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- 12 Guide for the work of the European Pharmacopoeia Commission
- 13 The Commission has prepared this Guide in order to build an efficient network for the
14 activities of the European Pharmacopoeia Commission and those who participate in its work:
15 delegates, experts, specialists, national secretariats, EDQM as secretariat, European
16 organisations, industry, the universities and others.
- 17 The Guide describes the desired working methods that should be followed unless in
18 exceptional and justified cases, there are good reasons for not doing so. It explicits and
19 complements the Rules of Procedure of the European Pharmacopoeia Commission.
- 20 The work of the Commission and its Groups of Experts and Working Parties requires a certain
21 commitment from the participants and a willingness to respect established procedures so that
22 public health authorities and the public have an assurance that the human and scientific
23 resources have been used in a timely and efficient manner.
- 24 1. EUROPEAN PHARMACOPOEIA COMMISSION
- 25 1.1 Activities
- 26 1.1.1 The legal framework for the use, elaboration and updating of the European
27 Pharmacopoeia in close collaboration with its stakeholders is summarized in Annex 1.
- 28 1.1.2 A notification for suspected deficiencies in European Pharmacopoeia monographs to be
29 used by the licensing authorities is given as Annex 2.
- 30 1.1.3 The Commission defines its Code of Practice.

1 1.1.4 The Commission elaborates detailed working procedures for the elaboration of
2 monographs (See Annex 3)

3 1.1.5 The Commission establishes a list of basic documents that are to be provided to each
4 appointed expert and specialist (see Annex 4).

5 1.2 Delegations

6 1.2.1 If a delegation intends to raise technical matters relating to an item on the agenda for a
7 forthcoming session of the Commission it should notify in written in advance the Chair of the
8 Commission, the Chair of the Group of Experts or Working Party concerned and the
9 Secretariat. Appropriate steps should then be taken to resolve the points at issue before the
10 item is discussed in session.

11 1.2.2 Delegations should submit in writing editorial comments on documents for adoption to
12 the Chair of the Commission, the Chair of the Group of Experts or Working Party concerned
13 and the Secretariat.

14 1.2.3 Delegations may propose Experts and Specialists for appointment to the Groups of
15 Experts and Working Parties. When making proposals, the delegations should take into
16 account whether the nominees have at their disposal the facilities necessary to contribute to
17 the work of the Group of Experts or Working Party. The proposal should be accompanied by
18 information on the relevant experience of the nominee (curriculum vitae). The curriculum
19 vitae is held by the Secretariat and provided to the Presidium.

20 On request it might also be provided to Chairs of Groups of Experts or Working Parties.

21 1.2.4 When proposing an Expert or a Specialist for re-nomination, the delegation should
22 consider the past contribution of the nominee and may consult the Chair of the Group of
23 Experts or Working Party concerned, the Secretariat and the Presidium for advice on this.

24 1.2.5 Delegations should make every effort to send their comments or other contributions to
25 matters to be treated by correspondence within the agreed deadlines. A delegation failing to
26 observe a deadline should consider the disadvantages involved in delaying adoption of a text
27 before asking the Commission to take a comment or contribution into consideration.

28 1.2.6 Delegations should send to the Chair of the Commission copies of all correspondence
29 relevant to the work of the Commission.

30 2. GROUPS OF EXPERTS AND WORKING PARTIES

31 2.1 Activities

32 2.1.1 The procedures for elaboration of monographs and general chapters of the European
33 Pharmacopoeia are described in Annex 3.

34 2.1.2 During the work, due consideration is taken of the relevant Technical Guide for the
35 Elaboration of Monographs wherever applicable. Editorial style is taken care of by the
36 Secretariat.

1 2.1.3 Where relevant, draft monographs, general chapters or other texts submitted by Experts
2 and Specialists must be accompanied by validation reports relating to the methods proposed
3 together with batch analysis for the full range of tests. Validation reports are archived at
4 EDQM and are not released to third parties. The tests should be verified in at least a second
5 laboratory. Specifications in monographs should be based on those for products approved in
6 Member States.

7 2.1.4 Experts and Specialists should submit their monograph proposals together with a report
8 including experimental results and summarising all available scientific information, including
9 validation data.

10 2.1.5 Wherever possible work should proceed by correspondence between a limited number
11 of Experts or Specialists (co-ordinator and co-workers). Copies of all relevant correspondence
12 are sent to the Chair of the Group of Experts or Working Party and to the Secretariat. The aim
13 of the preliminary exchange by correspondence between the co-ordinator and co-workers is to
14 provide a good basis for the Group of Experts or Working Party to finalise the drafts as
15 promptly as possible.

16 2.2 Chairs of Groups of Experts and Working Parties

17 2.2.1 Wherever possible, the Chair holds a preparatory meeting with the Secretariat prior to
18 the meeting.

19 2.2.2 The Chair, with the support of the Secretariat, ensures that drafts are based on the
20 Commission's relevant Technical Guides and are supported by the necessary documentation
21 in the form of experimental results, reports of group meetings, validation data and an
22 explanatory note, particularly for revision proposals.

23 The Chair ensures that scientific grounds are adequately reflected in the decisions of the
24 Group of Experts or Working Party.

25 The Chair monitors, together with the Secretariat, that the present Guide for the Work is
26 respected.

27 The Chair, with the support of the EDQM, follows up the appropriate work for establishing
28 the reference standards.

29 2.2.3 The Chair decides, in consultation with the members, when a draft can be published in
30 Pharmeuropa for comment.

31 2.2.4 Comments received after publication in Pharmeuropa are considered by the Group of
32 Experts or Working Party concerned. The Chair ensures that the comments are considered
33 according to their merits. Wherever a proposal for change is not accepted, the Chair ensures
34 that the reasons are clearly formulated. When a substantial change is introduced in the light of
35 the results of the enquiry, the text is published in Pharmeuropa again for comment.

1 2.2.5 The Chair decides, in consultation with the members, when a draft for a monograph,
2 general chapter or other text can be submitted to the Commission for adoption. The Chair
3 should be prepared, on behalf of the Group of Experts or Working Party, to resolve in session
4 minor points raised by delegations of the Commission.

