GUIDE ON THE DECLASSIFICATION OF DOCUMENTS PERTAINING TO THE WORK OF THE EUROPEAN PHARMACOPOEIA

The *Guide on the declassification of documents pertaining to the work of the European Pharmacopoeia* is to be read in conjunction with the *Rules of Procedure of the European Pharmacopoeia Commission,* the *Guide for the Work of the European Pharmacopoeia* and the *Code of Practice for the work of the European Pharmacopoeia.*

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1 Background information

This Guide has been drafted having regard to:

- the Convention on the Elaboration of a European Pharmacopoeia (ETS No. 050);
- Resolution *Res(2001)6* on access to Council of Europe documents.

2 Scope

This Guide applies to all documents and other written communications (referred to as "documents" hereinafter) distributed by the European Directorate for the Quality of Medicines and HealthCare (EDQM) (such as the European Pharmacopoeia (Ph. Eur.) Department (also known as the Secretariat to the Ph. Eur. Commission [EPC] and to the Ph. Eur. groups of experts and working parties or "Secretariat")) and pertaining to the work of the Ph. Eur..

It covers the declassification of documents for the purpose of rendering them accessible to the public. It does not cover access to documents by the individuals taking part in the work of the Ph. Eur. This is covered by the *Code of Practice for the work of the European Pharmacopoeia.*

3 Need for confidentiality

According to the *Convention on the Elaboration of a European Pharmacopoeia*, the EPC shall meet in private (Art. 8) and shall draw up its own Rules of Procedure (Art. 5), entitled *Rules of Procedure of the European Pharmacopoeia Commission*. The latter also stipulates that the groups of experts and working parties shall meet in private.

The importance of confidentiality is further highlighted in:

- the *Guide for the Work of the European Pharmacopoeia*;
- the *Code of Practice for the work of the European Pharmacopoeia*.

The Ph. Eur. is committed to finding the best possible balance between transparency and confidentiality and strives to ensure that its processes and decisions are transparent. However, the Ph. Eur. is also constrained by the need to:

- ensure the confidentiality of the documents submitted by stakeholders (regulators, manufacturers and others);
- allow the individuals taking part in the work of the Ph. Eur. to freely share their knowledge and express their views and opinions without fear of reprisal.

In view of these needs, the EPC decided that neither details of the decision-making process nor any detailed documents provided to the Ph. Eur. would be disclosed to the public, with the effect that no detailed information is released before or after the adoption of a Ph. Eur. text.

4 Involvement of stakeholders and other interested parties

There are various ways for stakeholders and other interested parties to become involved in the work of the Ph. Eur.:

- By becoming an expert in a Ph. Eur. group of experts or working party.
  The terms of reference of all Ph. Eur. groups of experts and working parties – to which candidates may apply – are provided in a *Terms of reference and profile for members of Groups of Experts and Working Parties* document. More information on how to become an expert is provided in the *Guide for the Work of the European Pharmacopoeia* mainly.
- By submitting a new draft that may be used as the starting point for a future Ph. Eur. text or proposing a request for revision of a Ph. Eur. text. The procedures for submitting such proposals are provided in the *Guide for the Work of the European Pharmacopoeia*.
- By commenting on draft Ph. Eur. texts that are published in Pharmeuropa.
  Pharmeuropa is a free online EDQM publication and forum on which draft Ph. Eur. texts or general policy matters concerning the Ph. Eur. are posted for public consultation.

The documents referred to above and more information on how to become involved are available on the EDQM website.

In 2022, the EPC revised the *Code of Practice for the work of the European Pharmacopoeia* to acknowledge the need for greater transparency. Since this revision, commenters have, on request, been able to receive high-level feedback on why their comment was not supported by

a group. This feedback is provided either via the commenter's National Pharmacopoeial Authority (NPA) or via the EDQM HelpDesk, depending on how the comment was initially submitted.

5 Access to documents

The rules concerning the level of confidentiality of documents, the involvement of third parties and the distribution of documents can be found in the *Code of Practice for the work of the European Pharmacopoeia.*

6 Decision with regard to declassification of documents distributed by the EDQM

6.1 Documents that will be declassified

The following documents will be declassified:

- Draft Ph. Eur. texts once approved by the relevant group of experts or working party for publication in *Pharmeuropa;*
- Ph. Eur. texts once adopted by the EPC for publication in a new Ph. Eur. edition or supplement.

6.2 Documents that will not be declassified

Any document submitted by stakeholders (regulators, manufacturers, etc.) or opinions or views of individuals taking part in the work of the Ph. Eur. will **not** be declassified. Some examples (non-exhaustive list) are provided below:

- (Extracts of) batch records, validation reports and/or analytical records as well as SOPs and other related documents provided by stakeholders or generated under the EDQM's responsibility.
- All documents (such as summaries of decisions, reports and short reports) related to sessions or meetings of the EPC, the Ph. Eur. groups of experts or working parties, NPAs, etc.
- Comments received from stakeholders during a public enquiry as well as the documents compiling these comments.
- Documents compiling the decisions or recommendations made by the Ph. Eur. groups of experts or working parties, the EPC, further to comments received.
- Requests for revision of Ph. Eur. texts as well as drafts proposed by stakeholders (because they are usually supported by batch data or validation data).

6.3 Information that will be declassified

While many documents will not be declassified (see §6.2), information that is of relevance for the public is made available on the EDQM websites (EDQM institutional website, Pharmeuropa, Knowledge database) e.g.:

- publication schedule of the Ph. Eur.;
- list of texts adopted by the EPC in any given session;
- update to the Ph. Eur. work programme;

- status of a text including reasons for the revision, i.e. comments concerning revised texts;
- revision history;
- information on pharmacopoeial harmonisation.

7 Request for derogation

In the event that a user or stakeholder requests access to information contained in a classified document that is deemed absolutely necessary for the effective implementation of a Ph. Eur. text, a written request, duly substantiated, shall be sent to the Secretariat via the EDQM HelpDesk.

This request shall include information such as:

- the name and number of the Ph. Eur. text concerned;
- the reason for the request (including possible consequences if the request is refused by the EPC);
- any information that the applicant may provide in order to help identify the document(s) to which access is requested;
- the name, capacity/function and employer of the applicant (including contact details).

The request will then be forwarded to the EPC for consideration at an upcoming session. *It is important to note that the response time may be several weeks or months as there are three sessions per year (usually March, June and November). If the request is urgent, this should also be clearly explained and justified in the request made via the HelpDesk.*

The EPC will decide on the request and the applicant will be informed of the decision by the Secretariat. If the request is granted, the applicant may consult the document at the EDQM premises but will not be given an electronic version because such documents are still considered to be classified. Likewise, the applicant will not be able to make copies, in whatever form, on the EDQM premises.