DRAFT PROCEDURE FOR SUPPRESSION OF A TEXT

Addition of a public consultation stage to the Ph. Eur. text suppression process

The draft procedure for the suppression of a text - which now includes a public consultation stage - has been approved by the European Pharmacopoeia Commission (EPC) for a trial phase starting from the June 2024 session.

Although the duration of this trial phase will be decided by the EPC, it is expected that the draft procedure will be applied to a minimum of 3 texts, each of a different nature, in order to be able to take an informed decision on:

- whether or not to maintain a public enquiry phase;
- whether or not to modify the proposed procedure.

As the sole decision-making body, the EPC may decide not to include certain texts proposed for suppression in the trial phase (and thus not to carry out a public consultation for these texts).

During this trial phase, section 9 of the GUIDE TO THE WORK OF THE EUROPEAN PHARMACOPOEIA - as currently described - is replaced by the following draft procedure:

9.- SUPPRESSION OF THE TEXTS OF THE EUROPEAN PHARMACOPOEIA

The procedure for suppression of a text of the Ph. Eur. is as follows:

(a) A delegation or the Chair of the EPC or of a group, an NPA or the Secretariat, having noted the need to suppress a Ph. Eur. text, shall present a reasoned proposal.

(b) If considered helpful, the group concerned may be consulted by the Secretariat to provide a preliminary evaluation of the suppression request.

(c) The Secretariat sends a questionnaire (that includes the request itself, if applicable the group's preliminary evaluation and a draft briefing note to inform users of the reasons for the suppression) to NPAs to determine whether they can support the initiation of the suppression process and the draft briefing note. Any NPA that is not in favour shall provide substantiated justification.

(d) The Secretariat transmits the questionnaire, the responses to the questionnaire and the draft briefing note, potentially updated after the feedback of the NPAs, to all the delegations, for information, at the next session of the EPC.

(e) Only after the EPC session, the Secretariat publishes the proposed suppression (including the briefing note) in *Pharmeuropa* for comment.

(f) The comments received are considered by the group for the latter to make a final recommendation regarding the fate of the text (keep in or suppress from the Ph. Eur.).

(g) The Secretariat transmits the comments received during the public enquiry as well as the group's final recommendation to all the delegations.

(h) The EPC decides whether the text shall be suppressed and therefore cease to be part of the Ph. Eur.

(i) If the EPC decides that the text shall be suppressed, this decision is published in the form of a *Resolution of the European Committee on Pharmaceuticals and Pharmaceutical Care* with the date on which the suppression shall take effect.
The briefing note is then posted in the "View History" field of the Knowledge database, after editorial adaptation where necessary, to inform users of the reasons for the suppression.