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**Certification of suitability to the Monographs of the European Pharmacopoeia**

# SUSPENSION OR WITHDRAWAL OF A CERTIFICATE OF SUITABILITY, CLOSURE OF AN APPLICATION

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| Implementation date | 1st July 2024 |

## Revision history of the document

| Revision N° | Date | Reason |
|---|---|---|
| Initial | January 2009 | |
| R4 | July 2014 | |
| R5 | June 2024 | Revised to:<br>- Include updated terminology related to the Decision Making Process (DMP) of the Certification procedure.<br>- Clarify the restoration process for a certificate of suitability (CEP).<br>- Clarify the process related to closure of applications. |

This document describes the policy of the EDQM for suspension or withdrawal of a certificate of suitability (CEP) and for closure of a CEP application in accordance with the provisions of Resolution AP-CSP (07) 1 of the Council of Europe. It also describes the conditions and the process for restoration of a suspended CEP.

## 1. DEFINITIONS

- **CEP**: Certificate of suitability to the monographs of the European Pharmacopoeia, granted by the EDQM.

- **Closure**: Cancellation of an on-going CEP application, where no CEP has been granted yet, made either upon request of the holder of the CEP or by a decision of the EDQM.

- **DMP**: Decision Making Process of the CEP procedure. Two stage process composed of (Stage 1) an internal discussion within the Certification Department of EDQM which may subsequently be presented to (Stage 2) the EDQM *Ad hoc Committee* for decision (see Annexes to the *Rules of procedure of the European Pharmacopoeia Commission*).

- **Expiration:** When a certificate of suitability has exceeded its expiry date (5 years from initial granting), and the CEP holder has not requested its renewal. Expiry of a CEP is definitive.

- **Hearing**: A hearing provides an opportunity for the applicant or the holder of a CEP to submit a written request for re-consideration of a decision taken by EDQM regarding the validity of a CEP or an application for a CEP, either in the context of the EDQM inspection programme or in the context of the evaluation of a CEP application.

- **Restoration:** The process by which the temporary cancellation of a granted CEP (suspension) is reversed. Restoration of a CEP is conditional and requires that the reasons for the suspension have been suitably addressed.

- **Suspension**: Temporary cancellation of a granted CEP made either upon request by the holder of the CEP or by a decision of the EDQM. Under certain conditions, the CEP may be restored.

- **Withdrawal**: Definitive cancellation of a granted CEP made either upon request by the holder of the CEP or by a decision of the EDQM.

## 2. SCOPE

This policy is applicable, but not limited to, the following situations:

### 2.1. Suspension of a CEP:

2.1.1. Following implementation of the decision-making process (DMP) of the Certification procedure, the EDQM may decide to suspend a CEP in the following situations:

- Inspection of a company,
  - carried out by the EDQM, shows non-compliance with EU GMP and/or non-compliance with the dossier submitted for the CEP.
  - carried out by an inspectorate of a European Economic Area (EEA) or of a country with which reliance agreements on GMP inspections have been made, shows non-compliance with GMP.
- When a CEP dossier is not in compliance with the requirements of the Certification procedure and the holder has not submitted suitable information to maintain it.

2.1.2. The suspension of a CEP may also be requested by the holder of a CEP. Typical examples are temporary cessation of production, upgrades or a partial destruction of the production site, or a temporary inability to meet the requirements of a revised Ph. Eur. monograph.

A suspension is normally limited to a period of 2 years. Failure to meet the conditions to lift a suspension (i.e. restoration) leads to the withdrawal of the CEP if no justified extension to the suspension has been requested by the CEP holder and accepted by the EDQM.

