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10 September 2010

Dear Sir/Madam

Please find enclosed comments from Elan in respect of the public consultation document "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')"

Sincerely,

Muriel O'Byrne, PhD

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Cc: Dr Grainne Quinn

VP Global Pharmacovigilance & Risk Management
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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')

Public Consultation Paper
Deadline for Consultation 10th September 2010

Table of Comments

Draft Guidance Document Section	Comments
1. Section 4.7.2 1, 'Timelines (1) Follow-up information received before the 15 days reporting timeline Relevant follow-up information is to be communicated within an additional eight days.'	Section 4.7.2 1: If follow-up information is received for a fatal and/or life-threatening case, previously submitted as an incomplete initial seven day report, Elan agrees that additional information should be submitted by the sponsor in the 'additional eight days'. However, if follow-up information is received for a fatal and/or life-threatening case, previously submitted as a complete initial seven day report, Elan prefers that the sponsor have an additional fifteen days to submit, from the date of receipt, the new information. In this scenario, if the initial seven day report was provided with complete information, the proposed requirement to report the follow-up information in the 'additional eight days' could jeopardize the quality of the follow-up report. For example, if the sponsor were to receive new information on day fourteen for a previously submitted complete seven day report, this proposed guidance states that sponsor would be required to submit on the next calendar day to meet the timeline of the 'additional eight days' not allowing the sponsor much time to produce a quality report to the agency.

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	Our opinion is consistent with the existing language found in the ID 004 of the Question and Answer Guidelines specific to adverse reaction reporting in Clinical Trials. Elan has found the existing Question and Answer Guidance Document useful in clarifying this scenario. Elan proposes that additional clarification be added for this section.
2. Section 4.8, 'Reporting of non fatal or life-threatening SUSARs to the national competent authority (Line 88) There may be cases where a SUSAR turns out to be fatal or life-threatening, whereas initially it was not considered as fatal or life-threatening. The fatal or life-threatening follow-up report should be reported by the sponsor or delegated person as soon as possible, but within a maximum of seven days after first knowledge of the reaction being fatal or life-threatening.'	Section 4.8: Elan agrees with the proposed language but proposes that language be added to clarify this section to prevent possible varied interpretations by Sponsors. Elan proposes that the language to be added should be consistent with the existing language provided in ID 006 and ID 007 of the Question and Answer Guidelines specific to adverse reaction reporting in Clinical Trials, as this clarification has been useful for clarifying this scenario.

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