CODE OF PRACTICE FOR THE WORK OF THE EUROPEAN PHARMACOPOEIA

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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 European Pharmacopoeia, 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 working 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 adopts the monographs, general chapters and other texts of the European Pharmacopoeia (Ph. Eur.) which will become legally binding in all signatory parties to the Convention on the Elaboration of a European Pharmacopoeia. Its members are not therefore prohibited from holding interests in the pharmaceutical or an associated industry but they must comply with this Code of Practice 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. Many experts in the field of standards for pharmaceutical substances and products 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, 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 transparency reasons 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.*

"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 European Pharmacopoeia Commission 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 European Pharmacopoeia Commission, its Groups of Experts and Working Parties 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 European Pharmacopoeia provide a written undertaking to respect this Code of Practice (see EDQM Form 226).

5 Scope

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

This Code of Practice applies to the individuals taking part in the work of the European Pharmacopoeia i.e.:

- the Chair of the European Pharmacopoeia Commission,
- the Vice-Chairs of the European Pharmacopoeia Commission,
- members, alternates and observers of the European Pharmacopoeia Commission,
- members of Groups of Experts of the European Pharmacopoeia Commission,
- members of Working Parties of the European Pharmacopoeia Commission,
- substitutes for Experts (as defined in the Guide for work).

Members of Groups of Experts and Working Parties of the European Pharmacopoeia Commission are defined as the Chair, the Experts, the *ad hoc* Specialists and the Observers.

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 the scenarios possible.

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 European Pharmacopoeia

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 European Pharmacopoeia 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.

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 European Pharmacopoeia (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

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. working for or providing expert advice to another standardisation body or to non-European pharmacopoeias, a 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 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 or session and a regular update of the DoI 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. Such requests must be made via the EDQM Helpdesk system.

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

Where an individual taking part in the work of the European Pharmacopoeia (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 of Experts or Working Party

Where an individual taking part in the work of the European Pharmacopoeia (including Observers) has an interest in an agenda item, this shall be declared during the meeting of the Group of Experts or Working Party 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 of Experts and Working Parties

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 of Experts and Working Parties 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 the Groups of Experts and Working Parties.

9.1 Chair and Vice Chairs of the EPC

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

9.2 Chair of the Groups of Experts or Working Parties

A Chair of a Group of Experts or Working Party may hold interests of category 1, 2 and 3 but needs to declare them. However, where the Chair has a direct interest in an agenda item, this may create a conflict of interest for him/her in carrying out his/her 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 of Experts or Working Party may hold interests of categories 1, 2 and 3, but need to 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 European Pharmacopoeia 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/her 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 Working documents

Working documents issued by the Secretariat are for use by the intended recipient and shall not be disclosed to third parties, except as described below.

13 Involvement of third parties

Experts and *ad hoc* Specialists may involve other persons in their work for the European Pharmacopoeia where this is useful for the advancement of the work, and are responsible for ensuring that these persons are aware of the confidential nature of the information and data provided and that the results of the work shall be used by the Pharmacopoeia only.

14 Use of data and confidentiality

Data provided in working documents or during discussions on work items shall be used only for the work allocated to the Group of Experts or Working Party by the Commission or for the work of the Commission. This restriction does not apply where an individual taking part in the work of the European Pharmacopoeia has legitimate access to the data via sources other than the EDQM working document or where the EDQM provides public access to a document (for example, Technical Guides, Rules of Procedure, Guide for Work).

Where necessary, the Chair or a member or all members of a Group may be requested to sign a confidentiality agreement before provision of data. In such cases, the data is not incorporated in an official document.

15 Reference to working documents and discussion at meetings

Working documents and the discussions that take place at any meetings (including sessions of the Commission) shall not be referred to in publications of any kind.