

ECPhA CRITERIA FOR THE ACCREDITATION OF LIVE EDUCATIONAL EVENTS (LEE)



The European Council for Pharmacy Education Accreditation is an independent organisation founded by the European Association of Hospital Pharmacists (EAHP) and the European Society of Clinical Pharmacy (ESCP)

ECPhA criteria for accreditation of live educational events

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1. <u>European Council For Pharmacy Education</u> Accreditation (ECPhA)

ECPhA aims at improving the quality of continuing education in pharmacy practiced in healthcare settings across Europe via accrediting live and online lifelong learning events throughout collaborating with national healthcare professional associations and accrediting bodies.

This will be achieved through applying high quality standards in the assessment of available educational programmes, which address the needs and current practice of pharmacists, pharmacy technicians and the pharmacy staff practicing in Europe.

ECPhA shall collaborate with international accreditation bodies and international healthcare associations in order to exchange and improve existing practices in the assessment of available European and international educational programmes.

ECPhA is an accreditation provider so the goal of ECPhA is to present an additional layer to the national accreditation systems and will not be a substitute of it.

In order to support this recognition, process the ECPhA introduced a common "CPE currency": the European CPE Credit (ECPEC – European Continuous Pharmacy Education Credit).

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

Europe

ECPhA will work to obtain signed agreements with national accreditation bodies from European countries. For a full and updated list of signed agreements in Europe please visit www.ecpha.eu. The countries with which the ECPhA has signed agreements will automatically recognise ECPhA credits.

Countries who have not yet signed an agreement with ECPhA may still recognise ECPhA credits on a voluntary basis. However, participants will also need to apply to the central or relevant regional accreditation authority in these countries.

International accreditation bodies

ECPhA could also obtain signed agreements with international accreditation bodies from outside Europe. The same conditions apply than for the accreditation bodies from European countries.

3. Glossary

Accreditation

A voluntary process in which an institution, organisation or agency submits to an in-depth analysis to determine its capacity to provide quality continuing pharmacy education in accord with standards, policies and procedures.

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.

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 e-learning component of the module separately.

Commercial Interest

A 'commercial interest' is any entity producing, marketing, re-selling, or distributing health care goods or services consumed by, or used on, patients. Providers of clinical service directly to patients are not 'commercial interests.'

Continuing Pharmacy Education (CPE)

Continuing education for the profession of pharmacy is a structured educational activity designed or intended to support the continuing development of pharmacists and/or pharmacy technicians to maintain and enhance their competence. Continuing pharmacy education (CPE) should promote problem-solving and critical thinking and be applicable to the practice of pharmacy.

Continuing Professional Development

A self-directed, ongoing, systematic and outcomes-focused approach to lifelong learning that is applied into practice. It involves the process of active participation in formal and informal learning activities that assist in developing and maintaining competence, enhancing professional practice, and supporting achievement of career goals.

E-learning material

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.

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. It does not include abstract/open paper/slide/poster presenters, speakers in non-CPE sessions, speakers in industry symposia and other non- accredited sessions.

Faculty should be selected based upon their knowledge of the subject matter; experience and teaching ability; and ability to meet the educational needs of the pharmacists.

Live educational event (LEE)

A meeting/event, the primary purpose of which is the provision of educational material of a pharmaceutical nature to pharmacists, with the aim that they will achieve educational benefit. It requires presence of a participant on the event's site. 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 pharmacists 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 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 an e-learning material if it complies with the criteria for the accreditation of e-learning materials.

Needs assessment

Identification of educational needs of the pharmacists and/or pharmacy technician that serve as the basis for planning CPE activities.

National Regulatory Authority

National Regulatory Authority is the national authority that delivers pharmacists the right to practice pharmacy.

Organising/Scientific Committee

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

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.

4. Who is eligible to apply for CPE accreditation?

ECPhA considers accreditation events submitted by:

- an individual pharmacist or a technician representing entity responsible for continuing pharmacy education
- a university or hospital department
- a scientific pharmacy society
- a national pharmacy association
- a pharmacy communication agency
- a professional congress organiser (PCO)
- applications by other types of providers will be considered on a case by case basis

as long as the application is supported by a person or entity who will take responsibility for the application.

5. ECPhA general principles

ECPhA provides accreditation for pharmacy education of the highest quality, thus supporting the best and most up-to-date patient care in Europe. In order to guarantee this high-level education, ECPhA has set the following principles:

Educational needs and learning objectives

- a needs assessment has to be performed prior to the LEE;
- learning objectives and educational outcomes have to be defined.

