# CODE OF PRACTICE FOR THE WORK OF THE EUROPEAN PHARMACOPOEIA

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**ANNEXE:**

**1.** Handling of unforeseen or complex situations: Best practice recommendations

*All references in this Guide for Work to functions, titles or positions shall be construed as applying equally to men and women.*

## 1 Introduction

This *Code of Practice* sets out the rules to be followed by individuals taking part in the work of the European Pharmacopoeia (Ph. Eur.), as defined under *5. Scope*, if they hold and therefore must declare interests in the pharmaceutical or an associated industry. 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 documents.

Unlike the Committee on Human Medicinal Products (CHMP) and similar committees of the European Medicines Agency (EMA), the European Pharmacopoeia Commission (EPC) is not involved in licensing matters but promotes public health by providing recognised common quality standards for medicines and their ingredients in the form of the Ph. Eur. The EPC adopts the monographs, general chapters and other texts of the Ph. Eur. that are published in the Ph. Eur. and that become legally binding in all signatory parties to the *Convention on the Elaboration of a European Pharmacopoeia*. Its members are therefore not prohibited from holding interests in the pharmaceutical or an associated industry but they must comply with this *Code* in declaring those interests and during their participation in the work.

Whilst decisions relating to the standard-setting process of the Ph. Eur. must be impartial, they must be taken by informed, skilled, experienced professionals who are well regarded in their respective fields. It is to be expected that many experts in the field of standards for pharmaceutical substances and products will have, or have had, connections with the pharmaceutical or an associated industry and/or other commercial organisations whose business is relevant to the work of the EPC and its groups of experts and working parties (hereinafter ‘groups’), and this may have an impact on their impartiality.

To reassure the contracting parties and the public that the decisions of the EPC are impartial and for reasons of transparency, it is important to have in place a robust policy governing the declaration and management of relevant interests.

This *Code of Practice* complements the *Rules of Procedure of the European Pharmacopoeia* and should be read in conjunction with the *Guide for Work of the European Pharmacopoeia* and the *Privacy Statement of the European Pharmacopoeia*.

“Individuals taking part in the work of the European Pharmacopoeia” shall be understood as non-EDQM staff members.

## 2 Mission statement adopted by the European Pharmacopoeia Commission

The mission statement adopted by the EPC is included in the *Introduction* to the current edition of the Ph. Eur.

## 3 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. The members of the EPC and its groups who participate in the elaboration of the Ph. Eur. automatically

acquire this status. Their ethical principles and impartiality underpin the quality, legitimacy and credibility of the system of elaboration of European standards for medicinal products.

## 4 Acceptance of the *Code of Practice*

Prior to their appointment, individuals taking part in the work of the Ph. Eur. provide a written undertaking to respect this *Code of Practice* (see EDQM Form 226).

## 5 Scope

Individuals taking part in the work of the Ph. Eur. respect its primary responsibility in the protection of public health for the common interest of the Ph. Eur. Contracting Parties, as described in the mission statement.

This *Code of Practice* applies to the individuals taking part in the work of the Ph. Eur., i.e.:

— the Chair of the EPC,

— the Vice-Chairs of the EPC,

— delegations and observers of the EPC,

— members of groups of the EPC,

— substitutes for experts (as defined in the *Guide for Work*).

Members of groups of the EPC are defined as the Chair, the experts, the *ad hoc* specialists and the observers.

The principles laid down in §12 to 17 as well as in Annex 1 also apply to National Pharmacopoeia Authorities (NPAs).

## 6 Definitions

### *6.1 Direct versus indirect interests*

Interests may be either direct or indirect.

- Direct interests are:
  - 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 are:
  - 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.

*6.2 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 Ph. Eur. 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.

*6.3 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 Ph. Eur. belongs, or for which he 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.

*6.4 Other definitions*

There are a number of other definitions relevant to the EDQM's policy:

- **Close family members** shall mean: first-line members of the family of the individual taking part in the work of the Ph. Eur. (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.

