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Certification of suitability to the Monographs of the European Pharmacopoeia

Code of Practice for the Certification Procedure

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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 4. Scope.

Whilst decisions relating to the Certification procedure must be impartial, they must be taken by informed, skilled, experienced professionals who are proposed as assessors or inspectors by the National Competent Authorities or National Supervisory Authorities, respectively, or by the EDQM (for EDQM staff who undertake the roles of assessors or inspectors). Some of these experts may have or 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.

This Code of Practice is a stand-alone document which is however based on the code of practice established for the work of the European Pharmacopoeia (PA/PH/Exp. ROP/T (16) 2).

2. Independence and Impartiality

Independence and impartiality are fundamental principles imposed on any public authority or institute, or any persons working for those bodies with a public health duty. Individuals who participate in the Certification procedure acquire this status, and their ethical principles and impartiality are essential elements of the quality, legitimacy and credibility of the system.

3. Acceptance of the Code of Practice

Participants in the Certification scheme give a written undertaking as support of their appointment to respect this Code of Practice (see EDQM Form 226).

4. Scope

This Code of Practice applies to the individuals taking part in the Certification procedure, which include the following:

- For the evaluation of dossiers: assessors appointed for the procedure:
  - experts belonging to the national competent authorities responsible for the evaluation of medicines;
  - experts belonging to Official Medicines Control Laboratories;
  - other experts nominated by the national competent authorities and involved in the evaluation of medicines;
  - EDQM staff at time of appointment as assessors.

- For the EDQM inspection programme:
  - official inspectors appointed by the competent supervisory authority of their respective country: member states within the EU/EEA or countries that have a mutual recognition agreement (MRA) with the EU in the GMP sector to carry out inspections according to Article 111.1 of Directive 2001/83/EC as amended;
  - official inspectors appointed by the competent supervisory authority of their respective country or by their organisation to carry out inspections according to their respective legislative framework for countries/organisations with which the EDQM has set up appropriate agreements;
  - EDQM staff with the qualifications specified above at the time of appointment.

- For running the procedure:

the members of the Steering Committee (and their alternates).

- Other ad hoc roles:

Interpreters appointed to assist inspections may have direct access to applications for CEPs and are requested to respect this Code of Practice.

5. Definitions

In the context of Certification activities, interests may be

- Direct interests:
  - Employment with the pharmaceutical or an associated industry;
  - Consultancy to the pharmaceutical or an associated industry;
  - 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.

5.1 Direct interests

- Employment with the pharmaceutical or an associated industry shall mean: any form of occupation, part-time or full-time, paid or unpaid, in a pharmaceutical or associated industry.
- 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.

5.2 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.

5.3 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.

6. 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 in the pharmaceutical or an associated industry.

7. Declaration of Interests

7.1 Written Declaration

All parties within the scope of this Code are required to make a full declaration of interests (DoI) which are known and could have an influence on impartiality, using the standard form provided (see EDQM Form 226). The written declaration of interests must be submitted prior to appointment.

The written declaration must be updated to reflect any significant changes in the individual's interests arising during his/her period of tenure. Such information shall be provided in writing, prior to attendance at the next meeting, assessment session, inspection meeting or inspection and a regular update of the DoI will be requested by the EDQM.

The written declaration is kept by the EDQM.

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.

7.2 Access to information

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

8. 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, inspectors and other ad hoc roles (e.g. interpreters for inspections).

8.1 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 but 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 Certification Division, is responsible for handling declarations of interests identified during meetings and resolving the outcomes.

8.2 Assessors, inspectors and other ad hoc roles

Assessors, inspectors and other ad hoc roles must not be current employees of the pharmaceutical or associated industry.

They may hold other interests of category 1 or interests of category 2 and 3 but need to declare them. However, where the assessor, inspector or ad hoc role 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.

This will involve the assessor/inspector/ad hoc role being restricted from assessment or inspection activities related to the companies in which there is an interest held. See section 9.

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

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

The EDQM Certification Division screens declared interests at the time of appointment of the assessor/inspector/interpreter in order to identify possible impediments to taking part in the work of the Certification Procedure.

For assessment activities such cases shall also be handled during the planning of the assessment session and the actions and decisions to be taken will be decided by the EDQM Certification Division and implemented.

When the assessors receive the draft work programme for the assessment session they will attend, they also have a responsibility to inform the EDQM Certification Division of any conflicts 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 such cases shall be identified during the preparatory discussions held prior to the inspection being planned, and the actions and decisions to be taken will be decided by the EDQM Certification Division and implemented.

When the inspector/interpreter is requested to participate in a particular inspection, they also have a responsibility to inform the EDQM Certification Division of any conflicts for the inspection such that the programme can be changed to avoid their involvement in such inspection(s).

10. Records: achieving a transparent process

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;
- the names of those who have declared interests at a meeting or session or inspection; this is recorded by updating the record for the individual.

11. 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 Certification Division 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 Certification Division 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.