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

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 LEE.

Learners' engagement and feedback

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

Quality control

- ECPhA will randomly perform on-site quality controls of accredited events to ensure compliance with ECPhA accreditation criteria.

Other healthcare professionals

- ECPhA will consider supporting accreditation for other healthcare professionals (other than pharmacy) in collaboration with their relevant professional bodies.

6. Requirements for the accreditation of a CPE/CPD activity

All the criteria below are ESSENTIAL criteria.

THE PROVIDER MUST:

1. Structure the LEE to fulfil defined educational needs.

A needs assessment must be carried out prior to the development of a CPE/CPD activity. The provider should identify gaps between what pharmacists currently know or do and what is needed and desired in practice. Providers should identify the root of the identified gap (i.e. the specific knowledge, skill, attitude, experience) which should inform the activity, learning objectives, active learning exercises, and outcomes.

There are different types of needs assessment:

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

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

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

2. Define the "target audience" for whom the LEE is most likely to be suitable.

The target audience must fall within the remit of ECPhA (fully qualified pharmacists and technicians). The target audience must therefore be explained in terms of specialty and seniority of the learner.

An ECPhA accredited event is open to all interested pharmacists and other healthcare professionals, not only those fitting the described target audience.

ECPhA certificates can therefore be distributed to any other healthcare professional attending the accredited event (i.e. nurses, physicians, clinical scientists ...) who wishes to benefit from ECPhA credits. It is expected that the healthcare professional's association will recognise the ECPhA credits on a voluntary basis.

3. Identify and communicate the expected educational objective(s) of the LEE.

An expected educational objective is a formal statement of what participants are expected to learn in an event. Expected learning objective statements refer to specific knowledge, practical skills, areas of professional development, attitudes, higher- order thinking skills, etc. that faculty members expect participants to learn, develop or master after attending the event. Objectives must be: specific and measurable, developed to specifically address the identified educational need, addressed by an active learning activity and covered by a learning assessment.

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

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

A list of educational objectives must be provided.

4. Provide the title of the LEE, its venue, date(s), and a clear description of the nature of the event.

Title: must be identical with the title used in all materials related to the event. It is not permissible to have an industrial sponsor's or a commercial product's name in the title of the event.

Venue: ECPhA deals with the accreditation of international events in Europe and outside of Europe (with the exception of countries with which the ECPHA might sign agreements of mutual recognition of credits).

For international events in Europe, ECPhA will seek to have the approval from the National Accreditation Authority or other institution in charge, if applicable, of the country where the event takes place.

For international events outside of Europe, ECPhA accepts to consider such applications if these events are open for European participants and/or faculty to attend the event.

However, ECPhA encourages the accreditation of international events outside of Europe even though there are no European participants and no European faculty. In this case, ECPhA accreditation is considered as a "mark of excellence". For those events ECPhA will apply the standard ECPhA criteria. These events should attract participants from several countries. The application and programme must be submitted in English.

Date: ECPhA will accept one set of dates per event. A separate application must be submitted for each

repetition of the same event.

Nature of the event: You will need to state whether the event is a:

- Congress
- Conference
- Course
- Satellite symposium
- Hands-on workshop
- Other: applicant needs to clarify...

ECPhA will NOT consider for accreditation commercial symposia.

THE LEE MUST:

5. Be presented in a manner suitable for an international audience.

ECPhA accredits educational events across the world (with the exception of countries with which the ECPHA might sign agreements of mutual recognition of credits). The programme submitted with the application needs to be available in English.

International terminology for procedures and therapeutic agents must be used.

6. Include methods to promote active learning.

ECPhA encourages the use of methods promoting adult active learning. The methods used can be one or a combination of the following: discussion time, quiz, Q&A session, training session, groups, open space, electronic communication, other (applicant needs to clarify).

7. Be conducted in compliance with all relevant ethical, medico-legal, regulatory, industry-based and legal requirements.

THE PROVIDER MUST:

8. Provide detailed information on the duration of the LEE.

The provider will need to state the starting time and ending time for each day of the programme (including lunch breaks and coffee breaks), together with the number of educational hours per day and for the whole event.

Only purely scientific sessions will be considered for accreditation.

