Roles and Responsibilities of Providers in EBAC® Accredited Continuing Education

Providers should fulfil the IACPDA “Standards for Substantive Equivalency between CME/CPD Accreditation Systems”. This includes conduct of needs assessment, content development, faculty selection, handling of all issues regarding management of conflicts of interest, and outcomes evaluation.

In the EBAC® system commercial interests or subsidiaries of commercial interests are ineligible as providers of accredited CE.

For all EBAC® accredited CE activities a course director shall be appointed, belonging to the profession(s) targeted in the accredited CE activity.

In the EBAC® activity accreditation system the provider and the course director are equally held accountable to EBAC®. In case of non-compliance EBAC® assumes the right to not accept the provider/course director in future applications.

In the EBAC® provider accreditation system it is solely the provider who is held accountable to EBAC®.

The following principles and rules apply to all educational activities accredited in the EBAC® framework:

A. Needs assessment
   1. In general, all assessment procedures (applies also to the items below) should be
      - fair
      - objective
      - reliable and
      - show reasonable validity
   2. Assessment methods should be appropriate
      - according to acknowledged testing methodology
      - to detect needs/gaps in professional performance of either individual health professionals, teams of health professionals, professional groups (e.g. specialty of internal medicine) or interprofessional teams
3. Providers have to (be able to) make available source, methodology, and detailed results (beyond what has to be documented in the EBAC® Management System) of their needs assessment to EBAC®.

B. Content development

1. In general,
   - all content needs to comply with the principles of the UN Universal Declaration of Human Rights and the WMA Declaration of Helsinki
   - all content derived from clinical studies relates to studies only, which have been registered in universally recognised databases, e.g. ClinicalTrials.gov, European Clinical Trials Database (EudraCT).
   - selection of content is based on publicly accessible sources of information only (except expert opinions)
   - all scientific research referred to, reported, or used in accredited education in support or justification of a patient care recommendation must conform to the generally accepted standards of experimental design, data collection, analysis, and interpretation.
   - although accredited continuing education is an appropriate place to discuss, debate, and explore new and evolving topics, these areas need to be clearly identified as such within the program and individual presentations. It is the responsibility of providers to facilitate engagement with these topics without advocating for, or promoting, practices that are not, or not yet, adequately based on current science, evidence, and clinical reasoning.
   - organizations cannot seek accreditation if they advocate for unscientific approaches to diagnosis or therapy, or if their education promotes recommendations, treatment, or manners of practicing healthcare that are determined to have risks or dangers that outweigh the benefits or are known to be ineffective in the treatment of patients.
   - content should appropriately target the gaps identified by needs assessment
   - content should always contain a community health perspective

2. Providers of accredited education have a policy for integrated planning of content, educational design and time schedules of individual educational activities/programs to optimally achieve the desired outcomes, as inferred from identified needs. With regard to content development this includes
   - description of content and intended (learning) objectives from the learner’s perspective; and prior to the activity for review by potential participants
   - use of aggregate data (e.g. systematic reviews, meta-analyses) whenever available
   - development of a balanced view across all relevant options related to
the results of needs assessment
- adaptation of the length and order of educational units of the activity/intervention to deliver content, to maintain a sensible didactic flow related to the receptiveness of the participants, as well as sufficient breaks.

3. Providers have to be able to demonstrate to EBAC® that they have consistently applied the principles and rules as outlined under 1. and 2.

C. Educational design and faculty selection
1. Determination of educational design and selection of faculty include
   - to choose educational formats for activities/interventions that are appropriate for the setting, objectives, and desired results of the activity, incl. strategies to promote self-learning
   - public announcement of educational design prior to the CME-CPD activity/intervention
   - appropriate qualification and educational experience of speakers/authors/moderators/chairs (owners or employees of commercial interests cannot have a role in faculty selection, selection or presentation of content)
   - choice of appropriate educational method (e.g. simulation training to acquire practical skills)
   - a comprehensible content to time relation
   - appropriate translation of evidence into language

2. Providers have to be able to demonstrate to EBAC® that they have consistently applied the principles and rules as outlined under 1.

D. Outcomes evaluation
   • Event report
     After each CE activity (for enduring material: at the end of the accreditation period) an event report must be sent to the EBAC® office (please see also 8. below). This report consists of a) the evaluation results and b) the total number of participants
   • Evaluation:
     1. Assessment methods should be appropriate
        - according to acknowledged testing methodology
        - to detect changes of either individual physicians, physician teams, physician groups (e.g. specialty of internal medicine) or interprofessional teams
        - for the intended level of education (i.e. improvement of knowledge, competence, performance, patient and/or community health)
        - for assessment of needs-based outcomes
     2. Onsite/immediate outcomes measurement
        - has to be implemented for all educational activities/interventions, and
        - must include assessment of bias by participants
3. Providers perform at least a qualitative assessment in all educational activities/interventions.
4. If multiple choice questions are used as assessment method, they should consist of a stem and 5 alternatives of which only one is correct.
5. Pre/post tests are preferred, but are not obligatory
6. Assessments of long-term change are strongly encouraged, but are not obligatory
7. Providers have to (be able to) make available methodology and results of their outcomes assessment to EBAC®.
8. EBAC® provides a standard web-based electronic evaluation tool, but providers are encouraged to develop their own tailormade assessment (to be approved by EBAC® prior to the CE activity). If the EBAC® electronic evaluation tool is used providers only need to communicate the total number of participants as event report and will then receive automatic feedback on the evaluation results from EBAC®.

