

## How to comment

The Texts for comment database contains proposals for new and revised monographs and general texts that are intended for inclusion in the European Pharmacopoeia and are submitted for public comment. In the case of proposals for revision, text to be deleted is crossed out and replacements or additions are underlined.

According to the Guide for the work of the European Pharmacopoeia:

- for manufacturers and other interested parties from member states of the Ph. Eur. Convention:
  - comments on Pharmeuropa texts should be submitted via the national pharmacopoeia authority;
- for manufacturers and other interested parties from non-member states of the Ph. Eur. Convention, and for multinational interested parties:
  - comments on Pharmeuropa texts should be submitted preferably via the national pharmacopoeia authority of the member state where the product is authorised;
  - in cases where comments are submitted to the [EDQM Helpdesk](#) (preferably as attachments to the enquiry form), please indicate the member state(s) where the product is authorised;
- for industry associations or other associations:
  - communications should be made via the EDQM secretariat.

The addresses of the [national pharmacopoeia authorities](#) and of the EDQM are published on the [Pharmeuropa website](#) under the tab Useful information.

In order to facilitate the processing of comments received by the secretariats of the national authorities and the EDQM, please mention in any correspondence the PA/PH reference number indicated at the beginning of each text. If the comment refers to a specific part of the text, please also mention the corresponding line number. This number can be found in the HTML version of the text on Pharmeuropa online, in the Texts for comment database.

Comments that propose modifications of limits should be supported by analytical data obtained on a significant number of batches. Proposed changes of methodology should be supported by experimental results of a comparative trial of the method published in Pharmeuropa for comment and the proposed alternative.

Only comments sent before the deadline indicated at the top of each text will be considered for the preparation of the final version.

It is stressed that these proposals have not been adopted by the European Pharmacopoeia Commission and must not be regarded as official texts.



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