EUROPEAN DIRECTORATE FOR THE QUALITY OF MEDICINES & HEALTHCARE

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Certification of suitability to the Monographs of the European Pharmacopoeia

Rules of the CEP Procedure

1. INTRODUCTION

The Certification of Suitability (CEP) procedure is defined in Resolution AP-CSP (07) 1 adopted by the Council of Europe Public Health Committee (Partial Agreement) (CD-P-SP) in February 2007. It is run in accordance with the provisions of the *Terms of Reference of the Certification of Suitability procedure*, which are included in the *Rules of Procedure of the European Pharmacopoeia Commission,* and which describe the bodies and persons involved as well as their roles.

These *Rules of the CEP Procedure* are issued and maintained by the Steering Committee of the CEP procedure in accordance with the provisions of the abovementioned *Terms of Reference*.

2. INVOLVEMENT IN THE PROCEDURE AND IMPARTIALITY

The individuals and groups involved in the procedure are the following:

- the Steering Committee (SC)
- the assessors
- the inspectors
- the Technical Advisory Boards (TABs)
- the Ad hoc Committee
- the Certification Department of the EDQM (DCEP).

Integrity, independence and impartiality are fundamental principles that must be observed by any public authority or institution, as well as any individuals working for those bodies with a public health duty.
The same ethical principles are essential elements for the quality, legitimacy and credibility of the CEP procedure. This applies equally to SC members, assessors, inspectors, and DCEP staff as well as to any expert called to support the procedure. Measures taken to ensure that these principles are respected are described in the *Code of Practice for the Certification Procedure*. Any interest must be declared using the *Declaration of Interests and confidentiality undertaking of the European Directorate for the Quality of Medicines and HealthCare (EDQM) Group of Experts, Working Parties and Committees* and is handled according to the *Code of Practice*.

3. RULES OF PROCEDURE

3.1. The Steering Committee (SC)

The SC appoints a Chair for three years, renewable once, from amongst its members, preferably by consensus. If no consensus can be reached, a secret ballot is held where a simple majority of the members of the SC decides the outcome. The appointment may also be done in writing, in which case the DCEP collects the opinions and communicates the outcome to the SC.

3.1.1 Meetings

The SC meets at least once a year, on the EDQM premises, in hybrid format or by videoconference.

With the exception of standing experts, the members of this committee may appoint an alternate representing the same group/organisation to replace them in the exceptional event that they are unable to attend a meeting. Alternates have the same role as members in such circumstances.

In the absence of the Chair for a meeting, the SC shall elect an acting Chair from amongst the members present.

The chairs of the TABs are invited to SC meetings to report on their activities and/or to address specific issues. They participate in the SC meetings for the relevant agenda item(s).

The SC may decide to invite to a meeting the chairs or vice-chairs of relevant EU working groups, representatives of authorities or other ad hoc experts to discuss specific topics. These guests do not have any voting rights.

An agenda and any documents for decision shall be made available at least 2 weeks before a meeting. Within 3 weeks after the meeting, draft minutes shall be circulated to the participants in the meeting for review. A consolidated version is then circulated to members for final approval.

Approved meeting minutes shall be circulated to the network of CEP assessors and inspectors as well as to the relevant EU working groups and international partners.

3.1.2 Decisions

Quorum: the deliberations/decisions of the SC shall be valid only if at least a simple majority (half of the members plus one) participate in a meeting (including via videoconference).

The decisions of the SC should preferably be made by consensus. If no consensus can be reached, a vote takes place and the simple majority (half of the members plus one from those participating in a meeting) decides the outcome.

Decisions may also be taken in writing, in which case the same rules apply.

Any document prepared on behalf of the SC is signed by the SC chair (or any person designated by the SC chair).

3.2 The assessors

Assessors are proposed by their relevant authority or by the DCEP and should fulfil the following criteria:

- be a staff member of a competent authority from a Ph. Eur. member state responsible for the evaluation of marketing authorisations, or working for those bodies (external experts); or be a staff member of the DCEP;
- have at least 2 years of experience in assessment of marketing authorisation applications or CEP applications in the relevant field (e.g. chemical assessment, TSE assessment, etc.);
- should not have any direct interest that may impact his/her independence and impartiality.

When these criteria are fulfilled the appointment process is handled by the DCEP. If one of these criteria is not fulfilled, the SC decides on the request for appointment.

The SC may decide to accept assessors from authorities that are not part of the Ph. Eur. member states, but that are observers to the Ph. Eur., and that accept CEPs for their regulatory procedures.

The DCEP invites the relevant assessors to evaluate applications as often as needed, depending on their availability, the number of CEP applications received and the timelines for the applications. The assessors perform the scientific assessment of CEP applications in accordance with the relevant guidelines and operating procedures, and they produce an evaluation report. Assessments may be performed either at the EDQM during scheduled sessions or remotely using secure IT tools.

Where an assessor has not participated in any assessments for 3 years without justification (e.g. illness, leave, etc.) he/she will not be eligible to remain an assessor for the CEP procedure.