5 2.2.6 The Chair decides, in consultation with the Secretariat, the agenda for a meeting.
6 Documents that have not been received by members 14 days in advance of the meeting can
7 normally not be taken up on the agenda unless the Chair proposes this and the members of the
8 group agree to do so. Nevertheless experimental results should be added to the agenda
9 wherever possible.

10 2.2.7 The Chair ensures that only authorised persons are attending the meeting.

11 2.2.8 The Chair ensures that impartiality is maintained in case an interest is declared.

12 2.2.9 Where necessary, the Chair refers to the Commission in writing any question requiring a
13 decision of principle prior to continuation of work on a given item.

14 2.2.10 Chairs report regularly to the Commission on progress with the work programme,
15 highlighting items where the work has not advanced as expected and the reasons for this.

16 2.2.11 Chairs of Groups of Experts and Working Parties should be prepared to attend and play
17 an active role in conferences organised by EDQM on subjects relevant for the activities of
18 their Group of Experts or Working Party.

19 2.3 Experts and Specialists

20 2.3.1 Experts and Specialists should meet the selection criteria approved by the Commission.
21 They contribute on a voluntary basis having fully understood the commitment involved.

22 2.3.2 Experts and Specialists receive the basic documents decided by the Commission (see
23 Annex 4).

24 2.3.3 Each Expert or Specialist should make a fair contribution to the work of the Group of
25 Experts or Working Party, including the provision of results of experimental work, where
26 required, and respect the time limits set for assignments.

27 2.3.4 Experts and Specialists should maintain the correct degree of privacy concerning the
28 work of the group.

29 2.3.5 An Expert or a Specialist should maintain proper communication with the National
30 Pharmacopoeia Authority and the Secretariat, for example by making regular reports on the
31 progress of work.

32 2.3.6 An Expert or a Specialist should inform the National Pharmacopoeia Authority and the
33 Secretariat in good time if he/she is unable to attend a meeting.

34 2.4 Meetings

1 2.4.1 Meetings should be held in Strasbourg. If it is proposed to hold a meeting elsewhere, the
2 Chair should make a request in writing to the Director of EDQM providing justification for
3 this in terms of the contribution to the advancement of the work of the Group. National
4 Pharmacopoeia Authorities may be consulted.

5 2.5 Observers

6 2.5.1 Where so authorised by the Commission, observers may participate in the scientific and
7 technical discussion and experimental work organised by the Group of Experts or Working
8 Party, with a view to helping in its advancement.

9 2.5.2 An observer may contribute to the elaboration of a monograph, a general chapter or
10 another text.

11 3. EUROPEAN DIRECTORATE FOR THE QUALITY OF MEDICINES AND HEALTH 12 CARE

13 3.1 European Pharmacopoeia Department (EPD)

14 3.1.1 The Secretariat of the European Pharmacopoeia and its Groups of Experts and Working
15 Parties is performed by the European Pharmacopoeia Department (EPD) of EDQM. The Head
16 of this Department acts as scientific Secretary to the Commission.

17 3.1.2 The Secretariat arranges Sessions of the Commission and meetings of the Groups of
18 Experts and Working Parties and any other meetings asked for by the Commission.
19 Convocations, which should indicate the venue and duration of a session or a meeting are sent
20 to the Delegates and/or Experts/Specialists, to Liaison Sections of the European Committee
21 on Pharmaceuticals and Pharmaceutical Care and to central addresses of National
22 Pharmacopoeia Authorities in adequate time, normally not less than 4 weeks before the
23 meeting or session, to allow appropriate arrangements to be made.

24 3.1.3 For Sessions of the Commission, the Secretariat draws up a draft agenda, in consultation
25 with the Chair. This draft agenda is sent to delegations so as to be available not less than 6
26 weeks before the Session. The agenda is drawn up taking into account comments received
27 from delegations by the deadline indicated on the draft agenda. The agenda is sent to
28 delegations such as to be available at least 3 weeks before the Session. An addendum to the
29 agenda is prepared and provided to delegations at the beginning of the Session. The final
30 agenda is adopted by the Commission at the beginning of the Session on the basis of the
31 agenda and the addendum. If the addendum to the agenda contains an item submitted for
32 adoption at the Session, this item may be deleted from the agenda on request of a delegation
33 or adopted subject to confirmation by delegations following the Session.

34 3.1.4 For meetings of Groups of Experts and Working Parties, the Secretariat draws up a draft
35 agenda, in consultation with the Chair of the Group of Experts or Working Party.

1 This draft agenda is sent to Experts and Specialists so as to be available not less than 3 weeks
2 before the Meeting. The agenda is daily updated based on the contributions of members. The
3 final agenda is presented for adoption by the members at the beginning of the meeting.

4 3.1.5 Documents for adoption at a Session of the Commission are normally sent so as to be
5 available not less than 14 days before the Session.

6 3.1.6 The Secretariat draws up an annual plan for the meetings of the Groups of Experts and
7 Working Parties, in consultation with the Presidium. The Secretariat may propose, in
8 consultation with the Presidium, to hold additional meetings if needed.

9 3.1.7 The Secretary to the Commission issues a summary of proceedings of each session
10 within 14 days. The summary of the session shall briefly indicate for each item on the agenda
11 the decision taken (adoption, adoption subject to confirmation by one, several or all
12 delegations).

13 3.1.8 The Secretariat issues a summary of proceedings of a meeting within 3 days. The
14 summary of the meeting of a Group of Experts or Working Party shall briefly indicate for
15 each item on the agenda the decision taken (discussion during the next meeting, Pharmeuropa,
16 Commission) and any follow-up to be made.

17 3.1.9 The Secretary to the Commission issues the draft records of sessions of the Commission
18 in the two official languages within 4 weeks. A deadline for comments on the draft record is
19 set at not more than 6 weeks before the beginning of the next session. The record, amended if
20 necessary, is issued promptly after the deadline.

21 3.1.10 The Secretariat issues the reports of meetings in one of the official languages within 4
22 weeks and the translations within 7 weeks of each meeting. Each report shall indicate inter
23 alia the names of the participants and the duration of the meeting; it shall have the summary
24 of proceedings as a preface and the work programme of the group on new and revised texts,
25 with the state of advancement, as an appendix. When a change proposed in writing by a
26 National Pharmacopoeia Authority or by a manufacturer is not agreed, the Secretary clearly
27 indicates the reasons for nonacceptance of the proposal in the report.

