EUROPEAN DIRECTORATE FOR THE QUALITY OF MEDICINES & HEALTHCARE

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

SSCH/HB

PUBLIC DOCUMENT
(Level 1)

PA/PH/CEP (02) 04 4R

Strasbourg, June 2025

Certification of suitability to the Monographs of the European Pharmacopoeia

Code of Practice for the Certification procedure

Implementation date	June 2025

Revision history of the document

Revision N°	Date	Reason
PA/PH/CEP (02) 04 3R	2019	
PA/PH/CEP (02) 04 4R	2025	Implementation of Declaration of Interests for experts database (DOIX) – updates following revision of "*Terms of Reference of the CEP procedure*"

1. Introduction

This Code of Practice sets out the rules to be followed by individuals taking part in the work of the Certification of Suitability to the monographs of the European Pharmacopoeia (CEP) Procedure (Certification procedure), as defined under section 3. Scope.

Integrity, independence and impartiality are fundamental principles that must be observed by any public authority or institute, as well as any individuals working for those bodies with a public health duty. The same ethical principles are essential elements of the quality, legitimacy and credibility of the CEP procedure.

All decisions relating to the Certification procedure must be impartial and must be taken by informed, skilled, experienced professionals who are proposed as assessors or inspectors by their relevant authority or by the EDQM Certification Department (DCEP), as defined in *Terms of Reference of the Certification of Suitability (CEP) Procedure* (Annex 1 of Rules of Procedure of the European Pharmacopoeia Commission. Resolution AP-CSP (07) 1 establishes that assessors that examine applications for a CEP are persons without direct or indirect interests that may compromise the protection of the confidential trade information they have access to. This applies equally to inspectors participating in the inspections of related manufacturing sites as well as to any person participating in the Certification Procedure, including the Steering Committee (SC) members and other ad-hoc experts. Some of these experts may have had previous connections with the pharmaceutical or associated industries and/or other commercial organisations whose business may be related to the Certification procedure and hence this may have (or be seen to have) an impact on their impartiality.

To reassure the stakeholders of the Certification procedure, including the public, that the decisions relating to CEPs are impartial it is important to have in place a robust policy governing the declaration and management of relevant interests to ensure that holding of direct or indirect interests does not compromise the independence and impartiality regarding the specific tasks (assessment or inspection) undertaken by the individuals participating in the Certification procedure.

All participants must commit to protect the confidentiality of information and to declare interests in the pharmaceutical industries or associated industries. The Code also provides guidance on holding and declaring other relevant interests, on how interests that have been declared will be managed, and on maintaining the confidentiality of information.

2. Acceptance of the Code of Practice

To accept this Code of Practice, participants in the Certification procedure fill-in and sign an electronic declaration of interests (DoI) in the EDQM's DoI for experts database, as support of their appointment. Any interest must be declared using the principles of this document.

3. Scope

This Code of Practice applies to the individuals and groups taking part in the Certification procedure, which are described in *Terms of Reference of the Certification of Suitability (CEP) Procedure* (Annex 1 of Rules of Procedure of the European Pharmacopoeia Commission).

- Other ad hoc experts:

Any ad hoc experts appointed by the EDQM to support CEP activities may have direct access to applications for CEPs and must fulfil the requirements of this document.

4. Definitions

In the context of Certification activities, interests may be

- Direct interests in the pharmaceutical or an associated industry:
  - Consultancy
  - Financial interests.
- Indirect interests in the pharmaceutical or an associated industry:
  - Grants or other funding awarded to an organisation/institution;
  - Interests related to close family members.

Each of these interests is further defined below. However, it should be emphasised that some of these definitions cannot cover all possible scenarios.