2.2. Withdrawal of a CEP:

2.2.1. Following implementation of the DMP, the EDQM may decide to withdraw a CEP, for example, in the following situations:

- After an EDQM inspection,
  - has concluded that urgent action needs to be taken and no corrective actions are considered possible within an appropriate timeframe.
  - has revealed that the CEP dossier consists of falsified data or when there is evidence of systematic falsification of documents on site.
- After suspension of a CEP, when the company is not able to fulfil the requirements of the Certification procedure regarding update of the CEP dossier and/or compliance with GMP (*e.g.* repeated GMP non-compliance even if the inspections are not consecutive).
- When a company refuses to be inspected. This includes any oral or written request from the company to discontinue an inspection, or delaying or restricting access to documents or areas which are considered part of the inspection scope.
- In cases where a CEP dossier is not in compliance with the requirements of the Certification procedure and where the holder is not able or unwilling to, provide critical updates as requested by EDQM.
- If the CEP holder no longer exists or has definitively ceased production of the substance without informing the EDQM.

2.2.2. A CEP may be withdrawn by the holder of the CEP due to, for example, cessation of production, closure of the site, or because the holder no longer wishes to retain the CEP.

A CEP that has been withdrawn cannot be restored. In the future should the CEP holder wish to have a CEP for the same substance then a new CEP application would need to be submitted.

2.3. Closure of a CEP application:

2.3.1 Following implementation of the DMP, the EDQM may decide to close an on-going CEP application in the following situations:

- Inspection of a company,
  - carried out by the EDQM, shows non-compliance with EU GMP and/or non-compliance with the dossier submitted for the CEP.
  - carried out by an inspectorate of a European Economic Area (EEA) or of a country with which reliance agreements on GMP inspections have been made, shows non-compliance with GMP.
- Refusal by a company to be inspected in the framework of the EDQM inspection programme, i.e. the CEP applicant does not fulfil its commitment of willingness to be subject to an inspection.

2.3.2 The assessors of the Certification procedure may decide to close a CEP application in the following situations:

- If, after assessment of the initial application and/or the reply to a deficiency letter, the information provided by the CEP applicant does not demonstrate compliance with the requirements of the CEP procedure, leading to the conclusion that a CEP cannot be granted.
- If the CEP applicant fails to provide an answer to a request for information from EDQM within the given deadline for response when no justified extension has been accepted by EDQM.

2.3.3 A CEP applicant may also request the closure of an on-going CEP application. Fees are not refunded.

**Notes:**

- *A CEP that reaches the 5-year validity period and for which the holder has not submitted a request for renewal expires automatically and is, therefore, invalid at the date of expiry. The CEP cannot be restored. This case is considered outside of the scope of this document.*

## 3. DECISION-MAKING PROCESS (DMP) AND COMMUNICATION TO THE CEP HOLDER

### 3.1. Suspension of a CEP:

Any suspension of a CEP must be justified:

- When initiated by the EDQM in the situations described in point 2 (Scope No 2.1.1) above, following recommendation from the relevant scientific officer (assessor and/or inspector).
- When requested in writing to the EDQM by the CEP holder outlining the reasons for the request and proposing a timetable for its restoration (Scope No 2.1.2).

In both scenarios, the suspension is treated via the DMP of the Certification procedure. As part of this process the recommendation for suspension and any need for additional supportive information is reviewed and the EDQM Ad-hoc committee decides on the suspension of the relevant CEP(s), the conditions for subsequent restoration, and the information to be shared with the relevant authorities, if applicable. The outcome of the DMP is generally rendered within two weeks following initiation of the process. The detailed reasons for suspension and the conditions for restoration of the relevant CEP(s) are communicated to the CEP holder.

### 3.2. Withdrawal of a CEP:

Any withdrawal of a CEP must be justified:

- When initiated by the EDQM in the situations described in point 2 (Scope No 2.2.1) above, following recommendation from the relevant scientific officer (assessor and/or inspector).
- When requested in writing by the CEP holder to the EDQM outlining the reasons for the request (Scope No 2.2.2).

When the withdrawal of a CEP is initiated by the EDQM, a DMP applies. As part of this process the recommendation for withdrawal and any need for additional supportive information is reviewed and the EDQM *Ad-hoc committee* decides on the withdrawal of the relevant CEP(s) and the information to be shared with the relevant authorities, if applicable. The outcome of the DMP is generally rendered within two weeks following initiation of the process. The detailed reasons for withdrawal of the relevant CEP(s) are communicated to the CEP holder.