28 3.1.11 The Secretariat prepares new versions of working documents as necessary and sees to
29 it that the correct editing style is used in draft monographs, general chapters and other texts of
30 the Pharmacopoeia using the Style Guide.

31 3.1.12 Where a document is to be adopted by the Commission by correspondence, the
32 Secretariat distributes the document to all delegations and to National Pharmacopoeia
33 Authorities and indicates a deadline for adoption. If no delegation opposes adoption by the
34 deadline, the Secretariat forwards the document for publication and informs the Commission
35 at the next Session.

36 3.1.13 The Laboratory Department (DLAB) organises the adoption of reference standards.

1 Reference standards are adopted by correspondence. Reference standard establishment reports
2 are approved by correspondence, unless an issue has arisen which makes the approval by the
3 Experts/Specialists possible only after discussion in a meeting.

4 3.1.14 For adoption of reference standards by correspondence, the members of the relevant
5 Group of Experts or Working Party are alerted by the DLAB and requested to approve the
6 reference standard laboratory report within 3 weeks. In case of urgency this deadline might be
7 shortened. The reference standard establishment report is considered approved by the Group
8 of Experts/Working Party when no objection is received within the given deadline. The
9 delegations are contacted after that by the DLAB for agreement of the adoption of the
10 reference standard within 14 days, after which the reference standards are considered adopted
11 and will be released. At each Session of the Commission, a document is presented which
12 gives the detail of substances adopted, with the dates of approval by the Groups and adoption
13 by the Commission.

14 3.1.15 The Secretariat, in consultation with the appropriate Chair, makes the necessary
15 contacts with manufacturers or other suppliers in order to obtain samples of material needed
16 for work on monographs, general chapters and other texts and for use as reference standards
17 and to request proposals for specifications and validated methods to be included in
18 monographs, general chapters or other texts.

19 3.1.16 The Secretariat submits to the Commission any proposals made in accordance with
20 rules 20-23 of the Rules of Procedure for elaboration, revision or suppression of monographs,
21 general chapters or other texts.

22 3.1.17 The Secretariat provides to the Commission, National Pharmacopoeia Authorities and
23 delegations at regular intervals a document showing the state of advancement of all items
24 (new and revised) on the work programme.

25 3.1.18 The Secretariat organises public conferences on subjects related to the work of the
26 Commission where this is useful for achieving progress.

27 3.1.19 The Secretariat maintains suitable liaison with other parts of EDQM to ensure proper
28 co-ordination of work.

29 3.1.20 Following the decision of the Commission to create a Group of Experts or Working
30 Party, the Secretariat sends to National Pharmacopoeia Authorities and delegations an
31 invitation to submit proposed nominations, indicating the terms of reference of the group and
32 the profile expected for its members.

33 3.1.21 Not later than 6 months before the end of the term of office of Groups of Experts and
34 Working Parties, the Secretariat sends to National Pharmacopoeia Authorities and delegations
35 an invitation to submit proposed nominations, indicating the terms of reference of the group
36 and the profile expected for its members.

1 3.1.22 Where a change to the work programme is proposed (addition or deletion of an item),
2 the Secretariat sends a questionnaire to National Pharmacopoeia Authorities to determine
3 whether they are in favour of the proposed change. Where deletion of an item is proposed
4 because of lack of information on producers, if a National Pharmacopoeia Authority is in
5 favour of maintaining the item on the work programme, the Authority shall endeavour to
6 provide the information needed.

7 3.1.23 Where it is proposed to suppress a published monograph, a general chapter or another
8 text, the Secretariat sends a questionnaire to National Pharmacopoeia Authorities to determine
9 whether they are in favour of the proposed suppression.

10 3.1.24 The Secretariat organises an annual meeting of Secretaries of National Pharmacopoeia
11 Authorities to facilitate and co-ordinate the activities of common interest and to provide a
12 forum for exchange of information. This meeting is normally hosted by one of the Authorities
13 on a rotation basis.

14 3.1.25 When needed, the Secretariat may organise hearings of relevant industry associations.
15 Wherever possible, the Chair of the Commission and, where applicable, the Chair of the
16 Group of Experts or Working Party concerned attend the meeting.

17 3.1.26 The Secretariat maintains the Knowledge database on the EDQM web site, providing
18 supplementary information on monographs, general chapters and other texts for the assistance
19 of users.

20 3.1.27 The Secretariat participates in the activities of the Pharmacopoeial Discussion Group
21 together with representatives of the Japanese Pharmacopoeia and the United States
22 Pharmacopoeia and ensures that work is carried out with due respect for the Commission's
23 established procedures. The secretariat makes liaison with the relevant groups of Experts and
24 Working parties and informs the Commission of the state of work.

25 3.1.28 The Secretariat participates in the work of other bodies which have an impact on the
26 work of the Commission, notably relevant committees of the European Medicines Agency
27 (EMA), the Commission of the European Community, the World Health Organization and the
28 Organisation Mondiale de la Santé Animale (OIE). Reports are made to the Commission on
29 this participation.

30 3.2 Laboratory Department (DLAB)

31 3.2.1 The Laboratory contributes to the work on elaboration of monographs, general chapters
32 and other texts at the request of the Commission or of a Group of Experts or Working Party.

33 3.2.2 A member of the scientific staff of the Laboratory should, wherever possible, attend the
34 meetings of Groups to advise on aspects related to reference standards and for the discussion
35 on work in which they have participated and on which they have reported to the group.

