

PROCEDURE FOR THE EUROPEAN PAEDIATRIC FORMULARY

This procedure applies to the sourcing, selection, elaboration and maintenance of monographs for the European Paediatric Formulary.

The formulary contains monographs describing unlicensed pharmaceutical preparations for use by paediatric patients. Unlicensed pharmaceutical preparations include according to the Ph. Eur. monograph on Pharmaceutical Preparations (2619) extemporaneous and stock preparations.

1. SOURCES OF MONOGRAPHS

1.1. The Secretariat requests National Competent Authorities to submit suitable existing monographs/preparations for paediatric use taken for example from national formularies or national pharmacopoeias.

1.2. The monographs shall be provided in one of the official languages of the Council of Europe by the National Authority.

1.3. Possible monographs for inclusion which are well-established or included in national formularies may also be provided to the Paediatric Formulary (“PaedForm”) working party at any time by

- members of the PaedForm working party,
- the chair of the European Pharmacopeia (Ph. Eur.) Commission,
- the chair of the Committee on Pharmaceutics and Pharmaceutical Care (CD-P-PH),
- a Ph. Eur. or CD-P-PH delegation,
- a National Pharmacopoeia Authority,
- the Secretariat,
- interested parties via the Secretariat.

1.4. The Secretariat aggregates the monographs/preparations received and provides them to the PaedForm working party.

2. SELECTION OF SUITABLE MONOGRAPHS

2.1. The Paediatric Formulary (PaedForm) working party assesses the provided monographs and data and decides on suitable preparations following the criteria for inclusion and selection especially in view of the therapeutic criteria adopted by the CD-P-PH.

2.2. The PaedForm working party proposes suitable monographs for addition to its work programme to the Ph. Eur. Commission for approval.

2.3. The CD-P-PH shall be kept informed of the decisions taken by the Ph. Eur. Commission and refer any item back to the Ph. Eur. Commission for further consideration in case of disagreement.

1 3. DRAFTING OF MONOGRAPHS
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3 3.1. Following addition to the work programme, a rapporteur and if appropriate co-
4 rapporteur in the PaedForm working party is appointed.

5 3.2. The Secretariat would request additional data, e. g. from the provider of the original
6 national monograph, if necessary.

7 3.3. The first draft, conforming to the list of criteria adopted by the CD-P-PH, is prepared in
8 English language by the rapporteur(s) in cooperation with the Secretariat.

9 3.4. The draft monograph and a report on the assessment carried out are presented to the
10 PaedForm working party.

11 3.5. If the PaedForm working party considers that further work or amendments are required,
12 this task may be undertaken by the rapporteur(s) and the results are preferably presented
13 at the next meeting of the working party.

14 3.6. Once the PaedForm working party has confirmed the draft monograph, the necessary
15 amendments are incorporated and final editorial verification is performed by the
16 Secretariat.
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19 4. PUBLIC CONSULTATION
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21 4.1. The monograph is published in English in Pharmeuropa for public consultation and
22 simultaneously sent for information to the National Pharmacopoeia Authorities and the
23 CD-P-PH.

24 4.2. Whenever necessary, the rapporteur of the monograph prepares an explanatory note to
25 be published at the same time as the monograph.

26 4.3. The deadline for comments on the draft monographs by the public is set at 3 months
27 from the publication date of Pharmeuropa.

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29 5. CONSIDERATION OF COMMENTS
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31 5.1. The secretariat uses an electronic “Document Review Tool” to prepare the compilation
32 of the comments received which are made available to the rapporteur/co-rapporteur and
33 to the PaedForm working party for the next meeting.

34 5.2. The rapporteur reviews the comments, tries to resolve the difficulties and submits
35 proposals to the group.

36 5.3. The comments are considered by the PaedForm working party and the monograph is
37 then agreed on for approval by the Ph. Eur. Commission. If necessary, to avoid delaying
38 the publication of new texts, the working party submits a text for approval and proposes
39 further work on an unresolved matter.

