Response to Concept Paper from Chugai Pharma UK LTD

Questions for clarification	Response to Consultation questions
1. One Global Implementing Measure • What exactly is meant by one Global Implementing Measure? ☐ MAHs should implement the same measures globally for all their products, or ☐ MAHs should implement the same measures globally for all products with a MA in the EEA	**CONSULTATION no 1** ✓ NO. The processes and pharmacovigilance tasks have been adequately covered.
2. PV Masterfile 2. Location The word "operates" is unclear. PV operations may in various countries in the EEA and QPPV oversees all /operates in all EEA sites of relevance. Furthermore contracted QPPV maybe located elsewhere and operate from a location where there is no company affiliate. 3. Content (2) (a) What is meant by "description of delegated tasks"? ☐ MAH to QPPV or ☐ QPPV to others (2) (b) What is meant by "registrations"? 6. Delegation Is it correct to assume that the description of delegated activities and/or services, as well as copies of signed agreements, relates to the system relevant for and products authorised in the EEA only?	**CONSULTATION no 2** ✓ NO. As MAH is expected to keep PV Master File up to date and it is foreseen that regular changes are made, notifying CAs would be unnecessary cumbersome for CAs and MAH alike. ✓ YES. PV Master File should contain date when it was last reviewed (even if no changes were made) as this is normal document management and is already stipulated in section 5 of II. A.

7. Audit • Should all audits or only those impacting products authorised in the EEA be recorded? • The word "main findings" of the audits needs further clarification e.g. critical findings as defined in the EEA or …? 8. Inspection • "A copy" is meant to be a paper copy or is also a copy in an electronic format by email or CD-rom acceptable? • Upon request of a copy, should also annexes be provided as e.g. indicated in II.B. section 11 on performance indicators/	**CONSULTATION no 3** ✓ No, as both description of the delegated activities and/or services as well as the copies of signed agreements will provide that information. It is suggested to include copies of the agreements as annexes and not in the body of the text.
II. **B. Quality Systems General** 10. Audit • An audit of the quality system is mandated not less frequently than every two years. If a company has a valid ISO-9001 certificate, including yearly audits, is that considered adequate?	**CONSULTATION no 4** ✓ No, requiring copies of an audit report will potentially negatively impact the quality of audits of the PV systems by QA. It will become extremely difficult for auditors to conduct audits truly independently and against the highest quality. Yes, it is fine to ask for audit schedules as it provides insight as to audit approach and the number of audits conducted.

II.C. Quality Systems PV <u>13. Resource Management</u> • Duties of managerial and supervisory staff are not in all countries -often culturally determined- defined in job descriptions but in other means such as in procedures or department descriptions; will that be acceptable? • Training records signify the initial and on-going training of staff in an adequate manner; mandating training plans is, in some organisations, an administrative activity not ensuring adequate training is conducted. Training is moreover, and particularly in PV, required when e.g. non-compliance occurs and changes in regulations.	**Consultation no 5** ✓ No, the level of detail required AND the need to have it continuously up-to-date makes it a very resource demanding exercise. The DDPS was a helpful tool for both authorities and companies to obtain a quick overview of how key PV aspects were dealt with. The requirement to keep the PV Master File succinct has disappeared in the text in this Concept Paper and it threatens to become a "paper" monster without much benefit.
	Consultation no 6 ✓ No, compliance management, in terms of meeting requirements in time and in full, is an inherent part of every activity in PV. So, it is suggested to minimise this section with a requirement that adequate processes and procedures must ensure compliance in terms of meeting requirements in time and full.
	Consultation no 7 ✓ In principle yes, but some details are over-regulated.

	Consultation no 9 ✓ Work sharing is definitely efficient and a good principle. Currently, competence levels in the MSs vary and the risk exist of inconsistency in evaluations. Moreover, experience over time shows that approaches in the MSs towards MAHs varies considerably creating inequality. ✓ It is advised that minimally two, ideally coupling less and more experienced, countries are evaluating. Moreover, and very important, is to ensure products in one class are dealt with in an equal way and so, by one couple.
	Consultation no 10 ✓ Proposed revision at this point sufficient clear. ✓ Note however: It is advised that minimally two, ideally coupling less and more experienced, countries are evaluating. Moreover, and very important, is to ensure products in one class are dealt with in an equal way and so, by one couple.