A DMP is not routinely required when a CEP holder requests a withdrawal of a CEP. However, a DMP may be initiated to review the request and any supportive information provided and authorities may be informed by the EDQM under circumstances where the scientific officers believe there is a public health risk or GMP non-compliance.

### 3.3. Closure of an on-going application:

Any closure of a CEP application must be justified:

- When initiated by the EDQM in the situations described in point 2 (Scope No. 2.3.1) above, by a justified recommendation from the relevant scientific officer (assessor or inspector).
- When advised by the assessors of the Certification procedure in the situations described in point 2 (Scope No. 2.3.2) above and where supported by a justified rationale.
- By a letter from the CEP applicant to the EDQM asking for the closure of the application and explaining the reasons for the request (Scope No. 2.3.3).

When the closure of an on-going CEP application is initiated by the EDQM as described in point 2 (Scope No. 2.3.1), a DMP applies. As part of this process the recommendation for closure and any need for additional supportive information is reviewed and the EDQM *Ad-hoc committee* decides on the closure of the relevant application(s) and the information to be shared with the relevant authorities, if applicable. The outcome of the DMP is generally rendered within two weeks following initiation of the process. The detailed reasons for closure of the relevant CEP application(s) are communicated to the CEP holder.

Any request for the closure of an on-going CEP application made by the assessors as described in point 2 (Scope No. 2.3.2) is reviewed and endorsed by a panel within the Certification Department of EDQM before any closure of a CEP application is implemented. The detailed reasons for closure of the CEP application are communicated to the CEP holder.

## 4. HEARING

When the EDQM has decided to withdraw or suspend a CEP via the DMP process or to close a CEP application, the holder/applicant is given the possibility to submit a written request for re-consideration of the decision(s) (request for hearing). This request must be submitted within 14 calendar days of receiving the decision and should include a fact-based rationale that demonstrates that the decision was unjustified. No new information may be introduced.
Within 14 days of receipt, any suitable request is reviewed by the EDQM Ad Hoc committee via DMP and either the original decision is maintained (i.e. request rejected), or a new decision is implemented.

## 5. INFORMING CUSTOMERS AND AUTHORITIES

Once a CEP has been suspended or withdrawn, the CEP holder must immediately inform its customers of the situation to allow them to take responsibility regarding the substance concerned and any related marketing authorisation or marketing authorisation application (CEP holders responsibilities towards their customers PA/PH/CEP (21) 57).

When confirmed, decisions to suspend or withdraw a CEP become publicly available on the EDQM Certification database along with the reason. In addition, details on decisions to suspend or withdraw a CEP, or to close a CEP application are communicated by EDQM, in confidence, to the relevant authorities of the member states of the Convention on the Elaboration of a European Pharmacopoeia, as well as to the countries/organisations with which special agreements have been made. This is to enable them to take appropriate actions regarding the marketing authorisations or marketing authorisation applications concerned.

## 6. EXTENSION OF A SUSPENSION

A CEP is generally suspended for 2 years. In exceptional cases, the suspension may be extended, provided that the CEP holder submits a justified request for the extension for review by the EDQM before the end of the 2-year period.
The extension to the suspension may be accepted, but if the situation cannot be positively resolved, the EDQM may decide to withdraw the CEP as described in point 3 above.

## 7. RESTORATION OF A SUSPENDED CEP

After a suspension, a CEP may be restored as soon as the conditions for lifting the suspension are met by the CEP holder and there is no other impediment (e.g. no new GMP issue and the dossier is compliant with the requirements of the CEP procedure). The CEP restoration follows the same DMP process as that for the suspension of the related CEP(s). In this case, a revised CEP is granted. The CEP appears as valid in the public Certification database, together with its new revision number. The decision to restore a CEP, are communicated by EDQM to the relevant authorities of the member states of the Convention on the Elaboration of a European Pharmacopoeia, as well as to the countries/organisations with which special agreements have been made.

## 8. RELATED DOCUMENTS

- Resolution AP-CSP (07) 01 Certification of suitability to the monographs of the European Pharmacopoeia
- Rules of procedure of the European Pharmacopoeia Commission.
- PA/PH/CEP (21) 57 CEP holders responsibilities towards their customers