## 7 Categories of declared interests

The declared interests can be categorised as follows:

- Category 1: Direct interests
- Category 2:
  - Indirect interests.
  - Any other matter that is not listed in Category 1 and that could affect impartiality or could reasonably be perceived to do so.
- Category 3:
  - Any other matter that might be of interest for transparency purposes, e.g. working for or providing expert advice to another standardisation body or to non-European pharmacopoeias, former employment in the pharmaceutical or an associated industry.

## 8 Declaration of interests

### *8.1 Written declaration*

All parties within the scope of this *Code* are required to make a full declaration of interests that 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 period of tenure. Such information shall be provided in writing, prior to attendance at the next meeting or session and a regular update of the declaration of interests will be requested by the EDQM.

The written declaration is kept by the EDQM.

### *8.2 Access to information*

All completed declarations of interests may be consulted at the EDQM by submitting a request via the EDQM HelpDesk. More information on this can be found in the *Privacy Statement of the European Pharmacopoeia*

### *8.3 Declarations pertaining to a specific agenda item of the EPC session*

Where an individual taking part in the work of the Ph. Eur. (including observers) has an interest in an agenda item, this shall normally be declared in advance of an EPC session, attached to the agenda and recorded in the meeting report. The Chair, in consultation with the Secretariat, is responsible for handling declarations of interests identified during sessions, and resolving the outcomes.

### *8.4 Declarations pertaining to a specific agenda item of a meeting of a group*

Where an individual taking part in the work of the Ph. Eur. (including observers) has an interest in an agenda item, this shall be declared during the meeting of the group and recorded in the meeting report. The Chair, in consultation with the Secretariat, is responsible for handling declarations of interests identified during meetings, and resolving the outcomes.

## 9 Restricting involvement in the activities of the EPC and of its groups

Involvement of the individual in such 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 Ph. Eur., different rules apply:

- The requirements for the Chair and the Vice-Chairs of the EPC and the Chairs of groups are stricter than for experts, *ad hoc* specialists and observers.
- The requirements are also stricter for the Chair and the Vice-Chairs of the EPC than for the Chairs of groups.

### *9.1 Chair and Vice-Chairs of the EPC*

The Chair and Vice-Chairs of the EPC must not hold Category 1 interests. They may hold Category 2 and 3 interests but must declare them.

### *9.2 Chairs of groups*

A Chair of a group may hold Category 1, 2 and 3 interests but must declare them. However, where the Chair has a direct interest in an agenda item, this may create a conflict of interest for him in the performance of his duties. In this case, the duties of the Chair shall be carried out by an expert from the group who does not have a direct interest in the matter in question.

Such cases shall be identified during the preparatory meeting held prior to the group meeting and the actions and decisions to be taken discussed with the Secretariat. The expert who shall replace the Chair for the pre-defined agenda item(s) will be proposed by the Secretariat and approved by the group members.

### *9.3 Experts, ad hoc specialists and observers*

Experts, *ad hoc* specialists and observers of a group may hold Category 1, 2 and 3 interests , but must declare them.

## 10 Action to be taken following a declaration of interests: achieving an efficient process

The EDQM screens declared interests proactively in order to identify possible impediments to taking part in the work of the Ph. Eur. as early as possible, i.e. before a nomination is forwarded to the Commission for approval or before a meeting or session takes place.

Where an individual in a meeting or session declares an interest in an agenda item, the Chair shall inform all participants. This person may participate in the discussion provided there is transparency on his declared interest, but may not take part in the decision.

It is the role of the Chair, with the support of the Secretariat, to manage any conflicts of interest that may arise during sessions or meetings and to ensure the impartiality of the decision.

## 11 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; this information is recorded in the meeting report together with details of the interest declared (product, company); the report also indicates whether the individual took part in the proceedings.

## 12 Documents and level of confidentiality

Any document distributed by the EDQM is for use by the intended recipient and shall not be disclosed to third parties (see §13), except as described in this *Code* (see especially §14).

The two levels of confidentiality for documents are typically as follows:

- "**SECRET**": this is the standard or "default" level. This level applies to all documents issued or sent by the Secretariat except those covered by the higher level of confidentiality.
- **"INDUSTRIAL PROPERTY"**: This higher level of confidentiality applies to documents related to Procedure 4 that contain data entrusted to the EDQM/Ph. Eur. by the innovator (data owner). As stated in the *Guide for Work* (see Annex 3, Procedure 4) access to such documents is restricted to the relevant groups, composed of representatives of competent authorities, and EDQM staff members involved in the work of these groups.

