11 April 2022
Questions and Answers document on the quality of homeopathic medicinal products (Q 13) - Stability

Template for submission of comments on draft document

Written procedure decided by the HMPWG	**30 May 2013**
Adoption by written procedure	**15 September 2013**
Report of the outcome of the written procedure	**21 November 2013**

Submission of comments on draft document

Table 1: Origin of comments

Questions and Answers document on the quality of homeopathic medicinal products (Q 13) - Stability

Organisation or individual	Contact details (e-mail address, telephone number, name of contact person)
ECHAMP Rue Washington 40 B-1050 Brussels	Amandine OSET amandine.oset@echamp.eu +32 2 649 94 40

Interested parties are invited to send
comments together with a copy of the cited references.
This will facilitate the assessment of comments, suggestions and corresponding justifications.

When the reference consists of a book chapter, the copy must include
the page of the book showing the year of publication.

Comments without copies of the supporting literature will not be considered.

Comments should be sent electronically and in Word format (not pdf).

Comments and the identity of the sender will be made public
unless a justified objection is received at the time of the submission.

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Please submit comments on each document separately.

Table 2: Comments

GENERAL COMMENTS ON DRAFT DOCUMENT

Interested party	Comment and Rationale	Outcome

SPECIFIC COMMENTS ON TEXT

Section number and heading	Interested party	Comment and Rationale	Outcome
Line12-15	ECHAMP	For other approaches than the transfer of stability data of a homeopathic stock to its subsequent dilutions/triturations, it should not be necessary to include detailed descriptions of the entire approach on stability into the application dossier since this is within the responsibility of the manufacturer by GMP rules. It is seen as consensus that not all detailed GMP documents have to be included into the application dossier, since this essentially increases the workload of both, applicants and the competent authorities, especially with regard to potential variation procedures. A balanced approach would reduce regulatory burden for both sides. Furthermore, it should be considered, that approaches, like the above, might be complex and require a lot of time and efforts to gather the necessary amount of data to create an appropriate basis for a feasible concept. Due to their complexity, established approaches often cannot simply be adapted to different requirements fixed by other competent authorities. Competent authorities should therefore be willing to accept approaches, already registered in other countries. This should also be reflected in the answer to this question.	