Therefore, commercial sessions, coffee/lunch breaks, opening/closing ceremonies, assessments etc. will not be awarded ECPEC.

9. Indicate the mechanism(s) by which it will be verified that the learner has engaged with the LEE in order to fulfil the educational objective(s).

Simple registration of attendance at the event is not sufficient.

You will need to explain how the participants' attendance is monitored during the event and to include in

the learner's feedback form questions related to the relevance of the content and speakers.

10. Provide a short description of the Provider organisation(s).

The Provider must submit a short description of its own organisation, and any other(s) with which they are working with regard to the LEE. Where the Provider is a CPE company producing a programme on behalf of or supported by another organisation (e.g. pharmaceutical or device manufacturer) their relationship must be fully disclosed, and any financial sponsorship must be under the form of an unrestricted educational grant.

11. State the name and job title of the individual responsible for preparing the LEE.

This person cannot be a pharmacist/professor/member of staff working for the industrial sponsor or educational company of the LEE.

12. Provide the name, title and contact details of the person and or entity who will take responsibility for the application for accreditation of the LEE. This person or entity must be registered with a National Regulatory Authority and his/her registration details must be provided.

The person or entity who will take responsibility for the application is the person who will complete and sign the director's declaration to be provided at the time of the application .

13. Provide the name(s), job title(s) and contact details of the head, and all other members of the Organising and/or Scientific Committee.

See template "Organising/Scientific Committee" to be completed and provided at the time of the application.

No member of the industrial sponsor's (of the LEE) staff is allowed to be on the Scientific/Organising Committee.

14. Ensure that all members of the Organising and/or Scientific Committee provide written declarations of potential or actual conflicts of interest.

Each member of the Scientific/Organising Committee must state its financial interests for the last three years. The COI forms must be dated and signed. The COI forms of the members of the Scientific/Organising Committee must be provided at the time of the application.

The COI forms of the members of the Organising/Scientific Committee must be made available online on the event website and in the printed scientific programme.

Providers who have been granted the status of "Trusted Provider" do not need to supply the COI forms at the time of submission of the application but the forms have to be completed before the LEE takes place and have to be available for an on-site control by ECPhA.

15. Confirm that any actual conflicts of interest have been resolved.

This criterion is applicable to members of the Organising/Scientific Committee and is the personal responsibility of the scientific head of the faculty (including chairmen, moderators, presenters...).

The provider must ensure that any actual conflict of interest has been resolved. This can be done in several ways:

- Every faculty member must provide a declaration of COI as a second slide of his/her presentation.
- The evaluation form completed by participants must include a question on the faculty's bias.
- The COI form of all members of the Organising/ Scientific Committee and faculty must be made available in the printed scientific programme and on the event website.
- The Member of the Organising/ Scientific committee or faculty with a COI is excluded from the preparation of the scientific programme.
- 16. Ensure that all members of the Faculty provide written declarations of potential or actual conflicts of interest.

All members of the faculty must provide written declarations of COI. These declarations must not be submitted at the time of the application but must be made available in case of on-site control by the ECPHA.

17. Provide the latest version of the programme of the LEE at the time of application.

The programme must contain as a minimum:

- details of faculty members
- titles of lectures, etc.
- start and end time of individual lectures, workshops and sessions
- overall expected learning outcomes

The conflict of interest from a member from the industry to be on the scientific programme needs to be approved by the applying person/entity and by ECPhA.

ECPhA will not permit major changes to the programme following confirmation of accreditation. Major changes will require a new application to be submitted.

Following the LEE, the Provider will send the final version of the programme to ECPhA highlighting any differences from the version submitted with the original application for accreditation.

18. The source(s) of all funding for the LEE must be declared and be made available to Learners in a readily accessible manner.

The source of all funding must be declared. Funding can occur via:

- provider's own funds
- participants' registration fees
- unrestricted educational grant from sponsor
- exhibition booths during the event
- commercial symposia organised during the event (not eligible for accreditation)
- advertisements outside the scientific programme
- provision of a range of tools during the event
- if other: please specify

Sponsorship (from one or more sponsors) of an event can only be considered as long as the grant is in the form of an "unrestricted educational grant" and all other ECPhA's LEE criteria are met.

ECPhA reserves the right to ask for the contractual arrangement between the provider and the sponsor.

THE ORGANISING AND/OR SCIENTIFIC COMMITTEE MUST:

19. Ensure that the LEE will provide a programme that presents a scientifically balanced perspective of

the subjects included.