36 3.3 Reference standards

- 1 3.3.1 The Laboratory Department (DLAB) and the Department of the Biological
2 Standardisation and OMCL (DBO) participate in the establishment and monitoring of
3 reference standards.
- 4 3.3.2 The DLAB, in co-operation with the relevant Groups of Experts or Working Parties,
5 undertakes work necessary for establishing reference standards. It carries out the
6 establishment of reference standards and reports to the relevant Group of Experts or Working
7 Party on work done.
- 8 3.3.3 The DBO, in co-operation with the relevant Groups of Experts or Working Parties,
9 undertakes work necessary for establishing Biological Reference Preparations. It carries out
10 the establishment of reference preparations and reports to the relevant Group of Experts or
11 Working Party on work done.
- 12 3.3.4 The DLAB and the DBO ensure that the work for establishing any new reference
13 standard is carried out so that the standard can be made available in good time for the entry
14 into force of the monograph, preferably at the time of publication.
- 15 3.3.5 The DLAB and the DBO ensure that the work for establishing any replacement batch of
16 reference standard is carried out so as to ensure continuous supply to users.
- 17 3.4 Publications and Multimedia Department (DPM)
- 18 3.4.1 The Publications and Multimedia Department (DPM) arranges for the publication in
19 suitable form of monographs, general chapters and other texts adopted by the Commission.
- 20 3.4.2 The DPM arranges for publication of Pharmeuropa, which contains all texts issued for
21 public enquiry and comment together with scientific notes, general information on the work
22 of EDQM etc.
- 23 3.4.3 The DPM issues a definitive version of each text for publication adopted by the
24 Commission. Corrections made to definitive texts before publication are notified to the
25 interested parties, notably delegations and National Pharmacopoeia Authorities.
- 26 3.4.4 The DPM exercises general oversight for the drafting style of texts to be published and
27 notifies the Secretary of the Group concerned of any problems.
- 28 3.4.5 The DPM prepares and updates the Style Guide.
- 29 3.5 Quality management system
- 30 3.5.1 The EDQM elaborates and implements a quality management system for its work in
31 each of its departments according to an internationally acknowledged standard .
- 32 4. NATIONAL PHARMACOPOEIA AUTHORITIES
- 33 4.1 General role

1 The general role of the National Pharmacopoeia Authorities is outlined in Annex 1.

2 4.2 Activities

3 The National Pharmacopoeia Authority is the department within each Contracting Party,
4 responsible for maintaining proper communication with the EDQM. By virtue of Rule 8.1 of
5 the Rules of Procedure, each National Pharmacopoeia Authority must have (a) qualified
6 person(s) (pharmacist or equivalent), responsible for implementation of the decisions of the
7 Commission.

8 The necessary secretarial support is provided to the National Pharmacopoeia Authority to
9 fulfil and assure the coordination of the following essential functions:

- 10 - preparation of and/or implementation of the European Pharmacopoeia and its supplements at
11 national level;
- 12 - responding to questionnaires from EDQM on the work programme of the European
13 Pharmacopoeia;
- 14 - provision of information on local manufacturers and other interested parties who wish to
15 contribute to the work;
- 16 - inform their Expert Committees and local manufacturers, where necessary, on advanced
17 drafts considering the necessary degree of confidentiality,
- 18 - forwarding to EDQM of national comments on Pharmeuropa drafts,
- 19 - briefing of Commission members before sessions;
- 20 - forwarding proposals for Experts and Specialists as members of Groups of Experts and
21 Working Parties;
- 22 - provision of information on the European Pharmacopoeia to local users, in addition to the
23 user support provided by EDQM (HelpDesk);
- 24 - attendance at annual meetings of National Pharmacopoeia Authorities to promote exchange
25 on working methods etc. within Member States;
- 26 - notification of elaboration of national texts to the Commission.

27 4.3 Duties

28 4.3.1 National Pharmacopoeia Authorities are required to send their comments on a draft for a
29 monograph or other text to the Secretariat within the indicated deadline. The deadline is
30 usually 60 days from the deadline for public comment indicated in Pharmeuropa. If an
31 amended draft is resubmitted for comment, no new matters can be raised in the comments.
32 Comments received after the deadline will be taken into account at the discretion of the Chair
33 of the Group of Experts/Working Party and only where it is indispensable to do so.

1 4.3.2 Proposals for a fundamental change in a draft text should be well founded and should be
2 supported, wherever necessary, by experimental evidence. Proposals that are not well founded
3 or not supported by experimental evidence are considered but normally rejected on these
4 grounds.

5 4.3.3 Any comment on a document should contain a substantiated proposal for its
6 improvement or should clearly state the action expected and the reasons for this. Comments
7 which do not fulfil these requirements will be considered but will normally be rejected on
8 these grounds.

9 4.3.4 National Pharmacopoeia Authorities should maintain communication with the Experts
10 and Specialists from their country whilst respecting their independent position as scientific
11 advisers to the Commission.

12 5. OTHERS

13 5.1 Manufacturers and other interested parties from Member States of the Ph. Eur.
14 Convention

15 5.1.1 Comments on Pharmedropa texts should be submitted via the National Pharmacopoeia
16 Authority.

17 5.1.2 Proposals for new items for the work programme or for revision of monographs or
18 general chapters should be submitted via the National Pharmacopoeia Authority (according to
19 the Rules of Procedures proposals from observers can be made via a delegation or via the
20 Secretariat in Strasbourg).

21 5.1.3 Technical enquiries on monographs and other texts should be submitted, preferably in
22 writing, either to the National Pharmacopoeia Authority or via the EDQM HelpDesk.

23 5.2 Manufacturers and other interested parties from non-Member States of the Ph. Eur.
24 Convention or multinational interested parties:

25 5.2.1 Comments on Pharmedropa texts should be submitted preferably via the National
26 Pharmacopoeia Authority of the Member State where the product is authorised.

27 5.2.2 In case the Manufacturer or other interested party from non-Member States or
28 multinational interested party selects the EDQM HelpDesk for submitting comments on
29 Pharmedropa texts (preferably as attachments to the enquiry form), it shall indicate the
30 Member State(s) where the product is authorized.

31 5.2.3 Proposals for new items for the work programme or for revision of monographs or
32 general chapters should be submitted to the Secretariat in Strasbourg.

33 5.2.4 Technical enquiries on monographs and other texts should be submitted via the EDQM
34 HelpDesk.

35 5.3 International organisations

1 5.3.1 Communications should be made via the Secretariat in Strasbourg.

2 5.4 Industry associations or other associations

3 5.4.1 Communications should be made via the Secretariat in Strasbourg.

4 6. REVISION OF TEXTS

5 This chapter details the requirements and procedure for revisions of European Pharmacopoeia
6 monographs in accordance with Rule 21 of the Rules of procedure.

7 6.1 Technical revisions

8 6.1.1 Requests for revision should be submitted using the standard form (see Annex 5) for this
9 purpose. The parts of the text to be revised should be clearly identified and where possible a
10 concrete proposal should be formulated. The Group of Experts or Working Party may make a
11 preliminary evaluation of the revision request before examination by the Commission if this is
12 convenient taking account of meeting dates.

