PDA
Parenteral Drug Association

Connecting People, Science and Regulation®

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6 June 2017
EMA
30 Churchill Place
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qwp@ema.europa.eu

RE: EMA/CHMP/CVMP/QWP/BWP/428135/2016 Submission of comments on Concept paper on the need for revision of note for guidance on quality of water for pharmaceutical use (H+V)

Dear Sir/Madam:

PDA appreciates the opportunity to provide feedback on this concept paper and fully supports the need for revision of note for guidance on quality of water for pharmaceutical use. In addition, PDA endorses the revision for allowing the use of non-distillation technologies for WFI production and harmonization with other monographs and position statements.

PDA recommends that the early parts of the Note where processes to make the various monographed waters are mentioned should be either deleted or consideration should be made for future advancements in technology which would allow for flexibility and agility of this document. PDA recommends maintaining the end portion of the Note as it may still be relevant. However, those applications where HPW (High Purity Water) is specified should be changed to WFI (Water for Injections) due to changes in EP Monographs.

PDA recommends referencing existing technical documents for best practices and allowing manufacturers to make science and risk based choices rather than limiting the possibilities by writing overly prescriptive regulatory guidance or monographs.

PDA is a non-profit international professional association of more than 10,000 individual member scientists having an interest in the fields of pharmaceutical, biological, and device manufacturing and quality. Our comments were prepared by a committee with expertise in pharmaceutical water systems representing the Science Advisory Board, the Board of Directors and including authors of PDA Technical Report 69 Bioburden and Biofilm Management in Pharmaceutical Manufacturing Operations.

If there are any questions, please do not hesitate to contact me.
Sincerely,

Falk Klar
General Manager, Vice President PDA Europe
CC: Richard Levy, PDA, Jahanvi (Janie) Miller, PDA

06June2017

Submission of comments on Concept paper on the need for revision of note for guidance on quality of water for pharmaceutical use (H+V) (EMA/CHMP/CVMP/QWP/BWP/428135/2016)

Comments from:

Name of organisation or individual

Please note that these comments and the identity of the sender will be published unless a specific justified objection is received.

When completed, this form should be sent to the European Medicines Agency electronically, in Word format (not PDF).

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Send a question via our website www.ema.europa.eu/contact

1. General comments

Stakeholder number *(To be completed by the Agency)*	General comment (if any)	Outcome (if applicable) *(To be completed by the Agency)*
	PDA fully supports the EMA's initiative to update and revise the *Note for guidance on quality of water for pharmaceutical use* (CPMP/QWP/158/01 EMEA/CVMP/115/01) due to a revision of the European pharmacopoeia monograph for Water for Injections (0169). This allows for the use of non-distillation technologies for WFI production (the revised monograph will be published in the Ph. Eur. Supplement 9.1 and will become effective in April 2017) and potential to harmonize with other monographs and position statements (e.g. CPMP Position Statement on the Quality of Water used in the production of Vaccines for parenteral use (EMEA/CPMP/BEP/1571/02 Rev.1)). Since this is a Concept Paper that only discusses a "need to update and revise" the Note for guidance on quality of water for pharmaceutical use (CPMP/QWP/158/01 EMEA/CVMP/115/01) (herein referred to as "the Note"), PDA's recommendation for future revision of the Note will be made and applied to "Recommendation" section of the Concept paper. PDA recommends that the early parts of the Note document where the processes to make different monographed grades of water are mentioned should be	

Stakeholder number *(To be completed by the Agency)*	General comment (if any)	Outcome (if applicable) *(To be completed by the Agency)*
	either deleted or a statement should be made to take into consideration future advancements in technology which would allow for flexibility and agility of this guidance document in the future. In addition it should be noted that these sections are redundant with European Pharmacopeia (EP) monographs for different grades of water and would require changes any time monographs would change. A direct reference to EP monographs could be considered as a viable option for this part of a document rather than reiteration of EP sections. Furthermore, this could be considered during harmonization of international pharmacopeia or by developing an ICH Q4B Annex. In addition, the presence of sections on "how to produce the various waters" in this Guidance document may not be consistent with document's title. We also recommend maintaining the end portion of the Note as it may still be relevant. However, those applications where HPW (High Purity Water) is specified should be changed to WFI (Water for Injections) due to changes in EP Monographs. PDA will abstain from further comments until the draft of an updated Note is available.	

2. Specific comments on text

Line number(s) of the relevant text *(e.g. Lines 20-23)*	Stakeholder number *(To be completed by the Agency)*	Comment and rationale; proposed changes *(If changes to the wording are suggested, they should be highlighted using 'track changes')*	Outcome *(To be completed by the Agency)*
		Comment: No specific comments to this document as it is a concept paper Proposed change (if any): N/A	

Please add more rows if needed.