This must include impartiality in the scheduling of subjects, lecturers and opportunity for discussion.

20. Confirm that it has determined the content of all aspects of the LEE to be free of any attempt by sponsors to influence the Committee's decisions.

All funding must be provided free of any attempt to influence the programme, individual sessions, subjects for discussion, content or choice of faculty members.

In the case the sponsor is a pharmaceutical or medical device industry, the sponsor cannot be directly involved in the provision of the event. The sponsor therefore cannot:

- Invite participants and speakers
- Cover travel/accommodation costs of participants and speakers
- Take part in the organisation of the event (invitation of participants, registration of participants, staffing, catering, speaker's fees...)
- Take part in the development of the scientific programme (no funding company member on Organising/ Scientific Committee, no influence on the choice of the speakers/selection of topics...)
- Be on the scientific programme (no speaker from the industry will be allowed on the scientific programme...).
- 21. All educational material must be free of any form of advertising and any form of bias.

ECPhA will reject any application that, in its opinion, includes advertising of any product or company directly related to any educational material. The educational content must be presented with full disclosure and equitable balance.

Guidance:

The provider must:

- ensure independence in planning and delivery of CPE activities, and
- implement a mechanism to prospectively identify and resolve conflicts of interest during the planning process, and
- use commercial support appropriately, and
- manage commercial promotion appropriately, and
- present content that is without commercial bias, and
- disclose required information.

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

- the use of a sponsor's name in the title of the scientific programme, a scientific session or a scientific lecture:
- the display of brand names and/or individual company logos in scientific lectures or in the scientific programme.

ECPhA will accept a single page acknowledgement, clearly separated from the scientific programme, where all sponsors are recognised for their support of the LEE. The details of industry satellite symposia (title, speakers, sessions, sponsors...) may only be published in a separate section after the scientific programme.

All advertising components (including the listing of exhibitors) must be clearly separated and distinguished from the scientific/educational components of the programme and identified as such.

The event website cannot be hosted on the industry sponsor's website and cannot bear the industry

sponsor's logo (except under a separate tab "sponsor" where the sponsor will be acknowledged).

Full instructions on the acknowledgement of sponsors and sponsored symposia in the event material are available in chapter XVI.

Where there is a valid evidence base for a specific therapy or agent, this may be stated, but this must be referenced in a manner that is appropriate for a scientific journal. Only generic names will be permitted.

THE PROVIDER MUST:

22. Submit information regarding the expected total number of participants attending the LEE and the schedule of registration fees for these Learners.

Expected total number of participants:

This number includes all participants in the event whether they are specialist pharmacists or not. It also includes speakers and exhibitors/sponsors participating in the event.

The applicant will have no right to reduce the expected number of participants after submission of the application.

Registration fee:

A LEE may be provided free of charge but only if all participants are admitted without fee (supported for example from an unrestricted grant or subsidised by a scientific society...) and there is no sponsorship from industry.

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

Providers are encouraged to ensure that a feedback form is completed by the participants at the end of the event. The feedback form must include questions on the lecturer, presentation, content, value of each session and possible bias.

The Applicant will provide the blank Feedback Questionnaire that will be distributed to participants at the event.

Participants will only be able to receive their certificate of attendance once they have completed the feedback form. They can only receive the number of credits corresponding to their actual attendance.

Based on the participants' individual feedback, the provider must submit a feedback report (better known as "event report") to ECPhA within four weeks of the completion of the event. This report must include the participants' feedback, information on the total number of participants and any perception of bias by participants. Failure to provide feedback could jeopardise recognition of any future applications.

Appendix 1: participant's evaluation form Appendix 2: provider's feedback report

24. Confirm that it will comply with the applicable national rules, regulations and industry standards regarding exhibition areas where companies are permitted to present their products.

The provider has a duty to check if special arrangements regarding accreditation and recognition of CPE

credits apply in the country/region where LEE takes place. ECPhA strives to monitor local regulations but it is not always notified of local changes in a timely manner and the provider has responsibility to make sure that participants, particularly local participants, will have their CPE credits recognised.

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

The recommended time for submission of an application is at least 14 weeks from the planned start date of the event. The latest date for receipt of a fully completed application form, supporting documents and confirmed payment of the ECPhA fee is 12 weeks before the planned start date of the event. A different timeline applies to trusted providers (see point 12).