4.1 Direct interests

- Consultancy to the pharmaceutical or an associated industry shall mean: any activity where the individual taking part in the work of the Certification procedure provides consultancy services/business advice to the pharmaceutical or an associated industry regardless of contractual arrangements or any form of remuneration.
- Financial interests shall mean any economic stake in the pharmaceutical or an associated industry including:
  - Holding of stocks and shares, stock options, equities, bonds and/or partnership interest in the capital of the aforementioned pharmaceutical or associated industry. The holding of financial interests through an investment fund, pension fund and/or interests in non-nominal unit trusts or similar arrangements need not be declared provided that they are diversified (i.e. not exclusively based on the pharmaceutical sector) and independently managed (i.e. the individual has no influence on their financial management);
  - Intellectual property rights including patents, trademarks, know-how and/or copyrights relating to a medicinal product owned by the individual or of which the individual is a direct beneficiary.

4.2 Indirect interests

- Grant or other funding awarded to an organisation/institution shall mean: any funding received from the pharmaceutical or an associated industry by an organisation/institution to which the individual taking part in the work of the Certification procedure belongs, or for which he/she performs any kind of activity, and which is used to support any activity of the Expert whether or not it is related to research work.
- Interests related to close family members: shall mean known interests of close family members.

4.3 Other definitions

There are a number of other definitions relevant to this Code of Practice:

- Close family members shall mean: first-line members of the family of the individual taking part in the work of the Certification Procedure (i.e. a spouse or partner, children and parents).

- Pharmaceutical or an associated industry shall mean: any legal or natural person whose focus is to research, develop, manufacture, control, market and/or distribute medicinal products and their ingredients. For the purposes of this policy, the definition includes companies to which the aforementioned activities are subcontracted.

  In this regard, consultancy companies providing advice or services relating to the above activities, fall under the definition of the pharmaceutical or an associated industry.

  Legal or natural persons that do not fall within the scope of the above definition but (i) control (i.e. own a majority stake in, or otherwise exercise a significant influence in the decision-making processes of the relevant pharmaceutical or associated industry), (ii) are controlled by or (iii) are under common control of – the pharmaceutical or associated industry, shall be considered as pharmaceutical and associated industries for the purposes of this policy.

  Independent researchers and research organisations including universities and learned societies are excluded from the scope of the present definition.

5. Categories of declared interests

Looking at the nature of the declared interests, these can be categorised as follows:

- Category 1:
  - Direct interests
- Category 2:
  - Indirect interests.
  - Any other matter which is not listed in category 1 and that could affect impartiality or could reasonably be perceived to do so.
- Category 3:
  - Any other matters that might be of interest for transparency purposes e.g. a former employment (within the past 3 years) in the pharmaceutical or an associated industry.

6. Declaration of Interests

Electronic Declaration

All participants within the scope of this document, are required to make a full declaration of interests (DoI) which are known and could have an influence on impartiality, using the Declaration of Interests for experts database. The declaration of interests must be submitted prior to appointment.

The declaration must be updated on an annual basis and in case of any significant changes in the individual's interests arising during his/her period of tenure. Prior to performing any activities related to the procedure, (e.g. attendance of meetings, assessments, inspections) , participants should ensure their DoI is up to date.

The declaration is kept in the EDQM's DoI for experts database.

NB If a DoI has already been given in the context of another EDQM activity and is still valid, the EDQM will not require a new submission.

7. Restricting involvement in the activities of the Certification Procedure

Involvement of the individual in Certification procedure activities takes into account the following factors:

- the nature of the declared interest,
- the type of activity.

As a general principle, depending on the activity within the Certification Procedure, different rules apply:

- Requirements for the members of the Steering Committee
- Requirements for assessors and inspectors (including DCEP staff members)
- Requirements for other ad hoc experts

7.1 Members of the Steering Committee

The members of the Steering Committee must not hold interests of category 1. They may hold interests of categories 2 and 3 and need to declare them.

Where an individual taking part in a meeting of the Steering Committee has an interest in an agenda item, this shall be declared during the meeting and recorded in the meeting report. The Chair of the Steering Committee, in consultation with the EDQM DCEP, is responsible for handling conflicts of interests identified during meetings and resolving the outcomes in order to ensure the impartiality of the decisions.