  At the request of the data owner, the higher level of confidentiality may also be applied to documents other than those pertaining to Procedure 4, e.g., if the data owner perceives that a document contains trade secrets. See also §15.

  At the request of an NPA or a member of the EPC, the classification of documents initially defined as "Industrial Property" could be downgraded to "Secret" once the relevant draft monograph has been published in Pharmeuropa. The consent of the data owner to reclassify the data would be sought at the time of adding the item to the Ph. Eur. work programme.

## 13 Involvement of third parties (or "associates")

Any individual taking part in the work of the Ph. Eur. (see §5 Scope) may involve other persons in that work **only** where this is useful for its **advancement.**

In such cases, this individual might need to share document(s) received from the EDQM with third parties such as:

- Laboratory supporting the work of an expert,
- national expert groups working on related topics
- a legally defined national advisory body that advises its NPA, or its national delegation to the EPC.

When doing so, the individual taking part in the work of the Ph. Eur. is fully responsible for ensuring that the persons or parties to whom he has sent the document are entitled to receive the document (depending on the level of confidentiality, see §12) and have been made aware that the information and data provided are confidential and also that the results of the work shall be used for the purposes of the Ph. Eur. alone. See §14 for further details.

## 14 Distribution of documents

Documents distributed by the EDQM have an assigned level of confidentiality (see §12). Typical recipients of such documents are persons or parties directly involved in the elaboration of the Ph. Eur., such as:

- the relevant Ph. Eur. group
- NPAs
- the EPC

By default, these recipients shall not further distribute the received documents. However, exceptions may be made:

- for the involvement of third parties supporting the work of the Ph. Eur. (see §13);
- if the circumstances under which the documents may be further distributed are met (see §12) and if the persons receiving the document are made aware of the confidentiality management rules of the Ph. Eur.

The EDQM may also share document(s) to another Ph. Eur. group working on related topics. only where this is useful for the advancement of the work of the Ph. Eur.

## 15 Confidentiality and use of data and information

As laid down in the *Principles* of the *Guide for Work of the European Pharmacopoeia* (§10), the Ph. Eur. is committed to finding a balance between transparency and confidentiality. Thus, documents will be handled in accordance with the guidance described above and neither details on the decision-making process nor detailed data and information provided to the Ph. Eur. will be disclosed to the public (cf. §16).

Although no such detailed information can be provided before or after the adoption of a text, high-level feedback (preferably oral) on why a comment was not supported by a group may be provided at the request of the commenter, usually after the adoption of the text by the EPC.

Such requests should be submitted to the NPA to which the comment was addressed (or to the EDQM, via its Helpdesk, if the comment was sent directly to the EDQM). The status of a text can be communicated at any time and is also freely accessible in the Knowledge database.

If a manufacturer (data owner) requests its data to be treated in confidence (other than under Procedure 4) and the higher level of confidentiality (see §12) to be assigned, a written justification must be sent to the EDQM. The request is then transferred to the EPC which will decide on the course of action to take. The requester will be kept informed of the EPC's decision by the EDQM (see also Annex 1).

## 16 Reference to documents and discussions at meetings

Documents and the discussions that take place at any meetings (including sessions of the EPC) shall not be referred to in publications of any kind and shall not be disclosed to third parties, except as described in § 13 to 15.

Data or information provided in documents or during discussions on work items shall be used only for the work allocated to the group by the EPC or for the work of the EPC. This restriction does not apply in the event that an individual taking part in the work of the Ph. Eur. has legitimate access via sources other than the EDQM document or where the EDQM provides public access to a document (e.g. technical guides, *Rules of Procedure, Guide for Work, Privacy Statement*).

## 17 Handling of unforeseen or complex situations or issues

A group may be faced with unforeseen or complex situations or issues during the development of a standard or text. In such cases, it may be necessary to take specific measures to redress the situation or issue(s). Such measures may be either temporary or permanent. Further guidance is given in Annex 1.

