EUROPEAN COMMISSION
ENTERPRISE AND INDUSTRY DIRECTORATE-GENERAL

Consumer goods
Pharmaceuticals

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10/ENTR/CT/01

MEETING OF THE *AD HOC* GROUP FOR THE DEVELOPMENT OF IMPLEMENTING GUIDELINES FOR THE "CLINICAL TRIALS DIRECTIVE" 2001/20/EC ON 18 FEBRUARY 2010, 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 10/ENTR/CT/01)

3. Adoption of the minutes of the previous meeting of 19 November 2009 (Working document 09/ENTR/CT/25draft[2])

4. "Questions and Answers" Document of the European Commission - version 5.0; (Working document 10/ENTR/CT/04) (*for discussion prior to publication*)

    - New and revised Q&A in the version 5.0 (*for discussion prior to publication by Commission*)

    - Suggestions for new Q&A in the version 6.0

5. SUSAR reporting in *Eudravigilance* – Clinical Trials Module (short presentation by EMA) (Working documents 09/ENTR/CT/26 and 09/ENTR/CT/27)

6. First discussion on possible issues which could be addressed in implementing guidelines:

    - Collection, verification and presentation of adverse reaction reports arising from clinical trials on medicinal products for human use (Working document 10/ENTR/CT/03)

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

2 Sent by email on 27/11/2009.

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U:\Pharma\2. Legal and Regulatory - Human and general\2.20. Clinical Trials Directive\20. Committees etc\2. Clin Trials Group (ad hoc)\2010\Meeting 2010_02_18\10_ENTR_CT_01 Agenda.doc
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- Application format and documentation to be submitted in an application for an Ethics Committee opinion on the clinical trial on medicinal products for human use (Working document 10/ENTR/CT/02)

7. Assessment of the functioning of the Clinical Trials Directive (*Follow-up discussion to the public consultation. As working document shall serve the public consultation paper.*[3] *The responses to the public consultation are going to be published soon on the 'Clinical Trials website' of the Commission*[4])

8. Update on other, related initiatives

   – Revision of the detailed guidance for the request for authorisation of a clinical trial on a medicinal product for human use to the competent authorities, notification of substantial amendments and declaration of the end of the trial

   – Development Safety Update Report (DSUR)

   – Reporting of results-related information to EudraCT

9. Organisational issues (Working document 10/ENTR/CT/05)

10. Any other business

11. Closing of session (scheduled for 18:00h at the latest)

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NB: Meetings scheduled in 2010[5] for the *ad hoc* group for the development of implementing guidelines for the "clinical trials directive" 2001/20/EC:

~~06 May 2010~~

NB: This date has been changed to 11 May 2010

22 July 2010

~~**14 October 2010**~~

NB: This date has been changed to 13 October 2010

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[3] http://ec.europa.eu/enterprise/sectors/pharmaceuticals/files/clinicaltrials/docs/2009_10_09_public-consultation-paper.pdf

[4] http://ec.europa.eu/enterprise/sectors/pharmaceuticals/human-use/clinical-trials/developments/index_en.htm

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