The whole evaluation process should take no more than 7 weeks from the moment the applicant has been informed by ECPhA's office that the application is complete, and payment of the accreditation fee has been received. The application will be then sent out for review.

Every time there is a delay in the process for which the applicant is responsible (i.e. the reviewer(s) have questions for the applicants for which an answer is pending...), 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.ECPhA.eu
- No applications sent on paper or by email will be considered.
- ECPhA will not accept late applications.
- As applications can only be received in English, applicants will be responsible for the translation of all submitted materials when needed.

In order to have an application for accreditation considered by ECPhA the applicant must:

- submit a fully completed application, in English, via the ECPhA platform;
- provide this completed application form, with all relevant attachments and full payment for the application, no less than twelve weeks from the planned start date of the LEE, and preferably more than fourteen weeks;
- ensure that suitable information has been provided for each of the essential criteria;
- provide confirmation by the pharmacist who is taking responsibility for the application.
- provide confirmation by the Scientific Head of the Faculty who is taking responsibility for the scientific programme.

ECPhA commits to:

- providing all needed information and supporting documents via the ECPhA platform
- ensuring confidentiality regarding the application submitted;
- confirming for the Applicant the following dates:
 - a. on which the ECPhA application was made,
 - b. on which the ECPhA application was complete,
 - c. on which the application fee was cleared,
 - d. the "starting date" on which the ECPhA has begun its evaluation which will be determined by the above two criteria (b & c) having been met,
 - e. completing the accreditation process 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;

- following its published accreditation process;
- providing, via the ECPhA website, a progress record that is accessible by the Applicant;
- publishing, on the ECPhA website, the list of accredited events

Criteria and decision-making for accreditation

1. The Material and the application form will be reviewed simultaneously by the three ECPHA designated reviewers:

The ECPhA will be solely responsible for appointing these designated evaluations bodies.

- 2. For a positive decision by the ECPhA reviewers, all essential criteria set out in this document must be confirmed. The three designated reviewers also will be required to confirm whether, according to their assessment of the information provided, the application is for an activity that fits within the ECPhA's definition of a LEE, and whether the stated learning objectives are likely to be achieved.
- 3. In order for the ECPHA to accredit the material, both designated reviewers must support the application.

Amendment Procedure

- 1. The ECPhA recognises that some applications will fulfil almost all the criteria needed for accreditation but may not achieve the standard required for a small number of criteria. In accordance with its remit to encourage the improvement of the quality of CPE/CPD, the ECPhA will permit the Applicant, following request by the ECPhA, one opportunity to provide additional information.
- 2. Following activation of the amendment procedure, the clock for the processing time will stop pending receipt of the requested information or documents from the Applicant, and the deadline for ECPhA to provide their decision will be extended accordingly. Other than through the mechanism of appeal (see below), this decision by the ECPhA shall be final.

Automatic Reconsideration

Should the two ECPhA designated reviewers differ in their assessments, an automatic reconsideration will be triggered by the ECPhA system. This automatic reconsideration will be performed at no further cost to the Applicant and will be completed within the timescale applicable for a regular review. Automatic reconsideration will involve review by the three ECPhA designated reviewers and the ECPhA Chief Operating Officer

Appeal

- 1. Should both ECPhA designated evaluation bodies reject the application, the Applicant may still appeal. A decision to appeal must be lodged within one week and must be accompanied by full payment of the appeal fee. The appeal process will require a further two weeks from the date that the appeal was received. The fee will be € 250 for all such appeals.
- 2. The mechanism of the Appeal will be:
- the ECPhA Chief Operation Officer (or his/her nominee) will review all the information provided on the application form and any additional permissible correspondence. The ECPhA Chief Operating Officer

will then discuss the application with the three CPhA designated reviewers;

- the four will vote on the Application, with a majority (3:1) decision being permitted to confirm accreditation;
- the appeal decision of the ECPhA will be final.

8. Outcomes

- 1. Until confirmation of accreditation has been sent to the Provider, the only permissible statement that can be made by the Provider on material related to the LEE is "An application has been made to the ECPhA for CPE accreditation of this event".
- 2. Confirmation of accreditation of the LEE by the ECPhA will permit the Provider to use a statement to this effect (prepared by the ECPhA) on and within the material. This will be confirmed on the ECPhA website, where the maximum number of credits granted will be stated. Only after confirmation of accreditation has been received can the Provider use the ECPhA logo on material related to the LEE.

