

# CODE OF PRACTICE FOR THE WORK OF THE EUROPEAN PHARMACOPOEIA

## 1 Introduction

This Code of Practice sets out the rules to be followed by participants in the work of the European Pharmacopoeia, as defined under 5. Scope, if they hold and so must declare interests in the pharmaceutical and 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 working documents.

The European Pharmacopoeia Commission (EPC) is not involved in licensing matters, unlike the Committee on Human Medicinal Products (CHMP) and similar committees of the European Medicines Agency (EMA), but approves the monographs, general chapters and other texts of the European Pharmacopoeia (Ph Eur). Its members are not therefore prohibited from holding interests in the pharmaceutical and associated industries but must comply with this Code of Practice in declaring those interests and during the work.

Whilst decisions taken on the standard-setting process of the Ph Eur must be impartial, these decisions need to be informed by skilled professionals who are senior and 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 and associated industries and/or other commercial organisations whose business is relevant to the work of the EPC and its Expert Groups 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 it is important to have in place a robust policy governing the declaration and management of relevant interests.

## 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 EP Commission, its Expert Groups and Working Parties who participate in the elaboration of the Ph Eur automatically acquire this status. Their ethical principles and impartiality are essential elements of the quality, legitimacy and credibility of the system of elaboration of European standards for medicinal products.

## 4 Acceptance of the code of practice

Participants in the Elaboration of the European Pharmacopoeia give a written undertaking prior to their appointment to respect this code of practice (see form in Annex).

## 1 **5 Scope**

2 Participants in the work of the EPC respect its primary responsibility in the protection of  
3 public health for the common interest of the Ph Eur Contracting Parties, as described above in  
4 the mission statement adopted by the European Pharmacopoeia Commission.

5 This Code of Practice applies to the following:

- 6 — the Chair of the European Pharmacopoeia Commission
- 7 — the Vice-Chairs of the European Pharmacopoeia Commission
- 8 — members, alternates and observers of the European Pharmacopoeia Commission
- 9 — members (including specialists) and observers of Expert Groups of the European  
10 Pharmacopoeia Commission
- 11 — members (including specialists) and observers of Working Parties of the European  
12 Pharmacopoeia Commission
- 13 — ad-hoc Specialists (as defined in the Rules of Procedure)
- 14 — substitutes for Experts and Specialists (as defined in the Rules of Procedure)
- 15 — representatives of National Pharmacopoeia Authorities

## 16 **6 Interests to be declared**

17 It is the responsibility of each individual to identify and declare all relevant interests. The  
18 following interests must be declared:

- 19 a) Financial interests in the pharmaceutical and associated industries. In addition to paid  
20 employment by the pharmaceutical industry, these can include consultancies, fee-paid  
21 work, grants, share holdings, expenses and hospitality, and accrued pensions rights.
- 22 b) Financial interests in the pharmaceutical and associated industries held by members of  
23 their immediate family [Immediate family is defined as spouse or partner, and  
24 members of the family living in the same household.]
- 25 c) Any matter that can knowingly provide financial gain from the use of the information  
26 received as a member of the EPC, its Expert Groups or Working Parties.
- 27 d) Any other interests: where a participant has an interest in a matter under discussion,  
28 due impartiality shall be observed to achieve a result that respects the public health  
29 priority of the Commission; participation in the work shall not be used as a means of  
30 furthering interests, except where these coincide with the essential aims of the  
31 Commission.
- 32 e) Any other matters that could affect their impartiality or that could reasonably be  
33 perceived to do so, and any other matters that might be of interest for transparency  
34 purposes e.g. to work for, or provide expert advice to, another organisation as for  
35 example the CEN, non-European pharmacopoeias.

## 1 **7 Declaration of Interests**

### 2 *7.1 Written Declaration*

3 All parties within the scope of this code are required to make a full declaration of interests  
4 using the standard form provided (see Annex). The written declaration of interests must be  
5 submitted, with Curriculum Vitae, prior to appointment. This declaration will be reviewed  
6 and renewed at each subsequent re-appointment (normally every three years).

