Monographs of the European Drug Shortages Formulary - Procedure

This procedure applies to the sourcing, selection, drafting and maintenance of monographs for the European Drug Shortages Formulary (EDSForm).

The EDSForm contains monographs describing unlicensed pharmaceutical preparations that can be used during shortages of licensed medicinal products. Unlicensed pharmaceutical preparations are defined according to the European Pharmacopoeia (Ph. Eur.) general monograph on *Pharmaceutical preparations* (*2619*)

ELABORATION OF THE MONOGRAPHS

1. IDENTIFICATION OF A POTENTIAL MONOGRAPH

1.1 The EDSForm Working Party (WP) will consider for inclusion in the formulary unlicensed pharmaceutical preparations that could be used as a temporary substitute for essential/critical licensed medicines.

1.2 The essential/critical character of licensed medicines is identified by the EDSForm WP using national or regional lists of essential/critical medicines or any other relevant documents (e.g. assessment of potential supply chain vulnerabilities).

1.3 Requests for the elaboration of a EDSForm monograph may be submitted at any time by:

- the Chair of the EPC;
- the Chair of the CD-P-PH;
- a EPC or CD-P-PH delegation;
- national pharmacopoeia authorities (NPA);
- the EDSForm WP, via its Chair;
- the Secretariat;
- other interested parties, via the Secretariat.

1.4 Data on formulations for a potential monograph may be provided by the requester and are gathered by the EDSForm WP with the support of the Secretariat.

1.5 When relevant, the Secretariat may ask national pharmacopoeia authorities to provide data on existing monographs/preparations, e.g. taken from national formularies or national pharmacopoeias.

1.6 The Secretariat compiles the relevant data and provides it to the EDSForm WP.

2. FEASIBILITY CHECK

2.1 For each formulation identified as a potential monograph, the EDSForm WP assesses the available data set and decides on the feasibility of a monograph, on the basis of the criteria for inclusion and prioritisation given in the "*Monographs of the European Drug Shortages Formulary - Framework*" document, adopted by the EPC and CD-P-PH.

2.2 The requesting party (as listed in point 1.3) is notified of the outcome of the feasibility check.

3. REQUEST FOR ADDITION TO THE WORK PROGRAMME

3.1 The EDSForm WP proposes suitable monographs for addition to its work programme to the EPC for approval.

3.2 The Secretariat informs the CD-P-PH of the decisions taken by the EPC.

3.3 In case of disagreement, the CD-P-PH refers any item back to the EPC for further consideration.

4. DRAFTING OF THE MONOGRAPH

4.1 Following addition to the work program, the EDSForm WP appoints a rapporteur and, if needed, one or several co-rapporteur(s) to review the available data.

4.2 Elements that require experimental verification are highlighted by the rapporteur(s).

4.3 If necessary, additional data is gathered by the Secretariat.

4.4 The monograph is drafted by the rapporteur(s) with the support of the Secretariat, in compliance with the *Framework* of the formulary.

4.5 The draft monograph is presented to the EDSForm WP by the rapporteur together with the results of the review.

5. EXPERIMENTAL VERIFICATION

5.1 The purpose of the experimental verification step is to consolidate existing data and fill any gaps.
5.2 The EDSForm WP look for volunteers for sample preparation and laboratory work and is supported by the Secretariat.
5.3 The outcome of both the sample preparation and laboratory work steps are described in reports that are shared with the EDSForm WP.

6. PUBLICATION IN *PHARMEUROPA EDSFORM*

6.1 If necessary, the draft monograph is updated using the results of the experimental verification.
6.2 The resulting draft monograph and a report of the studies carried out are presented to the group.
6.3 If the group considers that further work is required, the results should be presented at the next meeting of the group.
6.4 Once the group has reviewed the draft monograph, and the Chair decides it is ready for publication in *Pharmeuropa EDSForm*, the Secretariat performs a final editorial verification of the draft monograph.
6.5 If necessary, the rapporteur, with the support of the Secretariat prepares an explanatory note to be published at the same time as the monograph.
6.6 The deadline for public comments on draft monographs is set at three months from the date of publication on *Pharmeuropa EDSForm*.
6.7 The draft monograph is published on *Pharmeuropa EDSForm* for public consultation and simultaneously sent to the national pharmacopoeia authorities and the CD-P-PH for information.