The EDQM may organise meetings with assessors to discuss implementation of guidelines or other topics of interest, share experience and network.

3.3 The inspectors

Inspectors are proposed by their relevant authority or by the DCEP and should fulfil the following criteria:

- be a staff member of a supervisory authority from an EU/EEA member state or a Ph. Eur. member state with an MRA with the EU/EEA, responsible for GMP inspections, or working for those bodies (external experts); or be a staff member of the DCEP;
- have at least 2 years experience in GMP inspections;
- should not have any direct interest which may impact his/her independence and impartiality.

When these criteria are fulfilled the appointment process is handled by the DCEP. If one of these criteria is not fulfilled, the SC decides on the request for appointment.

The SC may decide to accept inspectors from authorities that are not part of or do not have an MRA with the EU/EEA.

The DCEP invites the relevant inspectors to carry out either on-site inspections or real-time remote inspections (RTEMIS), depending on their availability and in accordance with the EDQM inspection programme. They contribute to the preparation of an inspection report and to any necessary follow-up actions, including the issuance of GMP certificates or of statements of non-compliance in the EudraGMDP database (inspectors from EU/EEA supervisory authorities).

Where an inspector has not participated in any EDQM inspections for 3 years without justification (e.g. illness, leave, etc.) he/she will not be eligible to remain an inspector for the CEP procedure.

Inspectors may be invited to meetings organised by the EDQM to discuss guidelines or other topics of interest, share experience and network.

3.4 The Technical Advisory Boards (TABs)

The TABs deal with scientific/technical issues related to assessment of CEP applications. The TAB chairs report regularly to the SC.

The TAB members and TAB Chair are appointed by the SC for a period of three years, renewable once. The SC may decide to renew and/or extend further the mandates of the members and the Chair in exceptional cases. If a seat becomes vacant, a call for candidates is initiated by the DCEP and all applications received are submitted to the SC for decision.

3.4.1 Meetings

The TAB meets one to three times a year, on the EDQM premises, in hybrid format or by videoconference. The TSE and Herbals TABs may meet less frequently or may remain dormant, depending on the needs.

The members of a TAB cannot be replaced in the event that they are unable to attend a meeting. If a member fails to attend any meetings for one year without proper justification (e.g. illness, temporary leave, etc.) this should be brought to the attention of the SC, which will decide whether the member should remain in the TAB and whether he/she would be eligible or not for renewal for the next term.

In the absence of the Chair for a meeting, the TAB shall elect an acting Chair from amongst the members present.

The TAB may invite assessors or other ad hoc experts to their meetings to discuss specific topics. These guests do not have any voting rights.

An agenda and any documents for decision shall be made available at least 2 weeks before the meeting. Within 3 weeks after the meeting, draft minutes shall be circulated to the participants in the meeting for review. A consolidated version is then circulated to members for final approval.

Approved meeting minutes shall be circulated to the Steering Committee, to the network of CEP assessors and to the relevant EU working groups.

3.4.2 Decisions

Quorum: the deliberations/decisions of the TAB shall be valid only if at least a simple majority (half of the members plus one) participate in a meeting (including via videoconference).

Decisions of the TAB should preferably be made by consensus. If no consensus can be reached, a vote takes place and a simple majority (half of the members plus one from those participating in a meeting) decides the outcome.

Decisions may be taken in writing, in which case the same rules apply.

3.5. The Ad hoc Committee

Assessors and inspectors participating in the Certification procedure are eligible for membership of the Ad hoc Committee. Calls for candidates are made by the DCEP when needed and volunteers are included on a list of potential Ad hoc Committee members for a period of three years, renewable (for an unlimited number of terms).

Meetings and decisions

The Ad hoc Committee meets when necessary, by videoconference. Participants in a specific meeting are selected from the list of volunteers on a rotational basis and depending on their availability. In each meeting, an assessor, an inspector, the Director of the EDQM (or a backup appointed by the Director) and the Head of DCEP (or a backup appointed by the Head of DCEP) shall participate.

The DCEP staff members involved in the relevant issues are invited to the meeting to present the case for decision. If considered necessary, an additional assessor or an additional inspector involved in a specific item may be invited.

The decisions of the Ad hoc Committee are taken by consensus and are recorded in specific documents.

3.6 The DCEP

The DCEP is in charge of the administration, co-ordination and execution of the CEP procedure, according to the rules established by the SC.

The DCEP organises the meetings of the SC and TABs and prepares drafts agendas and meetings minutes for adoption by the respective committee.

The DCEP works with other EDQM services for the execution of the procedure, including when needed for the use of samples or for advice on the status and content of monographs.

4. RELATED DOCUMENTS

- Annex to the Rules of Procedure of the European Pharmacopoeia Commission (current version)
- Resolution AP-CSP (07) 1 Certification of suitability to the monographs of the European Pharmacopoeia
- PA/PH/CEP (02) 4 Code of Practice for the Certification Procedure (current version).