From: Cédric De Boysson
To: SANCO PHARMACEUTICALS
Subject: PCIM /11/01 - public consultation on implementing measures for pharmacovigilance

Dear

Please find below a few comments about the concept paper submitted for consultation about PV activities:

- Page 5: in the chapters "*definition", "location*"……, it only concerns the MAH ; but, in France (I do not know the EU references), in the Public Health Code (articles R.5124-2 andR.5124-47), the "PV management" can be subcontracted within the nomination of the "PV responsible for the pharmaceutical company…..e.g. Laboratoire Biodim". Such a situation is missing in the current text.
- Moreover, page 5, the chapter 2 "*location*" should be amended as following "The MAH should ensure that the QPPV has permanent access to the PV System Master file and also the QP of the pharmaceutical company in charge of marketing the products (i.e. the so-called "French exploitant") since the latter is co-responsible (with the QPPV) about the PV of the marketed products. It was a remark following inspection by the national authorities (Afssaps).
- Page 6 : paragraph (3) : …..in accordance with Article 104(4) of Directive ……." :are you sure about the reference to the right article ?
- Answer item n°1: Page 6 : paragraph (6)(c): "Individual case safety report ……and reporting, **including transmission to Health Authorities of serious and non-serious PV cases according to regulatory timelines"**
- Answer item n°1 : page 6: add item (f) : follow up of international literature and results of clinical studies relating to PV
- Page 7 : partial answer item n°2: each document (e.g. the master file) anyway should be dated in order to avoid the use of expired document according to current regulation.
- Page 8 :answer item n°3: in case of co-marketing, the responsibilities of each party should be detailed in the obligatory agreement between both.
- Page 8: Chapter 7: answer to item n°4: the audit report is confidential ; only the agenda and the conclusions of it should be available in the master file.
- Page 8: chapter 9: "The quality system covers the organizational structure, …… processes **including back-up**"
- Page 9: chapter 10. Audit: "Audits of the quality system shall be performed …….~~and not less than~~ **on average** every two years… (it will allows not to be out of SOP in case of second audit performed 26 months after the previous one)
- Page 9: chapter 10. Audit: the sentence "Quality audits shall be conducted by individuals who do not have direct responsibility by the matters being audited". It seems to be not possible "not to have direct responsibility" since the audit is generally (always ?) performed following obligation by the company which has to perform an audit of its subcontractor. As such, how can this company have no responsibility in the audit ? . Yes nevertheless to perform an audit with no conflict of interest between both companies (audited and auditing) since it is the basis of an audit "to be impartial and remaining neutral.
- Page 11 chapter 14 : partial answer to item n°6: it generally exists SOP in the MAH and the "exploitant" for PV and the "management" of the cases relevant to PV and SOP for relation between Health Authorities and the MAH and also a SOP for the communication with Health professionals to be informed. Such SOPs can be considered as taking part of the quality system of the company.
- Page 13 chapter 19: answer to item n°8: comment: where come from the so long record of information of 10 years and 30 years ? The information and results about clinical studies and in

case of batch recall have to be respectively recorded for 15 and 20 years. “30 years” in the current case seems to be excessive.

- Page 26 annex III electronic PSUR: answer to item n°16: what about the bridging or binding report and other addenda extra the PSUR ? Do not forget them since there are especially according to PSUR synchronization (see: current EU HBD work sharing list)

Best Regards

Cédric de BOYSSON
Pharmacien Responsable Intérimaire – Responsable Affaires Réglementaires & Assurance Qualité
Laboratoire BIODIM