13 However, work on the revision should not start before the Commission has decided to add the
14 item to the work programme.

15 6.1.2 Requests for revision should be accompanied by sufficient information to enable the
16 Commission to decide whether revision is justified and necessary and to accord the
17 appropriate priority. Where a request for revision does not fulfil the above criteria, after
18 consultation of the Chair of the Group of Experts or Working Party and/or the Chair of the
19 Commission, the Secretariat will refer the matter back to the originator with a substantiated
20 request for further information.

21 6.2 Minor revisions

22 In the interest of simplification of working procedures, minor revisions may be submitted
23 directly to the Commission where the Chair of the Group of Experts/Working Party or the
24 Secretariat considers that prior publication in Pharmeuropa is not needed.

25 Submission of a minor revision implies that the change is not controversial and that the
26 Commission will be able to decide simply on the basis of the briefing note to the monograph
27 that the revision is justified and necessary. The briefing note is later posted in the “View
28 History” field of the Knowledge database, after editorial adaptation where necessary, to
29 inform users of the reasons for the change. Additions to the Impurities section of a monograph
30 arising from the Certification Procedure are approved by the Technical Advisory Board for
31 the Procedure and presented to the Commission as minor revisions after verification, where
32 relevant, by the Groups of Experts or Working Parties, where the analytical methods of the
33 monograph do not require revision in consequence.

34 6.3 Corrections of errors

35 The Secretariat arranges for prompt republication of a text wherever notification of an error is
36 received and informs the Commission and National Pharmacopoeia Authorities. Corrections

1 that can be made with simple notification include: differences between the English and French
2 texts where the correct version is evident; items that clearly do not correspond to the decision
3 of the Group of Experts, the Working Party and/or the Commission.

4

5

1 ANNEX 1

2 USE, ELABORATION AND UP-DATING OF THE EUROPEAN PHARMACOPOEIA

3 INTRODUCTION

4 The European Pharmacopoeia is elaborated under an international convention of the Council
5 of Europe. The Convention has been signed by 36 States and by the European Union. The
6 signatories to the Convention undertake:

7 “to take the necessary measures to ensure that the monographs which ... constitute the
8 European Pharmacopoeia shall become the official standards applicable within their
9 respective countries.”

10 The purpose of the European Pharmacopoeia is to promote public health by the provision of
11 recognised common standards for use by health-care professionals and others concerned with
12 the quality of medicines. Such standards are to be of appropriate quality as a basis for the safe
13 use of medicines by patients and consumers. Their existence:

- 14 – facilitates the free movement of medicinal products in Europe;
- 15 – ensures the quality of medicinal products exported from Europe.

16 European Pharmacopoeia monographs and other texts are designed to be appropriate to the
17 needs of:

- 18 – regulatory authorities;
- 19 – those engaged in the control of quality;
- 20 – manufacturers of starting materials and medicinal products.

21 The European Pharmacopoeia can only fulfil its role properly when each of the interested
22 parties participates actively in the process of elaboration and updating of standards. This note
23 is intended to outline the elements of active participation.

24 EXCHANGES BETWEEN THE PHARMACOPOEIA AND STAKEHOLDERS

25 The Pharmacopoeia, an integral part of the regulatory control system for the quality of
26 medicines, will remain useful only if it is promptly adapted to the needs of its users, notably
27 the experts dealing with applications for marketing authorisation (assessed by the competent
28 authorities and prepared by the manufacturers). Hence, the Pharmacopoeia has taken
29 measures to respond promptly to requests from competent authorities.

30 First, the role of the Pharmacopoeia with respect to that of licensing authorities should be
31 recalled:

32 Unlike licensing dossiers, which are prepared and assessed for an individual product, the
33 Pharmacopoeia is the indispensable communication and standardisation tool that allows a
34 uniform standard to be applied; it should be maintained up-to-date to avoid duplication of

1 work (and therefore increases in costs) and above all anarchy or differences in requirements;
2 by providing harmonised, validated analytical methods, specifications and units, by
3 establishing common reference standards for all European specialists, it acts as a reliable
4 reference tool for communication, it links individuals, and it facilitates national and
5 international administrative, commercial and scientific exchange between all the partners
6 responsible for the design, manufacture and quality control of medicines, in both the public
7 and private sectors.

8 This common tool continues to serve its users only if they wish and are able to make their
9 opinions or needs for adaptation known.

10 Legally, the tripartite relationship between the Pharmacopoeia - Licensing Authorities – and
11 Manufacturers is clarified by national legislation, notably EU directives (currently 2001/82,
12 2001/83 and subsequent amendments). They are summarized into the principles as follows:

13 Principle no 1: the European Pharmacopoeia and its standardised and validated specifications,
14 adopted unanimously by the national delegations, are binding.

15 This was codified in Annex 1 to Commission Directive 2003/63/EC,

16 - Introduction and general principles, (5): “With respect to the quality part (chemical,
17 pharmaceutical and biological) of the dossier, all monographs including general monographs
18 and general chapters of the European Pharmacopoeia are applicable.”

19 - Chapter 3.2(5):“The monographs of the European Pharmacopoeia shall be applicable to all
20 substances appearing in it...”

21 - “In the case of analytical procedures included in the European Pharmacopoeia, this
22 description shall be replaced in each relevant section “remark: of an application for a
23 marketing authorization” by the appropriate detailed reference to the monograph(s) and
24 general chapter(s).

25 Principle no 2: In exceptional cases , if it appears that the control of a product or specific
26 preparation in a licensing dossier is inadequate, the licensing authority and the applicant for
27 marketing authorisation must have additional tests.

28 “However, where a starting material in the European Pharmacopoeia or in the pharmacopoeia
29 of a Member State has been prepared by a method liable to leave impurities not controlled in
30 the pharmacopoeia monograph, these impurities and their maximum tolerance limits must be
31 declared and a suitable test procedure must be described...

32 In case where a specification contained in a monograph of the European Pharmacopoeia or in
33 the national pharmacopoeia of a Member State might be insufficient to ensure the quality of
34 the substance, the competent authorities may request more appropriate specifications from the
35 person responsible for placing the product on the market...”

