Comments on The Concept Paper submitted for Consultation per 8 Sep 2011

Page 5, section A.1., Question: given that the PV system also applies to SUSAR reporting, why is the scope limited to authorised medicinal products?

Page 5, section A.2., Question: in what way will the information provided in the EudraVigilance Medicinal Product Dictionary/future IDMP (information entry to be completed by July 2012) per Article 57(2)(c) be transferred/made publicly available on the European medicines web-portal? It appears these databases are interchangeable?

Page 5, section A.3.(1), Question: given that a pharmacovigilance system in general reflects all the MAHs medicinal products, and the fact that the information regarding these products needs to be captured in the EV MPD by July 2012, what is the added value of listing these products for MAHs with a single PV system? For some of them, this would require monthly updates to the PSMF.

Page 6: **Consultation item no.1**: In my opinion, the listed processes and tasks (in combination with those described in section A.3.(7) up to A.6. are adequately covering existing procedures minimally present in a PV system.

Page 7: **Consultation item no.2**: The summary of the PSMF as submitted in a dossier appears to be the only reference document for competent authorities (CAs) to evaluate the compliance of a PV system, other than actually inspecting the MAH. I suggest to provide a format for this summary in such a way that any changes to the PSMF that affect the summary description, require submission of a variation to the summary PSMF.

Page 8: **Consultation item no.3**: Suggest to list these in the format as describe in section A.3. as A.3.(6)(f) on page 6.

Page 8: **Consultation item no.4**: Suggest to store audit reports and audit schedules according to internal SOPs that are part of the Quality System for performance of PV activities and to not make these part of the PSMF otherwise. Agree with suggestion to list outstanding CAPAs as an appendix to the PSMF.

Page 8: **Consultation item no.5**: Yes, with note of the above comments, I agree with the requirements regarding content and maintenance of the PSMF.

Page 11: **Consultation item no.6**: Additional quality procedures in relation to
Study reporting: yes, compliance monitoring
Communication: maybe, but not to be included in the PSMF
CAPA processes: yes, requires time lines and monitoring of these
Detection of duplicates: yes, although I wonder whether this would be a shared effort by MAHs and NCAs/EMA alike?

Page 11: **Consultation item no.7**: What is considered with an existing PV system as described in the PSMF? Would this imply that documentation regarding procedures that have become redundant after an update to the PSMF can be discarded after 10 years?

Page 13: **Consultation item no.8**: Agreed, the quality system requirements here should be a model for MAHs as per the recommendation in Article 104(1) in Directive 2010/84.

Page 15: **Consultation item no.9**: In my opinion, as with peer reviewed medical publications, these are generally reviewed by experts in the field on the topic of the publication. This would be a plus regarding product specific knowledge that may lack in certain Member States as compared to others. However, I can see the gain in reduced efforts.

Page 15: **Consultation item no.10**: I would expect additional consideration on periodic review of the MAH's compliance to their own internal procedures regarding signal detection.

Page 16: **Consultation item no.11**: Agreed

Page 18: **Consultation item no.12**: Agreed

Page 18: **Consultation item no.13**: Regarding the transmission of suspected adverse reactions, will be need to adhere to current Volume 9A recommendations (National/MRP/DCP vs Centralized in regards to EU and non-EU reports) or from July 2012 onwards switch already to 15 day EV reporting for serious ADRs and 90 days for non serious ADRs? What transition approach is expected here?

Page 21: **Consultation item no.14**: Do not agree. Point (b) does not clarify whether we can include this with the xml message or whether we should report literature to the EVLit mail address. Point (i) seems to be already captured under point (f). Point (m) seems to be only applicable to serious reports, while we also need to report non-serious reports. All ADRs have a narrative that forms the basis of information to complete the other fields. What is the rationale to skip the narrative for non-serious cases?

Page 23: **Consultation item no.15**: What is the sense in submitting a Summary of the RMP for each medicinal product? If they are covered under the same RMP, then the same Summary applies. Generic manufacturers would be much helped with a format for abbreviated RMPs for low risk products, can this template also be provided?

Page 26: **Consultation item no.16**:
Question on point 4: should this not be covered in updated RMPs? It appears the legislation now foresees submission of an RMP during application for an MA, and submission of PSURs afterwards to provide assessment of RMP activities and risk-benefit assessments. Some clarification could be provided here.
Format questions: point 10. Non-clinical data: refers to pre-clinical or to post-marketing? ; point 12. Other Periodic Reports: refers to RMPs/DSURs? ; point 15. versus point 16: One of the two appears redundant? ; point 17. Benefit evaluation: only relating to post-marketing information or also including phase I/II/III clinical studies? ; point 20. Region specific information: Of what kind? Is the PSUR not intended to give a global review?

Page 34: **Consultation item no.17**: Agreed