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112 **ATTACHMENT II**

113 ***PDG Document Submission Provided for ICH Q4B EWG Evaluation***

114 For the purposes of the process, the Coordinating or Lead Pharmacopoeia, on behalf of PDG, is
115 asked to provide, as soon as possible after PDG Stage 5B sign-off and usually within six months,
116 the following texts and information (termed the "document submission" as defined in the
117 *Guideline*) to the Q4B EWG, via the ICH secretariat, with a copy to the Q4B EWG Rapporteur
118 (for awareness):

- 119 1) The PDG sign-off document containing the PDG-harmonised text (PDG Stage 5B).
- 120 2) A Briefing Note dealing in particular with:
- 121 a. Residual differences between one or more of the pharmacopoeias, to include a
 - 122 commentary on any difference from the point of view of harmonisation;
 - 123 b. Any specific issues relating to publication;
 - 124 c. If any equivalency study was conducted, a summary of the outcome;
 - 125 d. The projected publication schedule in each pharmacopoeia, with clear indication
 - 126 as to the anticipated final PDG Stage 7 implementation date; and
 - 127 e. Any additional clarifying or awareness information not covered above.
- 128 3) The texts as intended for adoption and publication in each pharmacopoeia together with a
- 129 statement of any local differences with respect to the sign-off text.
- 130 4) Additional clarifying information may be separately incorporated by one or more of the
- 131 PDG pharmacopoeias in their respective information chapters on pharmacopoeial
- 132 harmonisation. Therefore, the revised information chapter on harmonisation from each
- 133 pharmacopoeia incorporating such information (in draft form where this is available)
- 134 should accompany the provided documents.

135 If any changes occur or additional differences are discovered after submission to Q4B, the
136 Q4B EWG should be informed promptly by the pharmacopoeia concerned.

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Figure I – Topic-Specific Annexe Process