1 Principle no 3: Where it has been found that a monograph is not sufficient to cover all
2 products on the market , the licensing authority must inform the European Pharmacopoeia in
3 general terms without breaking confidentiality and must ask the manufacturer to contact the
4 Pharmacopoeia to up-date the monograph.

5 “...The competent authorities shall inform the authorities responsible for the pharmacopoeia in
6 question. The person responsible for placing the product on the market shall provide the
7 authorities of that pharmacopoeia with the details of the alleged insufficiency and the
8 additional specifications applied...”

9 Practically, the conditions for achieving these three principles merit clarification.

10 Regarding Principle no 1:

11 It is clear that application of principles 2 and 3 will be needed less if the texts of the European
12 Pharmacopoeia are updated regularly. This means setting up a mechanism in the European
13 Pharmacopoeia Commission allowing rapid up-dating and, outside the European
14 Pharmacopoeia, the organisation of frequent, regular and effective communications with its
15 different partners involved.

16 Within the European Directorate for the Quality of Medicines and HealthCare (Council of
17 Europe, Strasbourg), the European Pharmacopoeia has a permanent Scientific Secretariat and
18 a Laboratory dedicated to the elaboration and updating of monographs and general chapters.

19 The principles applied in elaboration of monographs are outlined in a series of Technical
20 Guides, available for download from the EDQM web site (www.edqm.eu). The methods
21 included are validated according to current guidelines. The monograph specifications are
22 based on currently approved medicinal products in Member States. This applies in particular
23 to impurity profiles and all specified impurities in monographs can be considered to be
24 qualified at or above the level of the acceptance criterion.

25 In view of the above, it is essential that manufacturers respond to invitations from the
26 Secretariat to participate in the work of elaboration and revision by providing samples and
27 data. The Secretariat regularly sends out such invitations via industry associations and via
28 individual pharmacopoeia liaison persons notified by manufacturers.

29 Different procedures are applied for elaboration of monographs but in all cases draft new
30 monographs and drafts of revision proposals are published in Pharmeuropa for public
31 consultation.

32 It is essential that competent authorities have in place a system for critical examination of
33 Pharmeuropa drafts and generation of comments to be provided to the Secretariat. Similarly,
34 manufacturers should have in place a system of alert for identification of drafts that are of
35 interest and development of comments.

1 EDQM sends notifications to interested parties whenever an item is added to the work
2 programme (new monograph or revision proposal). Interested parties are invited to contact
3 EDQM and participate in the work, notably by providing data and samples of their product.

4 It is essential that interested parties have in place a system for identification of items of
5 interest and that they contact EDQM in a timely manner. Appointment of a pharmacopoeia
6 liaison within the company and notification of EDQM of the contact details is the most
7 effective means.

8 Regarding Principle no 2:

9 A monograph may be incomplete and not cover an impurity present in a product
10 manufactured by a new route of synthesis or of purification. When a marketing authorization
11 is requested for a medicinal product containing such a substance for reasons of public health
12 the applicant must submit additional information and the licensing authority must demand it.

13 The National Pharmacopoeia Authority is the most effective liaison for notification of
14 suspected deficiencies in monographs. The form shown in the Annex 2 can be used for brief
15 notification of a suspected deficiency in a monograph. The HelpDesk on the EDQM web site
16 can also be used for communication of this type.

17 In the light of the international growth of trade, which is likely to make this situation more
18 common, the demonstration that the reference to the Pharmacopoeia is suitable for a given
19 source is requested by current guidelines of the Quality Working Party established under the
20 Human Medicinal Products Committee and the Committee for Veterinary Medicinal Products
21 (EMA)

22 To simplify the compilation of the marketing authorisation dossier and to make the reference
23 to the Pharmacopoeia directly usable, the procedure for certification of suitability has been set
24 up; this procedure allows the manufacturers to demonstrate the applicability of the monograph
25 to their product whilst protecting the confidentiality of intellectual property. If the monograph
26 does not provide adequate control, the certificate will be accompanied by additional
27 requirements, pending revision of the monograph.

28 Regarding principle No 3:

29 As the Pharmacopoeia is the instrument shared by the three partners (two use it, one
30 elaborates and up-dates it), the existing means of communication between them should be
31 optimised to respond better to the specific needs of each partner whilst respecting its
32 constraints.

33 Licensing authorities and manufacturers have similar needs:

34 •Reliable, accurate, transparent standards

35 •Up-to-date monographs

1 •Validated reference methods

2 Licensing authorities are constrained by the need for confidentiality of data submitted in
3 licensing applications. Manufacturers can submit data to EDQM knowing that it will be
4 treated in confidence if they so request, although the end result, a public standard will of
5 course be freely available.

6 The Pharmacopoeia has its particular needs:

7 •Information on the market situation

8 •Information on the needs of licensing authorities in terms of general policy on safety and
9 efficacy and public health policy

10 •Data and samples representative of approved products on the market. The main constraints
11 for monograph development are:

12 •the work involved in development of validated and standardised methods that cover the
13 range of available products;

14 •availability of substances needed to prepare reference standards.

15 Each partner should clearly understand the needs and constraints of the other two. For its part,
16 EDQM, is committed to the following:

17 •Openness in monograph development based on the principles laid down in the relevant
18 Technical Guide, available on the EDQM web site;

19 •Development of transparent monographs that can fully serve the needs of all users, with
20 support from the Certification Procedure;

21 •Priority drafting of monographs and general chapters requested by licensing bodies, notably
22 the Committees and Working Parties of EMA;

23 •Effective operation of the Certification Procedure to reduce the workload of assessors for the
24 relevant part of an application;

25 •Publication of monographs on active substances at least 2 years before patent expiry so that a
26 standard will be available when generic applications are made;

27 •Continuous development of the resources of the EDQM web site as a support for all aspects
28 of the work;

29 •Organisation of hearings of interested parties at regular intervals or on request to promote
30 exchange on all aspects related to our work

31 NATIONAL PHARMACOPOEIA AUTHORITIES

32 The process of monograph development is mainly undertaken at European level, with
33 Member States contributing resources to this collaborative process rather than developing

1 national standards. There is a consequent saving of resources and there is no subsequent need
2 to harmonise national positions. The role of national pharmacopoeia authorities has therefore
3 evolved and they have become part of an active network functioning in different direction for:

4 •Provision of expertise for European monograph development;

5 •Provision of information on the local market situation for medicinal products;

6 •Relaying of information on the pharmacopoeia at the local level

7 •Liaison at local level between interested parties and EDQM

8 EDQM organises an annual meeting of Secretaries of National Pharmacopoeia Authorities, to
9 facilitate and co-ordinate the activities of common interest and to provide a forum for
10 exchange of information.

