EUROPEAN COMMISSION
HEALTH AND CONSUMERS DIRECTORATE-GENERAL

Health systems and products
Pharmaceuticals

Brussels, 05/07/2011
SANCO/D/3/SF/jr D(2011)

11/SANCO/CT/09

MEETING OF THE *AD HOC* GROUP FOR THE DEVELOPMENT OF IMPLEMENTING GUIDELINES FOR THE "CLINICAL TRIALS DIRECTIVE" 2001/20/EC ON 13 JULY 2011, AT 10H IN THE "CENTRE DE CONFERENCE 'ALBERT BORSCHETTE'"(CCAB) RUE FROISSART 36, B-1040 BRUSSELS[1] DRAFT AGENDA

1. Welcome

2. Adoption of the draft agenda (Working document 11/SANCO/CT/09)

3. Adoption of the minutes of the previous meeting of 1 April 2011[2] (Working document 11/SANCO/CT/08draft)

4. "Questions and Answers" Document in EudraLex Volume 10: New and revised Q&A in the draft version 9.0 (Working document 11/SANCO/CT/10) (*for discussion prior to publication by Commission*)

5. Results-related information in EudraCT (Working document 11/SANCO/CT/11) (*for discussion*)

6. Revision of the Clinical Trials Directive (Working document 11/SANCO/CT/12) (*for discussion*)

7. Update on initiatives related to safety reporting

   - Detailed guidance CT-3[3] (*for information*)

   - Discussions re. ICH guideline E2A (*for information*)

8. Any other business

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1 For 'newcomers': Access plan is here http://ec.europa.eu/oib/pdf/building-map_en.pdf

2 Sent to participants on 3 April 2011.

3 http://ec.europa.eu/health/files/eudralex/vol-10/2011_c172_01/2011_c172_01_en.pdf

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U:\Pharma\2. Legal and Regulatory - Human and general\2.20.a Clinical Trials Regulation\Committees\ad hoc group\ready to be uploaded - temp\2011 July Agenda.doc
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9. Closing of session (scheduled for 18:00h at the latest)

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NB: Next meeting scheduled in 2011[4] for the *ad hoc* group for the development of implementing guidelines for the "clinical trials directive" 2001/20/EC:

- 06/10/2011

[4] Subject to change (availability of meeting rooms).