E. Management of conflict of interests

Transparency is a key prerequisite for management of conflicts of interest. Thus, EBAC® requires all presenters/authors/chairmen/moderators/course directors to declare their financial as well as non-financial interests. This should (ideally in advance to the CE activity) be made available to all participants and should also be used by organizing committees to structure their strategy to manage conflicts of interest.

Declarations
- have to be made for the last 3 years and the following 12 months (in case arrangements have already been made).
- have to cover the following categories:

1. Research:
   - all financial support at the disposal of the person declaring independent of whether payments have been made directly to the individual or to the institution or employer
   - also, all in kind support (like human resources, equipment etc.)

All sources of financial support must be considered, including not only pharmaceutical or device industry, but also government agencies, foundations etc. Please distinguish between sponsor(s) of the current activity (A) or of previous activities (B).
2. **Educational activities:**

- Honoraria (on top of reimbursement for travel and accommodation)
- Reimbursement of cost for travel/accommodation/participation fees in case of **passive participation**

All sources of financial support must be considered, including not only pharmaceutical or device industry, but also government agencies, foundations etc. Please distinguish between sponsor(s) of the current activity (A) or of previous activities (B).

3. **Promotional activities:**

These include

- Participation in non-accredited CE (in case that a nationwide accepted and/or legitimated accreditation system has been implemented)
- Consultancy
- Strategic advice
- Serving on a speakers’ bureau etc.

All sources of financial support must be considered, including not only pharmaceutical or device industry, but also government agencies, foundations etc. Please distinguish between sponsor(s) of the current activity (A) or of previous activities (B).

4. **Personal financial interests:**

These include:

- Holding a patent
- Holding shares or stocks (excluded: stock funds)
- Ownership (him-/herself, spouse, partner, child[ren])
- The person him-/herself is a part-time employee or
- A member of the household is an employee of an entity relevant to this section of the declaration (incl. pharmaceutical or device industry)

All institutions active or relevant to medicine, and whether they are active in the field dealt with in the CE activity must be considered.

5. **Non-financial interests:**

These include

- Affiliation
- position in this organisation
- list of scientific or other organisations (including professional political organisations, self-regulatory bodies etc.), in which the person declaring is a member and/or has a position.

**6. Short version for declaration of financial interests:**

In particular in CE activities with relatively short presentation times (15-30 minutes) EBAC® encourages to use the score derived from the declaration of financial interests to provide participants with a short, but concise information:

Please assign the following **number of points** for any “yes”: I A: 2, I B: 1, II A: 4, II B: 2, III A: 8, III B: 5, IV A: 16, IV B: 10

<table>
<thead>
<tr>
<th>Calculation</th>
<th>Score</th>
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<tbody>
<tr>
<td>number of points for any “yes”</td>
<td></td>
</tr>
<tr>
<td>I A: 2</td>
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<td>II A: 4</td>
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**Calculation of the score**

Take the highest number of points per category (i.e. do not sum up points inside a category, but take only the highest number achieved) and sum up the points per category, then calculate the score according to the rating scale below:

<table>
<thead>
<tr>
<th>Rating scale</th>
<th>Score</th>
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<tbody>
<tr>
<td>0: none</td>
<td>0</td>
</tr>
<tr>
<td>1-2: low</td>
<td>1</td>
</tr>
<tr>
<td>3-7: medium</td>
<td>2</td>
</tr>
<tr>
<td>8-12: high</td>
<td>3</td>
</tr>
<tr>
<td>&gt;12: very high</td>
<td>4</td>
</tr>
</tbody>
</table>

EBAC® offers a **standard template declaration** using the score (in pptx-format) on its website.

EBAC® holds providers of accredited CE accountable to manage conflicts of interest prior to the start of the educational activity. With this regard EBAC® encourages providers to develop a publicly accessible policy for management of conflicts of interest, including

- having declarations of interests available prior to the educational activity to allow potential participants to make an informed decision on participation
- provision of the “score” (see above) to program committee/participants
- provision of detailed information to participants on type and nature of the financial interest
- information on level of financial support (per source of money)
- information to participants which strategies have been applied to mitigate bias.