Technical recommendations of the European Drug Shortages Formulary Working Party

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Procedure

This document describes how technical recommendations of the European Drug Shortages Formulary Working Party (EDSForm WP) are elaborated.

The technical recommendations are aimed at supporting European pharmacists and healthcare professionals in making informed decisions when preparing unlicensed medicines during a shortage.

More details can be found in the "*Technical recommendations of the European Drug Shortages Formulary Working Party – Framework"* document.

1. IDENTIFICATION OF POTENTIAL TECHNICAL RECOMMENDATION

1.1 Requests based on reports of an on-going medicine shortage that could be covered by an technical recommendation, coming from the parties listed below, can be assessed by the EDSForm WP at any time:

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

1.2 Once a request is received, data that could be included in a technical recommendation is gathered by the individual members of the EDSForm WP and compiled by the Secretariat.

2. FEASIBILITY CHECK

2.1 Once a report of a medicine shortage that could be covered by a technical recommendation has been received, the EDSForm WP carries out a feasibility check to determine the feasibility/desirability of a technical recommendation in this situation.

2.2 The feasibility check might be carried out taking into consideration criteria described in the "*Technical recommendations of the European Drug Shortages Formulary Working Party – Framework*" document.

2.3 The requesting party (as listed in point 1) is notified of the outcome of the feasibility check.

2.4 In the case of medicine shortages that are already covered by a previously published technical recommendation (see 6.), the EDSForm WP assesses whether the technical recommendation is fit-for-purpose.

3. REQUEST FOR ADDITION TO THE WORK PROGRAMME

3.1 If the EDSForm WP considers that it is desirable/feasible to issue a technical recommendation for the reported medicine shortage, a request for addition to the work programme is then prepared by the Secretariat and submitted, either during a session of the EPC or by correspondence, to the national delegations of the EPC.

3.2 The Secretariat informs the CD-P-PH of the decisions taken by the EPC. In case of disagreement, the CD-P-PH refers any item back to the EPC for further consideration.

4. ELABORATION OF A TECHNICAL RECOMMENDATION

4.1 Following addition to the work programme, the EDSForm WP appoints a rapporteur, and if needed one or several co-rapporteur(s) to elaborate the technical recommendation.

4.2 The rapporteurs(s) assess the available data, determine the confidence level of each formulation described and prepares a first draft with the support of the secretariat, as described in the "*Technical recommendations of the European Drug Shortages Formulary Working Party – Framework*" document.

4.3 The draft technical recommendation is presented by the rapporteurs to the EDSForm WP for review, and approval.

5. PUBLICATION ON THE EDQM WEBSITE

5.1 The approved technical recommendation is proofread and then translated into French by the Secretariat before online publication.

5.2 The Secretariat informs both the CD-P-PH & the EPC of the publication of the technical recommendation on the EDQM website.

6. AFTER THE MEDICINE SHORTAGE EVENT

6.1 When the EDSForm WP considers that the medicine shortage covered by a technical recommendation is over or that this technical recommendation is no longer useful in the given situation, it decides its removal or archiving. The Secretariat informs the CD-P-PH and the EPC of this decision. In case of disagreement, the CD-P-PH or the EPC refers any item back to the EDSForm WP for further consideration.

6.2 When relevant, the EDSForm WP can consider for inclusion in the formulary one or several unlicensed pharmaceutical preparations described in a technical recommendation. See the "*Monographs of the European Drug Shortages Formulary – Procedure*" for more detail on the elaboration of the monographs of the European Drug shortages Formulary.