The logo may only be used in conjunction with, and in proximity to, the ECPhA 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 ECPhA accreditation statement.

- 3. Accreditation by the ECPhA of a LEE will be for the specific event designated on the application form. It is not permissible to transfer this accreditation to any other event.
- 4. Where a website, an electronic communication or a printed material lists ECPhA-accredited LEEs along with non-accredited LEEs, the provider must assure that learners can easily recognise the accreditation status. Listing a LEE not accredited by the ECPhA in a misleading way, suggesting that ECPhA has also accredited it, will lead to withdrawal of accreditation.

9. Major causes for rejection of an application at the level of initial review

- 1. Failure by a provider to disclose the means of funding of a LEE will lead to rejection of the application.
- 2. Grossly or significantly inaccurate attendance declarations will lead to automatic rejection of the application and any future application.
- 3. The Applicant must not attempt to influence the decision of the ECPhA. Specifically, any attempt to contact the reviewers of the application will result in automatic rejection of the application and forfeiture of the fee.
- 5. The use of any statement by the provider that suggests that accreditation has been granted or has been provisionally granted while the application review process is not yet completed with positive outcome will result in automatic rejection of the application.
- 6. Any unauthorised/inappropriate use of the ECPhA logo will result in action being taken by the ECPhA.

10. <u>Allocation of European CPE Credits - ECPEC</u>

The ECPhA awards credits on the following basis:

One hour of LEE CPE activity = 1 ECPEC credit

1 accredited hour of LEE = 60 mins of actual educational activity.

A participant can claim a maximum of 8 credits per day of the LEE.

It must be emphasised that:

the ECPhA does not award fractions of credits.

Pharmacists must only claim credits for those LEEs, or parts of LEEs that they have attended, and should ensure that they do so in accordance with their home country's criteria.

11. ECPhA fees

The fee for an application to the ECPHA for the accreditation of LEEs is determined in accordance with the expected total attendance of Learners and is not dependent on the number of credits awarded. As with any contractual agreement, all invoices must be paid.

1-100 participants: 175 euros
101-250 participants: 375 euros
251-500 participants: 675 euros
501-1000 participants: 1000 euros

1001-2000 participants: 1300 euros2001-5000 participants: 2550 euros

More than 5000 participants: 4400 euros

The ECPhA 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.

The applicant will have no right to reduce the expected number of participants after submission of the application.

12. Quick application checklist for providers

The following information is necessary to complete the application form template:

Description of the live educational event

o Event title: Please note that the use of an industry sponsor's or a commercial product's name in the event title will lead to automatic rejection of your application.

- o Event website: The event website cannot be hosted on the industry sponsor's website and cannot bear the industry sponsor's logo (except under a separate tab "sponsor" where the sponsor will be acknowledged).
- o Venue: Multiple venues for the same educational event require separate applications.
- o Start date end date: Only one date or set of dates is permitted for each event. A separate application must be submitted for each repetition of the same event.
- o Duration of the event: Please state starting time and ending time for each day of the programme (including lunch breaks and coffee breaks), together with the number of educational hours per day and for the whole event.
- o Target audience: Specify the speciality and seniority of the pharmacist(s) most likely to benefit.
- o Main specialty of the event: Please select the main specialty of the event. The ECPhA reserves the right to change the specialty of the event.
- o Expected total number of participants
- o Educational needs
- o Expected educational outcomes
- o Clear description of the nature of the event
- Methods to promote active learning
- o Confirmation of learner engagement
- o Compliance with all relevant ethical, pharmacy-legal, medico-legal, regulatory, industry-based and legal requirements
- o International audience
- o Main language of the event
- o Simultaneous translation

Details of the provider

- o Short description of the provider organisation(s): The provider must submit a short description of their own organisation, and any other(s) with which they are working
- o Lead person(s)/organisation(s) responsible for the preparation, planning and administration of the LEE
- o Person or entity who will take responsibility for the application

Organising and/or Scientific committee

- o Name, professional affiliation(s) and contact details of the Head of the Organising and/or Scientific Committee who will be personally accountable for the educational content of the event.
- o Name professional affiliation(s) and contact details of the members of the Organising and/or Scientific Committee
- o Please explain how any actual conflicts of interest involving members of the Organising and/or Scientific Committee have been resolved

Faculty

o Confirmation that all members of the faculty have provided written declarations of potential or actual conflicts of interest (tick box)