11

12

1 ANNEX 2

2 NOTIFICATION OF A SUSPECTED DEFICIENCY IN A MONOGRAPH OF THE
3 EUROPEAN PHARMACOPOEIA

4 According to Directive 2003/63/EC a licensing authority should inform the Secretariat of the
5 European Pharmacopoeia when, during the assessment of an application for marketing
6 authorization, requirements in a monograph of the European Pharmacopoeia have to be
7 supplemented in order to control sufficiently a raw material from a particular manufacturer.

8 Furthermore, the manufacturer has an obligation to cooperate with the European
9 Pharmacopoeia Commission with a view to updating the monograph.

10 The licensing authorities cannot submit to the Secretariat of the European Pharmacopoeia any
11 confidential information from a marketing authorisation application. Therefore, the
12 information submitted to the Secretariat of the European Pharmacopoeia, if possible with the
13 help of the National Pharmacopoeia Authorities, can be limited to a statement of the title of
14 the monograph, the name of manufacturer, and the nature of deficiency in the monograph, etc.
15 The Secretariat of the European Pharmacopoeia will then contact the manufacturer to obtain
16 directly the more detailed information to allow initiation of the revision process.

17 When informing the Secretariat of the European Pharmacopoeia the following standard
18 format may be used:

19 The information should be sent to:

20 European Pharmacopoeia Department

21 EDQM

22 Council of Europe

23 7, allée Kastner

24 CS 30026

25 F – 67081 STRASBOURG

26 France

27 Fax: (+33) 3.88.41.27.71

28 Name of monograph

29 Problem encountered (e.g. test for related substances, insufficient, additional testing needed,
30 test replace due to malfunctioning etc.)

31 Name and address of manufacturer of finished product

32 Name and address of licensing authority and name of assessor

1 Name and address of the national Pharmacopoeia Authority

2

1 ANNEX 3

2 PROCEDURES FOR ELABORATION OF MONOGRAPHS FOR THE EUROPEAN
3 PHARMACOPOEIA

4 The work programme is decided by the European Pharmacopoeia Commission. The
5 Commission considers for addition to the work programme monographs on active substances,
6 excipients and, for certain classes, medicinal products that are approved for use in Member
7 States. In the interests of public health, the Commission may decide to elaborate monographs
8 on articles that do not meet these criteria. At the time of addition to the work programme, a
9 monograph or general chapter is allocated to a procedure and to a group of experts or working
10 party.

11 PROCEDURE 1

12 ELABORATION BY A GROUP OF EXPERTS

13 1. INITIATION

14 1.1 Following addition of an item to the work programme, for items to be dealt with by
15 Procedure 1, the Secretariat circulates information to the public via industry associations,
16 pharmacopoeia liaison persons of manufacturers, the EDQM web site and Pharmeuropa
17 Interested parties are invited to contact the Secretariat with a view to providing samples and
18 data and participating in the work.

19 1.2 The Secretariat identifies the manufacturers of the substance from information provided
20 by the National Pharmacopoeia Authorities and any other information it may have.

21 1.3 The Secretariat sends manufacturers/suppliers of the substance a standard letter informing
22 them of the procedure and the programme to be followed and asking them to:

- 23 i) supply current production batches and small amounts of the known impurities;
24 ii) supply in-house specifications for period-of-use for all grades, as accepted by the licensing
25 authorities, methods of analysis and analytical validation data;
26 iii) supply batch analysis data for stability batches;
27 iv) if possible, supply a batch which can be subsequently used as a chemical reference
28 substance (CRS), if required.

29 2. PREPARATION OF THE DRAFT MONOGRAPH

30 2.1 Each substance is attributed to a co-ordinator and if necessary a co-worker within the
31 Group.

32 2.2 After receiving the samples and documentation requested, the Secretariat sends copies of
33 the documentation and portions of the samples to the co-ordinator and, if necessary, to the co-
34 worker.

1 2.3 After receiving the samples and the data, the co-ordinator agrees target dates for
2 completion of the laboratory work (preferably not more than 6 months) and initiates the work
3 required, if necessary, in collaboration with the manufacturer and the coworker.

4 2.4 The co-worker or, in exceptional cases, the Ph. Eur. laboratory carries out the necessary
5 verifications and sends comments to the co-ordinator who informs the Ph.Eur. Secretariat on
6 progress.

7 2.5 The first draft, conforming to the relevant Technical Guide for the Elaboration of
8 Monographs and the style guide is produced by the co-ordinator, ideally within 3 months after
9 the completion of the laboratory work.

10 2.6 The draft is then submitted to the Secretariat in one of the official languages, the
11 Secretariat is responsible for translation of the texts into the other official language and for
12 final editorial verification of the texts.

13 3. APPROVAL FOR PUBLICATION IN PHARMEUROPA

14 3.1 The draft monograph and a report of the studies carried out are presented to the Group of
15 Experts.

16 3.2 If the Group of Experts considers that further work is required, this should be undertaken
17 by the co-ordinator or the co-worker and, if necessary, the Ph. Eur. Laboratory and preferably
18 the results should be presented at the next meeting of the Group of Experts.

19 3.3 In general, the draft to be published in Pharmeuropa is approved by the group in not more
20 than two meetings.

21 3.4 If there are any non-scientific difficulties or differences in conception, the problem is
22 immediately submitted to the Commission.

23 4. PUBLICATION IN PHARMEUROPA

24 4.1 Once the Group of Experts has approved the draft monograph, the editorial amendments
25 are made by the Secretariat, and the monograph is published in Pharmeuropa and
26 simultaneously sent to the National Pharmacopoeia Authorities.

27 Whenever appropriate, the author of the monograph prepares an explanatory note to be
28 published at the same time as the monograph. The deadline for comment by the public is set
29 at 3 months from the publication date of Pharmeuropa.

30 5. EXAMINATION OF THE COMMENTS

31 5.1 The Secretariat uses an electronic "Document Review Tool" to prepare the compilation of
32 the comments received which are made available to the co-ordinator/co-worker and to the
33 group of experts for the next meeting of the Group of Experts.