7. CONSIDERATION OF COMMENTS

7.1 The Secretariat uses the document review tool (DRT) to prepare the compilation of comments received and that are made available to the rapporteur/co-rapporteur and the EDSForm WP in time for its next meeting.
7.2 Comments should contain a substantiated proposal or should clearly state the action expected and the reasons for it.
7.3 If the information provided appears to be incomplete, the Secretariat may request further information either directly from the commenter or via the NPA. Comments that are incomplete and/or unclear will be considered but are typically rejected on these grounds.
7.4 The rapporteur reviews the comments, tries to resolve any difficulties and makes proposals to the group. Where relevant, laboratory work is organised to help resolve difficulties or address comments.
7.5 The comments are taken into consideration by the EDSForm WP. The draft is modified if necessary. The group then agrees to submit it for approval by the EPC.
7.6 If necessary and in order not to delay the publication of new texts, the group may submit a text for approval while proposing further work on an unresolved issue. In cases where major changes are envisaged in the light of the results of the enquiry, a second round of public consultation takes place.

8. SUBMISSION TO GOVERNING BODIES

8.1 Once finalised, the draft monograph is submitted by the Secretariat to the EPC for approval at its next session or by correspondence.
8.2 Once approved by the EPC, the monograph is submitted by the Secretariat to the CD-P-PH for final adoption for publication at its next session or by correspondence.

9. PUBLICATION

9.1 Once adopted by the CD-P-PH, the Secretariat organises the publication of the monograph.

REVISION OF MONOGRAPHS

10. PROPOSAL FOR REVISION

10.1 Reasoned requests concerning the revision of monographs of the European Drug Shortages Formulary may be made by:

- the Chair of the EPC;
- the Chair of the CD-P-PH;
- a EPC. or CD-P-PH delegation;
- a national pharmacopoeia authority;
- the EDSForm WP, via its Chair;
- the Secretariat;
- other interested parties, via the Secretariat.

11. REQUEST FOR REVISION

11.1 A request for revision is submitted to the EPC for approval.
11.2 If approved by the EPC, the CD-P-PH shall be kept informed and refers any item back to the EPC for further consideration in case of disagreement.

12. REVISION OF TEXTS

12.1 The working procedure described above for elaborations is then followed.

13. CASE OF MINOR REVISIONS

13.1 In the interest of simplifying working procedures, minor revisions may be submitted directly to the EPC and the CD-P-PH if the Chair of the WP or the Secretariat considers that prior publication in *Pharmeuropa EDSForm* is not needed.

14. CASE OF CORRECTIONS

14.1 The revision of texts for the purpose of correcting errors in the text or editorial style modifications is done by the Secretariat without a discussion by the EPC and the CD-P-PH.
14.2 The EPC and the CD-P-PH shall be informed of the correction of errors or style modification made and the date of publication.

15. SUPPRESSION OF MONOGRAPHS

15.1 When it is necessary to suppress a text, the following procedure will be followed:
15.2 A delegation, the Chair of the EPC/CD-P-PH, the Chair of the EDSForm WP or the Secretariat that concludes that a monograph should be suppressed, presents a reasoned proposal.
15.3 The Secretariat carries out an enquiry amongst NPAs to ask for their agreement/disagreement (in case of disagreement, NPAs are requested to give an explanation).
15.4 The Secretariat submits the outcome of the enquiry to the EPC, which decides whether the monograph shall be suppressed.
15.5 The CD-P-PH is asked to approve a decision to suppress taken by the EPC before the final suppression or is kept informed about any other decision at its next session or by correspondence. It refers any item back to the EPC in the event of disagreement. Suppressed monographs are made available in an archive, together with the reason for suppression.