Funding of the LEE

- o Sources of all funding: Name of sponsor(s) / Type of funding / Details of pending applications for funding
- o Schedule of fees for learners
- o Confirmation that all funding is provided free of any attempt to influence the programme, individual sessions, subjects for discussion, content or choice of faculty members (tick box)

Promotional material

- o Confirmation that all the educational material is free of any form of advertising and any form of bias (tick box)
- o Confirmation that the event complies with the applicable national rules, regulations and industry standards regarding exhibition areas where companies are permitted to present their products (tick box)

Review by learners

- o Means for the learners to provide feedback on the LEE
- o Commitment to making available to the ECPhA a report on the learners' feedback and on the provider's responses to these (tick box)

Contact and billing information

- o Contact person for the application
- o Billing information

Documents to be uploaded in addition to the application form template

- o Latest version of the programme including: 1) details of faculty members, 2) titles of lectures, etc., 3) start and end time of individual lectures, workshops and sessions, 4) overall expected learning outcomes.
- o Programme overview (if available)
- o Director's declaration: To be completed and signed by the person taking responsibility for the application
- o Template Organising/Scientific Committee: To be completed with the names and details of all the members of the Organising/Scientific Committee
- o Conflict of interest disclosure form: To be provided for each member of the Organising/Scientific Committee. To be completed and signed by each member of the Organising/Scientific Committee
- o Learner's feedback form (evaluation form)
- o Event report (to be submitted no later than 4 weeks after the event has taken place)
 - Final programme (following the LEE highlighting any differences from the version submitted with the original application)

13. Quick application checklist for Trusted Providers

Please see "quick application checklist for providers".

Trusted providers do not need to provide:

- 1. COI disclosure forms for all the members of the Organizing/Scientific Committee at the time of the application. However, these must be available at the time of the event for possible on-site control by the ECPhA.
- 2. Payment of the accreditation fee at the time of the application. However, the payment must be received before the finalisation of the evaluation procedure.

14. Sanctions

Sanction if the final programme of the LEE is not compliant with ECPhA criteria

If the final programme that will be distributed to the participants at the LEE in a printed or electronic form differs from that accredited by ECPhA for this LEE and is not compliant with the ECPhA's criteria, the provider will be fined (€ 500) and will not be allowed to apply for accreditation for

- The following edition of its event in the case of an annual event
- The next 6 months in the case of any other event

15. <u>Instructions regarding event material such as announcements, posters, programme booklets, websites, website programmes, etc.</u>

INDUSTRIAL SPONSORS

All educational material must be free of any form of advertising and any form of bias. The ECPhA will reject any application that, in its opinion, includes advertising of any product or company directly related to any educational material (essential criterion).

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

- the use of a sponsor's name in the title of the scientific programme, a scientific session or a scientific lecture;
- the display of brand names and/or individual logos in scientific lectures or in the scientific programme.

The ECPhA will accept a single page acknowledgement, in the scientific programme, where all sponsors are recognised for their support of the LEE. The details of industry satellite symposia (title, speakers, sessions, sponsors...) may only be published in a separate section after the scientific programme. All advertising components (including the listing of exhibitors) must be clearly separated and distinguished from the scientific/educational components of the programme and identified as such.

In case of sponsorship being in the form of material used for hands-on courses (i.e. surgical instruments, equipment and any other medical devices etc.), the providers need to include in the programme a

statement informing the participants that there is a variety of different similar products that they can use beyond the ones provided at the event.

1. Programme booklet

Adverts and names of companies must not appear next to scientific and educational information. The booklet should be divided into two parts:

- I. A first section for all the scientific/educational information, such as:
- President's foreword, invitation, scope of the event, scientific/organising committees, list of faculty, programme overview, scientific programme etc.
- Within the scientific programme and overview, sponsored symposia should be identified as such, but the names of the sponsors must not be mentioned, neither the details such as title, speakers, etc. You therefore indicate them with a formula such as "industry-sponsored symposium";
- Within this first "scientific" section, must not appear adverts, acknowledgements of sponsors etc. Unless is clearly stated that the ads have no connection to the scientific programme and have been placed randomly in the programme book.
- II. A second section for all the other information, such as:
- Registration, venue, etc.
- Acknowledgement of sponsors, where the names and logos of sponsors may appear;
- (detailed) list of sponsored sessions, with the titles, speakers, names and logos of sponsors;
- Advertisement from industry.