7 The written declaration must be updated by the expert or specialist at any time during his/her  
8 period of appointment if any significant change to that declaration occurs. Such information  
9 shall be provided in writing, prior to the participation at the next meeting.

10 The written declaration is kept by the Secretariat (European Pharmacopoeia Department). The  
11 declarations are placed on the extranet (Commission folder for Commission members,  
12 group/working party folder for chair and members of each group/working party).

### 13 *7.2 Declarations during a Meeting of the EPC, its Expert Groups or Working Parties*

14 Where a participant has an interest in an agenda item, this shall be declared during the  
15 meeting and recorded in the meeting report. The Chair, in consultation with the Secretariat, is  
16 responsible for handling declarations of interests identified during meetings, and resolving the  
17 outcomes.

### 18 *7.3 Chair of the Commission*

19 The Chair of the Commission should not hold an interest in the pharmaceutical or associated  
20 industries. Where such an interest does exist, then wherever there may be a conflict of interest  
21 for the Chair in carrying out his/her duties, these duties shall be carried out by one of the  
22 Vice-chairs who does not have an interest in the matter to be dealt with.

### 23 *7.4 Chair of the Expert Groups or Working Parties*

24 Where the Chair has an interest in an agenda item, there may be a conflict of interest for  
25 him/her in carrying out his/her duties. In this case, the duties of the chair shall be carried out  
26 by an Expert from the Group who does not have an interest in the matter to be dealt with.

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

### 31 *7.5 Action to be taken following a Declaration of Interest*

32 Where a participant in a meeting or Session declares an interest in an agenda item or identifies  
33 a conflict of interest, the chair shall inform all participants. This person may participate in the  
34 discussion provided there is transparency on their declared interest.

35 It is the role of the Chair to ensure the impartiality of the decision.

### 36 *7.6 Records*

37 The Secretariat keeps a record of:

1 — the names of those who have declared interests on appointment or subsequently  
2 together with the declaration of interests;

3 — the names of those who have declared interests at a meeting or Session; this  
4 information is recorded in the report of the meeting together with details of the  
5 interest declared (product, company); the report also indicates whether the individual  
6 took part in the proceedings.

## 7 **8 Working documents**

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

## 10 **9 Consultation of third parties**

11 Third parties may be consulted on the content of working documents where this is useful for  
12 advancement of the work; the third parties shall be made aware of the code of practice  
13 relating to working documents.

## 14 **10 Use of data and confidentiality**

15 Data provided in working documents or during discussion on work items shall be used only  
16 for the work allocated to the group or working party by the Commission or for the work of the  
17 Commission. This restriction does not apply where a participant has a legitimate access to the  
18 data from sources other than the EDQM working document or where EDQM provides public  
19 access to a document (for example, Technical Guides, Rules of Procedure, Guide for Work).

20 Where necessary, the Chair, a member or the members of a group/working party may be  
21 requested to sign a confidentiality agreement before provision of data. In such a case, the data  
22 is not incorporated in an official document.

## 23 **11 Reference to working documents and discussion at meetings**

24 Working documents and the discussions that take place at any meetings (including Sessions  
25 of the Commission) shall not be referred to in publications of any kind.  
26



1 Should there be any change to the above due to the fact that I acquire additional interest, I  
2 shall notify the EDQM in writing prior to my participation in the next meeting and complete a  
3 new declaration of interests detailing the changes.

4 I undertake to participate in the work of the European Pharmacopoeia in accordance with the  
5 Code of Practice.

6 I undertake to respect the necessary degree of confidentiality for documents and discussions  
7 during meetings as described in the Code of Practice.

8 *Executed at .....*

9 *Date.....*

10

11 *Signature*

12

13 *These data are recorded by EDQM with access for consultation as described in the Code of*  
14 *Practice.*

15 \* Delete as appropriate.