July 2010 (Deadline 10th Sept 2010)
To: sanco-pharmaceuticals@ec.europa.eu

SUBMISSION OF COMMENTS ON

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')

COMMENTS FROM:

Name of Organisation or individual
Mundipharma Research Ltd

1. General Comments

No General Comments

2. Specific Comments on Text

Line No of the first line(s) affected. *<e.g. Line 20-23>*	**Comment and Rationale; proposed changes** *<if changes to the wording are suggested, they should be highlighted using "track changes">*
Sections 4.2.3 **Unexpectedness:** and 4.3.3 **Expectedness:** Page 6 and 7 Paragraph 45: "In the absence of information on the expectedness by the reporting investigator, the sponsor should consult the reporting investigator and encourage him to express an opinion on this aspect. The expectedness assessment given by the investigator should not be downgraded by the sponsor. If the sponsor disagrees with the investigator's expectedness assessment, both, the opinion of the investigator and the sponsor should be provided with the report."	**Comments:** There is a discrepancy between section 4.2.3 and 4.3.3 about who is assessing the expectedness of a SUSAR. As the sponsor knows their product better than the investigator, and different investigators may assess the same event differently with regards to expectedness, the sponsor should assess the expectedness of a SAE, and not be obliged to get an assessment of the investigator. **Proposed change (if any):** Paragraph 45 should be omitted.
Section 4.5. **Adverse reactions not to be reported** Page 8	**Comments:** SUSARs from trials performed (partly or exclusively) in the EU by other sponsors do not have to be reported. What about SUSARs from clinical trials performed exclusively in third countries, by other sponsors? **Proposed change (if any):** NA

Line No of the first line(s) affected. *<e.g. Line 20-23>*	**Comment and Rationale; proposed changes** *<if changes to the wording are suggested, they should be highlighted using "track changes">*
4.7.3. Addressee of report, reporting to EVCTM, reporting arrangements Page 11	**Comments:** The sponsors responsibility should be clarified in sections 4.7.3.1 and 4.7.3.3.
4.7.3.3. Transitional reporting procedures Page 12 Paragraph 78: "In addition to the SUSARs to be reported in accordance with section 4.4, sponsors should report SUSARs related to the same active substance of the IMP (independent of pharmaceutical form and strength) in a clinical trial performed exclusively in another Member State, ..."	**Comments:** In section 4.7.3.3, paragraph 78 it should also be clarified, if this includes clinical trials performed in another member state AND a third country.
4.7. Reporting of fatal or life-threatening SUSARs to the national competent Authority **Section 4.8 - Reporting of non fatal and non life-threatening SUSARs to the national competent authority**	**Comments:** Proposed changes reflect improved readability and clarity. **Proposed change (if any):** The guideline would be more readable if section 4.7 and 4.8 were united to one section with different timeline sub sections for: initial reporting, follow-up reporting of fatal/LT SUSARs and SUSARs that become fatal/LT upon FU.
Section 4.9. **Reporting of SUSARs to Ethics Committees** Paragraph 89	**Comments:** Seek clarification if SUSARs after the end of the trial have to be reported as ICSRs to the EC. It does make sense to report SUSARs to regulatory authorities, whose responsibility for a product does not end with the end of a trial. However an EC, which is only overseeing the conduct of one trial, will not have much benefit of a SUSAR report after this trial has ended.
4.11.1. Blinded IMPs Page 14-15	**Comments:** Breaking the blind: If a CT is performed exclusively in a third country, does the blind have to be broken for SUSARs, even if this is not a requirement in that country?