# ANNEX 1:

# HANDLING OF UNFORESEEN OR COMPLEX SITUATIONS:

# BEST PRACTICE RECOMMENDATIONS

A group may be faced with unforeseen or complex situations or issues during the development of a standard or text. In such cases, the Chair of the group together with the Secretariat shall consider the best possible approach to assist the group. The measures proposed may be either temporary (once or for a limited time only) or permanent.

This annex is intended to provide guidance and recommendations to the Chair of the group, the Secretariat and the group members on how to overcome such difficulties but also to indicate when and under what circumstances the EPC's agreement is to be sought before proceeding. For all cases not mentioned below, the advice (or decision) of the EPC shall be sought beforehand.

**Temporary measures:**

Such measures may be considered, for example, in the following situations:

- A document important to the work of the Ph. Eur. contains strictly confidential data to which access shall be restricted, for example to representatives of competent authorities (NPAs, regulatory authorities or OMCLs), when some members of the group are employees or consultants in the pharmaceutical or associated industry.

- Group discussions are come to a halt either because of a lack of expertise or because of a (perceived or confirmed) conflict of interest.

In such cases, the Chair of the group together with the Secretariat considers the best possible temporary measures to resolve the issue in question.

<u>Issue of confidentiality:</u>

As stated under §15, the data owner or the author of a document can request the data/document to be treated in confidence (other than under Procedure 4) and the higher level of confidentiality assigned. In this case, a written justification must be sent to the EDQM. The request is then transferred to the EPC who will decide on the course of action to be taken. Typical options are:

- Requesting all members of the group to sign a confidentiality agreement before the data/document are provided. Where appropriate, the Secretariat will also add a note on the document clarifying the conditions under which it may or may not be distributed to third parties (as decided by the EPC).
- Assigning the higher level of confidentiality i.e. “INDUSTRIAL PROPERTY” to the document and distributing it to members from competent authorities only in the group concerned or to members that do not hold an interest in the pharmaceutical or a related industry. In the event that these members express a desire or need to discuss the document, the Secretariat will arrange a meeting with them only. However, a summary of the discussion will be provided to the whole group, ensuring that no

confidential information or data is disclosed. If the Chair of the group is not from a competent authority, the Secretariat will ask a group member who is a competent authority representative to take the Chair for that topic.

- Refusing the request from the data owner or author. If so, the EDQM shall contact the latter to see whether the confidentiality level "SECRET" would suffice. If not, the document/data cannot be distributed and thus would not be considered for the work of the Ph. Eur.

In all cases, the requester will be kept informed by the EDQM of the EPC's decision.

Lack of expertise

The Secretariat will ask NPAs to nominate *ad hoc* specialists in areas where the group lacks expertise.

Creation of subgroups:

If the creation of a subgroup (either within the group or with nominated *ad hoc* specialists) would be useful for the advancement of the work of the Ph. Eur. and where no member of the group objects, the subgroup (which would be open to all members of the group as well as *ad hoc* specialists, based on their expertise) could be created without any need for prior approval by the EPC. This approach could be considered, for example, when a group has very diverse topics on its work programme and where working in subgroups would be more efficient and useful for the advancement of the work of the Ph. Eur.

*It is noteworthy that all the documents distributed to or produced by the subgroup could also be made accessible to the rest of the group if desired.*

Conflict of interest

If the measures described in the *Code of Practice* are judged insufficient, the situation encountered by a group arising from a perceived or confirmed conflict of interest as well as the proposed mitigation plan (e.g. to arrange a meeting or other event, an exchange via written correspondence with a defined number of people who are not necessarily members of the group) should be reported to the EPC by the Chair of the group together with the Secretariat. The EPC would then decide on the best possible approaches to address the situation.

**Permanent measures:**

Permanent measures generally concern the composition of a group, which may, for example, be restricted to competent authority representatives only (e.g. Group of Experts P4 or P4Bio Working Party) or by excluding members with a Category 1 (direct) interest (e.g. Group of Experts 15V). This decision is taken by the EPC, usually based on the recommendation of the Presidium, and documented through the approval of the *Terms of Reference and Profile for Experts* document.