10 September 2010

Submission of comments on Draft detailed guidance on the collection, verification and presentation of adverse reaction reports arising from clinical trials on medicinal products for human use ('CT-3')

(SANCO. Ddgl.c.8(2010) 384118)

Comments from:

Name of organisation or individual
Bristol-Myers Squibb (Contact person: Elliott Levy (elliott.levy@bms.com)

1. General comments

Stakeholder number	General comment (if any)	Outcome (if applicable) *(To be completed by the Commission)*

2. Specific comments on text

Location of the relevant text *(e.g. Lines 20-23)*	Stakeholder number *(To be completed by the Commission)*	Comment and rationale; proposed changes *(If changes to the wording are suggested, they should be highlighted using 'track changes')*	Outcome *(To be completed by the Commission)*
Section 4.3.3 - #44 and #45		Comment: The determination of expectedness is the responsibility of the sponsor and not the investigator, as suggested in this draft guidance. Proposed change (if any): This should be consistent with Volume 10, Detailed guidance on the collection, verification and presentation of adverse drug reaction reports arising from clinical trials on medicinal products for human use, Revision 2, April 2006.	
Section 4.6 - #52		Comment: The statement appears to imply that individual EU Health Authorities should not require additional reports from Clinical Trials outside of this guidance (e.g. it is not required to submit cases from interventional clinical trials to meet Volume 9a expedited reporting obligations). Proposed change (if any): Harmonize the reporting approach between the European Commission and the local EU Health Authorities.	
Section 4.11.2 - #98		Comment: It is unclear whether the initial assessment of IMP comparators remains as it is stated clearly in the 2006 Guidance, Section 5.1.8. Proposed change (if any): It would be much clearer if the unblinding steps were reproduced as stated in the 2006 Guidance.	
Page 1		Comment: Not mentioned in this guidance, but contained in previous April 2006 Detailed Guidance (Section 5.1.1.1 (3)) and referenced on Page 1 of "CT-3": Obligation to report SUSARs for IMP not registered in EU (i.e., registration in US and spontaneous or literature case reported). Proposed change (if any):Confirm obligation to report SUSAR for IMP not registered in EU.	