Industry names/logos may also not appear in the vicinity of the ECPhA accreditation statement.

Commercial adverts may not be printed on the second page (inside front cover) and inside the first section (scientific/educational information section) of the programme booklet. Unless is clearly stated that the ads have no connection to the scientific programme and have been placed randomly in the programme book. Sponsors' names and logos may not appear on the front cover of the programme.

2. Website

The same principle applies, whereby industry names/logos may not appear alongside scientific/educational information. In this respect:

- I. All versions of the programme (pdf and other "uploads", as well as programmes as webpages) must respect the rules above;
- II. Sponsors' names and logos, as well as adverts from industry, may not appear on the home page, on all the pages with scientific/educational information, and ideally should be placed under a separate tab dedicated to sponsors; again, do not have commercial logos where you will place the ECPhA accreditation statement. If any sponsors' names and logos are included in the website, it should specifically state the word "advertisement", to clearly differentiate it from the scientific programme.

16. 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 ECPhA accreditation system of live continuing pharmaceutical education events pursuant to the online process provided on the website http://www.ecpha.eu

"The ECPhA", "Ourselves", "We" and "Us" refer to the Belgian international non- for-profit organization European Council for Pharmacy Education Accreditation (ECPhA), having its registered seat at B-1200 Brussels (Belgium), Boulevard Brand Whitlock, 87 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 ECPhA website (http://www.ecpha.eu) and shall govern any service or any product supplied by the ECPhA 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 ECPhA accreditation application launched by it.

INTELLECTUAL PROPERTY RIGHTS

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

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

Only after confirmation of accreditation has been made can the Applicant use the ECPhA logos on material related to the live educational events. Any unauthorized use of these logos will result in action being taken by the ECPhA, including, but not limited thereto, legal proceedings.

CONFIDENTIALITY

The Applicant commits not to inform or disclose to third parties any confidential information regarding the ECPhA, its contractors, employees, suppliers, representatives, advisors, agents and/or any related company, except in case of a prior express consent in writing by the ECPhA. This obligation shall apply throughout the duration of the contract between the ECPhA 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 ECPhA 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 ECPhA accreditation application relating to a live event is determined in accordance with the principles set forth in the "Accreditation of Live Educational Events by the ECPhA" document which is available through this following weblink: www.ecpha.eu

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

The fee for a ECPhA accreditation application relating to a live event is determined in accordance with the expected total attendance of learners. The Applicant shall submit in good faith the number of learners expected to attend the accredited live educational event. If the Applicant submits a number of learners that is clearly below the number of learners that should reasonably be predictable, the ECPhA reserves the right to refuse any future application of this Applicant and to send an additional invoice based on the actual number of learners who attended the live educational event.

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 ECPhA reserves the right, in its sole discretion, to change its fees at any time. A ECPhA 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 ECPhA 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 ECPhA 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 ECPhA 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 ECPhA 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 ECPhA 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 ECPhA for damages that are the consequence of its failure to fulfil the contract shall, in any case, be limited to DATA.

The Applicant shall indemnify and hold harmless the ECPhA, 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 ECPhA by the Applicant, the ECPhA 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 ECPhA 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 ECPhA 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 ECPhA. 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 ECPhA without any additional charge or fee.

Once the application has been sent to review, the ECPhA will not accept any postponement anymore, except in exceptional circumstances to be duly justified by the Applicant and upon written acceptance of the ECPhA.

INCOMPLETE APPLICATION POLICY

If the Applicant does not complete his/her/its application within the deadlines set by the ECPhA, 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 ECPhA of their personal data, in accordance with the ECPhA Privacy Policy and any applicable privacy regulation. The ECPhA reserves the right to suspend the processing of any application until all necessary data has been provided. The ECPhA 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 ECPhA 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 ECPhA 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 ECPhA literature or via the ECPhA's stated telephone, facsimile or mobile telephone numbers.

ECPhA is registered in Belgium under the registration number: 0469.067.848 The registered office is located

at Boulevard Brand Whitlock 87, 1200, Brussels, Belgium.

AMENDMENTS

These Terms and Conditions shall not be amended, modified, varied or supplemented except in writing and signed by duly authorized representatives of ECPhA.

ECPhA reserves the right to change these Terms and Conditions from time to time as it sees fit it being specified that an ECPhA 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 ECPhA 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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