40 5.4. In cases where important modifications are foreseen a second round of consultation will
41 take place.

1 6. SUBMISSION TO THE EUROPEAN PHARMACOPOEIA COMMISSION AND
2 THE CD-P-PH

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4 6.1. Once finalised the monograph is submitted to the Ph. Eur. Commission at its next
5 session for its approval.
6 6.2. Once approved by the Ph. Eur. Commission the monograph is submitted to the
7 CD-P-PH for final approval for publication at its next session or by correspondence.

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9 7. PUBLICATION

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11 Monographs approved by the CD-P-PH are published by the Secretariat.

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13 8. MAINTENANCE

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15 8.1. The Ph. Eur. PaedForm working party performs a periodical re-evaluation of the
16 monographs.
17 8.2. The Ph. Eur. PaedForm working party through the intermediary of its Chair may
18 request – depending on the outcome of the re-evaluation – a revision or a suppression of
19 the monograph from the European Paediatric Formulary.

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21 9. PROPOSALS FOR REVISION OR SUPPRESSION

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23 Proposals concerning the revision or suppression of monographs in the European
24 Paediatric Formulary may be made by
25 - the chair of the Ph. Eur. Commission,
26 - the chair of the CD-P-PH,
27 - a Ph. Eur. or CD-P-PH delegation,
28 - a National Pharmacopoeia Authority,
29 - the responsible working party through the intermediary of its Chair,
30 - the Secretariat,
31 - interested parties via the Secretariat.

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33 10. REVISION OF TEXTS

34 Revision of texts shall be effected as follows:

- 35 10.1. A delegation, the chair of the Ph. Eur. Commission / CD-P-PH, the chair of the
36 PaedForm working party or the Secretariat presents a reasoned request for the revision
37 of the text to the Ph. Eur. Commission.
38 10.2. When the Ph. Eur. Commission has decided on the priority to be accorded to the
39 proposed revision, the PaedForm working party is informed.
40 10.3. The CD-P-PH shall be kept informed of the decisions taken by the Ph. Eur. Commission
41 and refer any item back to the Ph. Eur. Commission for further consideration in case of
42 disagreement.

- 1 10.4. The above described working procedure is then followed.
- 2 10.5. In the interest of simplification of working procedures, minor revisions may be
3 submitted directly to the Ph. Eur. Commission and the CD-P-PH where the Chair of the
4 PaedForm Working Party or the Secretariat considers that prior publication in
5 Pharneuropa is not needed.
- 6 10.6. The revision of texts for the purpose of correcting errors in the text or editorial style
7 modifications are done by the Secretariat without a discussion by the Ph. Eur.
8 Commission and the CD-P-PH. However, the Ph. Eur. Commission and the CD-P-PH
9 shall be informed promptly of the correction of errors or style modifications made and
10 the date of publication.

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12 11. SUPPRESSION OF TEXTS

13 When it is necessary to suppress a text, the following procedure shall be followed:

- 14 11.1. A delegation, the chair of the Ph. Eur. Commission / CD-P-PH, the chair of the
15 PaedForm working party or the Secretariat having formed the opinion that a monograph
16 should be suppressed, presents a reasoned proposal. The Secretariat performs an enquiry
17 amongst NPA to ask for their agreement / disagreement (in case of disagreement, NPAs
18 are requested to give an explanation).
- 19 11.2. The Secretariat submits the outcome of the enquiry to the Ph. Eur. Commission.
- 20 11.3. The Ph. Eur. Commission decides whether the monograph shall be suppressed.
- 21 11.4. The CD-P-PH is asked to approve a decision taken by the Ph. Eur. Commission to
22 suppress a monograph before the final suppression or kept informed about any other
23 decision at its next session or by correspondence. It shall refer any item back to the Ph.
24 Eur. Commission in case of disagreement.
- 25 11.5. Suppressed monographs are made available in an archive together with a reason for
26 suppression.