1 5.2 The co-ordinator reviews the comments, tries to resolve the difficulties by carrying out,
2 where relevant, any necessary laboratory work (the Ph. Eur. Laboratory may be asked to help)
3 and submits proposals to the group.

4 5.3 The comments are considered by the Group of Experts and the monograph is then
5 approved for adoption by the Commission. If necessary, to avoid delaying the publication of
6 new texts, the group of experts submits a text for adoption by the Commission while
7 proposing further work on an unresolved matter.

8 5.4 In cases where important modifications are foreseen in the light of the results of the
9 enquiry (change of a method, significant change of specifications), either a second publication
10 is envisaged or National Pharmacopoeia Authorities are consulted.

11 6. ADOPTION BY THE COMMISSION

12 6.1 The Secretariat prepares the document for the Commission and submits it for adoption at
13 the next Session.

14

15 PROCEDURE 2

16 ADAPTATION OF NATIONAL MONOGRAPHS

17 Procedure 2 is no longer used since the programme of adaptation of national monographs has
18 been completed.

19

20 PROCEDURE 3

21 NATIONAL SECRETARIAT ACTING AS CO-ORDINATOR

22 This procedure has been integrated into the modified Procedure 4.

23

24 PROCEDURE 4

25 This procedure applies to substances for which a single interested party amongst
26 manufacturers has been identified. It is usually applied to substances still under patent
27 protection where there is potential for future production of generics. The aim of the procedure
28 is to publish a monograph 5 years after the first approval in medicinal products in Europe, at
29 latest 2 years or more before patent expiry. The work is co-ordinated by EDQM and overseen
30 by the Group of Experts P4. Data provided by manufacturers is treated in confidence and
31 access is allowed only to EDQM staff and members of the Group of Experts P4, composed of
32 representatives of national pharmacopoeia secretariats or regulatory authorities.

33 1. INITIATION

1 1.1 Following addition to the work programme, a co-ordinator in the Group of Experts P4 is
2 appointed and responsible persons in the Secretariat and Laboratory. A National
3 Pharmacopoeia Authority may act as a co-ordinator and nominate a contact who for the
4 purpose of this monograph project becomes a member of the Group of Experts P4.

5 1.2 The Secretariat request data and samples from the manufacturer. Data are treated in
6 confidence and are accessible only to the Group of Experts P4 and EDQM staff members
7 involved in the P4 Procedure.

8 1.3 The Secretariat reviews the data and samples received. If the data and samples are
9 complete and satisfactory, a first draft of the monograph is prepared by the responsible person
10 within the Secretariat. If the data and samples appear to be incomplete the Secretariat requests
11 further data/samples before proceeding with the preparation of a first draft.

12 2. PREPARATION OF A FIRST DRAFT

13 2.1 The first draft is reviewed by the co-ordinator, the Secretariat and the Laboratory and
14 questions are compiled and forwarded to the manufacturer.

15 2.2 When all issues have been resolved with the manufacturer, the Laboratory tests one or
16 more batches according to the draft. Where necessary to confirm results from the EDQM
17 Laboratory, the tests are run in a second laboratory (of a national pharmacopoeia or OMCL).

18 If a National Pharmacopoeia Authority acts a co-ordinator, the draft is tested in its
19 laboratories and the confirmatory testing is carried out by the EDQM laboratory.

20 2.3 Laboratory reports are sent to the manufacturer and further questions may be raised. The
21 responsible person with the Secretariat endeavours to resolve with the manufacturer all points
22 of difference, in collaboration with the co-ordinator and the responsible person in the
23 Laboratory.

24 2.4 The amended draft, conforming to the relevant Technical Guide for the Elaboration of
25 Monographs and the Style Guide, is produced by the Secretariat in collaboration with the co-
26 ordinator, ideally within 3 months after the completion of the laboratory work.

27 2.5 The Secretariat is responsible for translation of the texts into the other official language
28 and for final editorial verification of the texts.

29

30 PUBLICATION IN PHARMEUROPA

31 3.1 Once the Group of Experts P4 has confirmed the draft monograph, the necessary
32 amendments are incorporated by the Secretariat. The monograph is published in Pharmeuropa
33 and simultaneously sent to the National Pharmacopoeia Authorities.

1 Whenever necessary, the author of the monograph prepares an explanatory note to be
2 published at the same time as the monograph. The deadline for comment by the public is set
3 at 3 months from the publication date of Pharmeuropa.

4 4. CONSIDERATION OF COMMENTS

5 4.1 The Secretariat uses an electronic “Document Review Tool“ to prepare the compilation of
6 the comments received, which are made available to the co-ordinator and to the Group of
7 Experts P4.

8 4.2 The co-ordinator and the responsible person in the Secretariat study the comments and
9 prepare a document showing the rationale for acceptance or non-acceptance of proposed
10 changes.

11 4.3 A revised draft is prepared for confirmation by the Group of Experts P4 in the light of the
12 rationale document. If necessary, to avoid delaying the publication of the new texts, the Group
13 of Experts P4 submits a text for adoption by the Commission while proposing further work on
14 an unresolved matter.

15 4.4 In cases where important modifications are foreseen in the light of the results of the
16 enquiry (change of a method, significant change of specifications), either a second publication
17 is envisaged or National Pharmacopoeia Authorities are consulted.

18 5. SUBMISSION TO THE COMMISSION

19 6. 1 The Secretariat prepares the document for the Commission and submits it for adoption at
20 the next Session.

21

22

- 1 ANNEX 4
- 2 LIST OF BASIC DOCUMENTS PROVIDED TO THOSE INVOLVED IN THE WORK OF
- 3 THE EUROPEAN PHARMACOPOEIA COMMISSION
- 4 1. Rules of procedure
- 5 2. Guide for the work of the European Pharmacopoeia
- 6 3. Code of Practice for the work of the European Pharmacopoeia
- 7 4. Technical guide (in the relevant field of work) for the elaboration of monographs
- 8 5. A document showing the composition of the Commission, Groups of Experts and Working
- 9 Parties, together with details of Liaison Sections for the Partial Agreement, central addresses
- 10 of Delegations and Secretaries of National Pharmacopoeia Authorities.
- 11 The Style Guide is made available on request.