EUROPEAN DIRECTORATE FOR THE QUALITY OF MEDICINES & HEALTHCARE

edqm
European Directorate for the Quality of Medicines & HealthCare | Direction européenne de la qualité du médicament & soins de santé

COUNCIL OF EUROPE
CONSEIL DE L'EUROPE

Certification of Substances Department

HB/CB

PUBLIC DOCUMENT
(Level 1)

PA/PH/CEP (23) 29

Strasbourg, January 2024

Certification of suitability to the Monographs of the European Pharmacopoeia

Guide for declassification of documents pertaining to the CEP procedure

Implementation date	January 2024

1. Introduction

This policy document is drafted having regard to:

- the Resolution Res(2001)6 of the Committee of Ministers on access to Council of Europe documents and

- the Resolution AP-CSP (07) 1 of the Public Health Committee on the Certification of suitability to the monographs of the European Pharmacopoeia (CEP) procedure and

- the Code of Practice for the Certification procedure.

It describes the principles for the declassification of documents pertaining to the CEP procedure, for the purpose of rendering them accessible to the public while ensuring confidentiality of information when necessary.

2. Scope

This policy applies to all documents received or distributed by the EDQM in the frame of the CEP procedure, covering its evaluation and inspection activities.

It covers the declassification of documents for the purpose of rendering them accessible to the public.

It does not cover access to documents by the individuals taking part in the work of the CEP procedure, which is described in the *Code of Practice for the Certification Procedure.*

It does not cover internal documents, which are handled according to the rules established by the EDQM, Council of Europe.

3. Definitions

'Documents' are defined as any content whatever its medium (written on paper or stored in electronic form or as a sound, visual or audio-visual recording) concerning a matter relating to the policies, activities and decisions falling within the activities of the CEP procedure.

'Commercial confidential information (CCI)' is information which is not in the public domain or publicly available and where disclosure may prejudice the economic interest or competitive position of the owner of the information. Disclosure of such information may also harm the interests and reputation of the EDQM in its ability to protect information. CCI is referred to as 'confidential information' in this policy.

4. Need for confidentiality

In the frame of the CEP procedure, the EDQM is committed to finding the best possible balance between transparency and confidentiality and aims to ensure that its processes and decisions are transparent. However, the EDQM is also constrained by the need to:

- protect the confidentiality of the documents received from manufacturers containing CCI and submitted as part of their applications for a CEP, as well as the documents produced by the EDQM and containing these data (eg. assessment reports and inspection reports);

- protect the decision-making processes, decisions, views and opinions of the individuals taking part in the CEP procedure, in particular the experts assessors and inspectors.

Since the disclosure of confidential information in the public domain may prejudice the interests of the owner of the information as well as the interests and reputation of the EDQM, confidential information, as a general rule, shall be protected and shall not be released to the public.

The same principles apply to other documents received or distributed by the EDQM in the frame of the CEP procedure, for example working documents for discussion or decision, meeting minutes including notes and records made by the participants in meetings. Therefore, neither details of decision-making processes nor any detailed documents would be disclosed to the public, with the effect that no detailed information is released unless it becomes public.

Information that is of relevance for the public is made available via the EDQM website (EDQM institutional website), e.g.:

- Draft policies, governance documents and guidelines once approved for sharing with stakeholders, in view of getting feedback (according to the policy "Management of CEP guidelines and operational documents");
- Policies, governance documents, guidelines and other documents once adopted;
- List of certificates of suitability granted and their current status;
- Actions taken on certificates of suitability following GMP or compliance issues for CEP applications.

5. Access to documents and declassification

Documents of non-public nature prepared by individuals or organisations involved in the CEP procedure (e.g. manufacturers, assessors, inspectors, regulators, etc.) shall not be declassified.

Some typical examples (non-exhaustive list) are provided below:

- CEP applications or other data submitted by manufacturers in the frame of the CEP procedure;
- Assessment reports or other documents generated under the EDQM's responsibility;
- Data related to GMP inspections submitted by manufacturers or generated under the EDQM's responsibility, including inspection reports;
- All documents (such as discussion documents, summaries of decisions, minutes, records) related to meetings of the Technical Advisory Boards, AdHoc Committee, Steering Committee, Technical Advice meetings, etc.
- Comments received from stakeholders on draft policies or guidelines during a public consultation as well as the documents compiling these comments and associated decisions.

6. Request for derogation

In the event that a user of a CEP requests to have access to information contained in a classified document related to the CEP procedure, that is deemed absolutely necessary to address a major public health risk during the review of a marketing authorisation application where the relevant CEP is included, a duly substantiated written request shall be submitted to the EDQM via the EDQM HelpDesk.

This request shall include following information:

- the public health risk to address with reference to the relevant CEP and marketing authorisation application;
- the reason for the request (including possible consequences if the request is refused);
- any information that the requester may provide in order to help identify the document(s) to which access is requested;
- the name, capacity/function and employer of the requester (including contact details).

The request will then be forwarded to the CEP Steering Committee for consideration. The CEP Steering Committee will decide on the request and the EDQM will inform the requester of the decision. Permission from the information owner may need to be gathered, which would potentially impact the response time. If the request is urgent, this should also be clearly explained and justified in the request.

If access is granted, documents may be redacted before disclosure in order to protect confidential information contained in them.

7. Reference documents

Resolution AP-CSP (07) 1 of the Council of Europe on the Certification of Suitability to the monographs of the European Pharmacopoeia

Resolution Res(2001)6 on access to Council of Europe documents

Code of Practice for the Certification procedure.