

ICH Q4b EWG – Regulatory Acceptance of Analytical Procedures and/or Acceptance Criteria (RAAPAC)
COMMENT SHEET for Step 2 Document (June 8, 2006)
Comments by the Generic Pharmaceutical Association

General Comments

- The document should provide registration guidance on the appropriate reference for the harmonized procedure. This would ensure consistent referencing that is acceptable by the regulatory authorities for the various geographical regions.
- The document needs to eliminate the term “Non-PDG”. We do not support the concept that JP, EP or USP could act unilaterally to suggest that they have harmonized a procedure without the agreement of the other pharmacopoeias even if the harmonized text only exists in one of the pharmacopoeias. In order for text to be recognized as harmonized it must have agreement of the entire PDG.
- Not all sectors of the pharmaceutical industry are represented by ICH. Many companies do not have access to the ICH documents until they are published by the regulatory authorities during the Step 2 consultation stage. ICH must allow for the PDG to obtain public review of any and all changes suggested and adopted as a result of the consultation period. It is unacceptable for the ICH to put companies at a disadvantage because they can not be represented at the ICH proceedings. The pharmacopoeias have a public review process that disseminates the information to a broader community than those represented by ICH.

Specific Comments

| Section | Line No. | Comment and Rationale | Proposed rewording (if applicable) |
|---------|----------|---|--|
| 1.3 | 28-29 | We do not agree with the statement that ICH should have the ability to accept non-PDG proposed text. It is important that the EP, JP and USP agree to the text and ICH accept the text as proposed by the PDG. If ICH were to accept text submitted by 1 or 2 of the members of the PDG the concept of global harmonization is negated. | It also provides flexibility so that the Q4B EWG can evaluate, and regulatory authorities can chose to accept, non-PDG text. |
| 1.4 | 44-45 | The statement needs clarity. It is the responsibility of 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. PDG 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 | This statement is in conflict with the reference to non-PDG text. If ICH recognizes non-PDG text then the pharmacopoeia that did not agree to the harmonized text would, technically, be able to revise their text unilaterally because they never agreed to the harmonized text. This statement is acceptable if references to non-PDG text is eliminated. If references to non-PDG text is retained then this sentence should be deleted. | Unilateral changes/revisions by any of the individual pharmacopoeias will void the ICH final status |

| Section | Line No. | Comment and Rationale | Proposed rewording (if applicable) |
|---------|----------|--|---|
| 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 blue) to clarify. | Regulatory consultation (generally within 3 months) focuses on the Q4B Outcome in the annexe. The annexe can be revised based on comments received and with the agreement and sign off of the PDG. |
| 2.2 | 82 | We are unclear regarding the reference section. When we looked at annexe provided for Residue on Ignition/Sulphated Ash it listed the 3 pharmacopoeial publications. The concept of what a company should reference, (all, one or ICH) for registration purposes is unclear. We suggest the ICH EWG consider addressing what regulatory authorities would accept for registrations. If they only want to accept the pharmacopoeial reference for their country it would seem to defeat the purpose of this guidance. | Not applicable |
| 3 | 92 | Delete reference to non-PDG sources as it is in conflict with the intent of this document |received from PDG or Non-PDG sources that..... |
| 3 | 95-96 | Delete definition for Non-PDG as it is conflicting with the intent of this document and it doesn't make sense. 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". | Non-PDG—One or two of the regional pharmacopoeias, but not all 3 pharmacopoeias acting together as the PDG. |
| Att. II | 112 | The title of this Attachment supports the concept that Non-PDG references should be stricken from the text. | Not applicable. |
| Fig. I | | The figure should address the issue of how comments received during regulatory consultation will be addressed by ICH EWG and PDG. | Not applicable |