The provider must distribute instructions for the participants on how to claim their credits online no later than at the start of the CME-CPD activity.

The provider must enter in the EBAH electronic system, on the date the participants' attendance is confirmed, an electronic list of participants which includes, per participant, first name, last name, e-mail address, and their EBAH personal account number. The provider must verify and confirm the attendance of all individual participants listed in the list of participants.

5.7. Evaluation and audit

5.7.1. Activity report

On completing a CME-CPD activity the provider must develop an activity report based on the learners' individual feedback. This report must include the participants' feedback, information on the total number of participants and any perception of bias by participants. The provider must keep track of the activities reports and must provide them to EBAH in case of request.

5.7.2. Random audits

The EBAH will randomly perform on-site quality controls of accredited by the provider live events to ensure compliance with EBAH accreditation criteria. The provider must allow for the eventuality that representatives appointed by the EBAH may attend or visit the accredited CME-CPD activity. Such attendees or visitors must be granted full access to spaces, persons, and materials that may be of importance to their assessment of compliance to these standards and guidelines.

5.7.3. Annual report

The provider must develop an annual report and provide it to EBAH latest 30th January of the next year. This report must include information on the total number of activities, including titles, type of activity [live event, e-learning material, etc.], number of participants per event, brief analysis of learners' feedback, information of any eventual case of COI and information how it was resolved. Failure to provide the annual report could jeopardize recognition of any future applications.

6. Fees

6.1. Provider status application fee

EBAH charges education organizers applying for provider status a one-off application fee of EUR 160. This fee is non-refundable and payable upon submission of the provider status application.

6.2. Annual provider fee

Accredited providers are subject to the following annual provider fees:

- National associations and societies: EUR 315 per year
- International associations and societies: EUR 525 per year
- Medical education companies: EUR 525 per year

In addition, an annual administrative fee of EUR 150 is charged to cover administrative and operational costs related to provider status.

The applicable fees are defined at the time of signature of the provider status contract and apply for the full duration of the contract. Any revisions to the fee structure apply only to new contracts or renewals, unless otherwise agreed.

7. Appendices

Appendix I. "EBAH Standards and Guidelines for Accreditation of CME-CPD Activities"

Appendix II. Checklist for the provider self-report

Appendix III. Checklist for the reviewer for provider eligibility

Appendix IV. Suggested data analysis for the annual provider report

7.1. Appendix I. - EBAH Standards and Guidelines for Accreditation of CME-CPD Activities

Please consult the latest version published here: https://ebah.org/cme-standards-and-guidelines/

7.2. Appendix II. - Checklist for the provider self-report

Mission statement of the organization
Narrative of the story of the organization's CME program (explanatory description):
Background information on how the organization accomplishes its CME mission
- standards for commercial support
- examples
- further relevant attachments
- descriptions of actual practice

7.3. Appendix III. - Checklist for the reviewer for provider eligibility

Mission statement of the organization – does it exist; does it include education?
Narrative of the story of the CME program: was the explanation and description clear?
Background information on how the organization accomplishes its CME mission:
- Were all relevant attachments submitted?
- Were examples and descriptions submitted satisfactory?
Is there anything missing that the reviewer would like to understand further?
- Missing important details
- Clarifications needed
Is an interview required?

7.4. Appendix IV. - Suggested data analysis for the annual provider report

Final Annual Report[i]

Accredited activity titles for the previous year:

Dates:

Venues (if applicable):

Actual number of participants of each activity:

- Breakdown (in %) of participants as seems relevant (e.g. geographical; nationality; per specialty; per profession; per category with specific educational needs; per age; per gender, etc.)
- Considering the participants breakdown of the activities in this annual report, would you plan any changes for your future CME-CPD activities?
- Provide anonymized results of post-activity evaluation completed by the participants.
- Comment on any particular (non-expected) changes in the delivery of the CME-CPD activities of previous year, if applicable.

Compliance with EBAH provider requirements:

- Any issues with compliance with EBAH provider requirements and if yes, in which activity, and the explanation:
- Any other comments:

Report prepared by:

[i] To be submitted by the end of January in the following year, at the latest.