

PDA's Specific Comments

Section	Line No.	Comment and Rationale	Proposed rewording (if applicable)
1.2	18	Change the phrase "in each regulatory region" to "across the regulatory regions." This change better conveys the concept that harmonization aims to facilitate a common testing strategy across the regulatory regions and not within each regulatory region.	This guideline is intended to facilitate regulatory acceptance of these proposed APAC and their interchangeability with those APAC contained in the local regional pharmacopoeias, thus avoiding redundant testing and different acceptance criteria in favor of a common testing strategy <i>across the regulatory regions</i> .
1.4	44-45	The statement needs clarity. It is the responsibility of PDG or members of the PDG to notify the ICH Q4B EWG. The statement as it reads does not assign this responsibility to PDG.	The EWG should be notified of any revisions to a text that has been submitted to the Q4B process. The lead pharmacopoeia must notify the ICH Q4B EWG of any revisions made to text that has been submitted and accepted utilizing the Q4B process.
1.4	47/48	The last sentence starting with " <i>Unilateral changes/revisions...</i> " should be removed. Lines 44-47 seem to satisfactorily cover the appropriate actions that should be taken if a revision to a text occurs. An automatic voiding of ICH status seems very drastic and in conflict with the text in lines 44-47.	Unilateral changes/revisions by any of the individual pharmacopoeias will void the ICH final status
2.1.3	66-67	This statement indicates that ICH will be able to revise agreed to text recommended by PDG once comments have been received during the regulatory consultation period. PDG should be consulted on the possible changes received during this step in the process and should have the ability to revise the text and re-propose it through their public review processes before the ICH EWG is allowed to officially adopt the text as being harmonized. We propose adding the text (in italics) to clarify.	Regulatory consultation (generally within 3 months) focuses on the Q4B Outcome in the annexed. The annexed can be revised based on comments received <i>and with the agreement and sign off of the pharmacopoeia producing the APAC.</i>
3	92	Delete reference to non-PDG sources as it is confusing and seems in conflict with the intent of this document	See General Comment #1 in our letter.
3	95-96	The definition for Non-PDG should be eliminated as it is confusing. The PDG is not the PDG if all three of the pharmacopoeias do not agree. Two of the three acting in coalition with out the consent of the third pharmacopoeia can not be considered "acting together as the PDG". Please see suggested replacement wording for "non-PDG" in bullet point 2 in the General Comment section above.	Non-PDG—One or two of the regional pharmacopoeias, but not all 3 pharmacopoeias acting together as the PDG.
Att. I	109	Remove the note from the "Colour and Clarity" box. We would encourage that both these tests be harmonized as part of the PDG Process.	Colour and Clarity (per ICH SC, work will just be on "Colour")
Att II	112-118	The title and/or introductory paragraph of Attachment II should indicate that this is an example of how the process would work using PDG as indicated in lines 54-55 of this document.	PDG Document Submission Provided for ICH Q4B EWG Evaluation for Harmonized Pharmacopoeial Text