11 April 2022
Questions and Answers document on the quality of homeopathic medicinal products (Q 9) - GMP provisions

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 9) - GMP provisions

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
ECHAMP	It may not in all cases be possible and appropriate to include manufacturing sites involved in early stages of the manufacturing of the final dilution (the final dilution is by definition the API for homeopathic remedies) into the Part A of the QP declaration as they may be sourced from very small entities and also may be atypical materials regarding use for medicinal products. This should somehow be respected and reflected in the Q9 answer.	

SPECIFIC COMMENTS ON TEXT

Section number and heading	Interested party	Comment and Rationale	Outcome
Line 11-13	ECHAMP	The word *homeopathic* should be deleted as follows: <<In case of raw materials of chemical/mineral origin, when the ~~homeopathic~~ stock is the chemical substance itself, GMP compliance should be at least ensured from the beginning of the manufacturing process of the dilution/trituration.>> Rationale: In the previous paragraph, the stock is also mentioned as such. The word “homeopathic” implies a homeopathic preparation/procedure, which is not applicable in this case. This would be in line with Ph.Eur. 1038, which states: “A stock is usually one of the following: …, or the substance itself for raw materials of chemical or mineral origin”	
Line 10	ECHAMP	Reference to EudraLex Vol.4 - Annex 2 (Manufacture of Biological active substances and Medicinal Products for Human Use) seems not appropriate and should be deleted. The definition of Biological medicinal products is not appropriate for homeopathic remedies since the manufacture is performed according to homeopathic manufacturing	

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		procedures, e.g. Ph.Eur. monograph 2371 Method 2.1.1. Furthermore, the Ph.Eur. monograph 1038 “Homoeopathic Preparations” is also applicable with regard to raw materials of botanical, zoological or human origin.	