7.2 Assessors, inspectors

Assessors and inspectors must not hold interests of category 1. They may hold interests of categories 2 and 3 and need to declare them. However, where the assessor or inspector holds such interests, this may create or be perceived as creating a conflict of interest for him/her in carrying out his/her duties with respect to a particular application or inspection.

In case any category 2 interests are declared, the assessor or inspector would be restricted from assessment or inspection or any other activities related to the companies in which there is an interest held. See section 8.

7.3 Other ad hoc experts

Ad Hoc experts must not be current employees of the pharmaceutical or associated industry. They may hold other interests of category 1, 2 and 3 and need to declare them. However, where they hold such interests, this may create or be perceived as creating a conflict of interest for them in carrying out their duties with respect to a particular inspection.

This will involve the ad hoc experts being restricted from assessments, inspections or any other activities related to the companies in which there is an interest held. See section 8.

8. Action to be taken following a Declaration of Interests: achieving an efficient process

The EDQM DCEP screens declared interests at the time of appointment of the experts and ensures adherence to the Code of Practice in order to identify possible impediments to taking part in the work of the Certification Procedure.

It is the role of the EDQM DCEP to manage any conflicts of interest that may arise during assessment sessions or inspections and to ensure the impartiality of the decisions.

The working procedures are designed in a way to minimise risks associated with conflicts of interest. For assessment activities, two assessors work as a team for the review of an application and they should agree on the conclusions. EDQM inspections are carried out by two inspectors who should agree on the outcome. For all activities, the EDQM DCEP is in charge of peer-review and ensures that European regulatory requirements and Certification policies are applied.

For assessment activities the allocation of dossiers to assessors is done in a way that the requirements of the Code of Practice are met.

When the assessors receive the draft work programme for the assessment session they will attend, they also have a responsibility to inform the EDQM DCEP of any conflicts of interest for the applications they are assigned to treat, such that the programme can be changed to avoid their involvement in such applications.

For inspection activities, compliance with this Code of Practice is ensured during the preparatory discussions held prior to the inspection being planned.

When the ad-hoc experts are requested to participate in a particular inspection, they also have a responsibility to inform the EDQM DCEP of any conflicts of interest for the inspection such that the programme can be changed to avoid their involvement in such inspection(s).

9. Records: achieving a transparent process

Access to information

The EDQM keeps a record of:

- the names of individuals who declared interests at the time of their appointment or thereafter, together with the declaration of interests;

All completed DoIs may be consulted at the EDQM. Such requests must be made via the EDQM Helpdesk system.

10. Use of data and confidentiality

Working documents means all CEP dossiers, evaluation reports, inspection reports, preparatory information, drafts, documents and any other material (including notes and records made by the participants and related to confidential information/documents), together with any information contained therein, to which access is given directly or indirectly, as a result of participation in Certification procedure activities.

Confidential Information means all information, facts, data and any other matters of which knowledge is acquired directly or indirectly as a result of Certification procedure activities.

Working documents and Confidential Information made available or issued by the EDQM DCEP are for use by the intended recipient and shall not be disclosed to third parties. This shall not be limited in time, but does not apply to information or documents which become public otherwise (e.g. policy documents when published on the EDQM website).

Working documents and Confidential Information made available or issued by the EDQM DCEP shall be used only for the work allocated by the EDQM and shall not be referred to in publications of any kind. This restriction does not apply where an individual taking part in the Certification Procedure has legitimate access to the data via sources other than the EDQM documents or where the EDQM provides public access to a document (for example, policy documents etc.).

Individuals taking part in the Certification procedure shall dispose of such documents as confidential material as soon as they have no further use for them.

11. Related documents

- *Terms of Reference of the Certification of Suitability (CEP) Procedure* (Annex 1 of 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