13/SANCO/CT/05

MEETING OF THE *AD HOC* GROUP FOR THE DEVELOPMENT OF IMPLEMENTING GUIDELINES FOR THE "CLINICAL TRIALS DIRECTIVE" 2001/20/EC ON 30 APRIL 2013

MINUTES (FINAL)

List of participants annexed

1. Welcome

   The Commission representative (COM) welcomed the participants.

2. Adoption of the draft agenda (Working document 13/SANCO/CT/01)

   The agenda was adopted without changes.

3. Adoption of the minutes of the previous meeting of 18 December 2012 (Working document 11/SANCO/CT/07draft rev 1)

   The minutes of the previous meeting were adopted without changes.

4. 'Questions and answers' Document in EudraLex Volume 10

   4.1 New and revised Q&A in the draft version 11.0 (working document 13/SANCO/CT/02)

   COM presented the 11th version of the Q&A document on Clinical Trials. The first new element was question number 1.7. concerning studies involving surgery, which was submitted by an academic sponsor.

   Some MS stressed that is a case by case assessment which depends from the objective of the study. A similar situation applies to Question 1.6. on clinical trials involving the use Medical Devices. COM agreed to adapt the Q&A document.

   COM introduced question 4.1. submitted by academic sponsors, concerning suspected *expected* serious adverse reactions. Participants made comments on the importance of reporting every adverse reaction. However they underlined that the way of reporting for *susars* and *sesars* should be different. COM clarified that *sesars* should not be reported in eudravigilance, and that the Q&A will be adapted accordingly.

   One participant asked clarifications on question 1.10. on 'non-interventional trials', and in particular on what should be intended as 'monitoring', and if for example a

socio economic questionnaire should be considered as 'monitoring'. Participants had an exchange of views on this issue.

4.2. Additional suggestions for Q&A from SE (working document 13/SANCO/CT/04)

SE presented 7 possible Q&A on Reference Safety Information. Following a discussion between participants it was decided for the moment not to include these questions in the existing document.

5. Template for the qualified person's declaration concerning GMP compliance of IMPs manufactured in third countries (working document 13/SANCO/CT/03)

COM presented the draft template produced by the working group. COM explained the changes made following the last meeting and asked the participants to comment. Subject to minor changes participants agreed on the content of the template which was then published in Eudralex volume 10.

6. Future EU clinical trials portal – COM gave a feedback from 1st meeting of sub-group

7. Update on other, relates issues

7.1. Public consultation on draft revised version of Declaration of Helsinki (working document is at: http://www.wma.net/en/20activities/10ethics/10helsinki/15publicconsult/DoH-draft-for-public- consultation_annotated.pdf)

COM informed participant on the public consultation and recalled that it is an opportunity to participate on the drafting of the revised version of Declaration of Helsinki. COM asked participant to be informed about eventual comments sent in the framework of this public consultation process.

7.2. Proposal for a Clinical Trials Regulation

COM updated on the state of play of the negotiations between the co-legislators. In Council the aim of the current Presidency would be to finish an initial reading on all articles. COM reminded that at the Parliament 3 committees had already voted, the vote of the leading committee, ENVI, is expected at the end of May.

7.3. Launch of selection procedure ('concours') for persons with experience in audit, inspection and evaluation in the area of clinical trials.

COM informed about the publication of the competition notice.

8. Any other business

There no being any other business, COM closed the meeting.

List of Participants

Country	Organisation
AT	BASG / AGES / MEA
AT	Forum of the Austrian Ethics Committees
BE	FAMNP
BE	Belgian Ethics Committees
CZ	State Institute for Drug Control
DE	Ministry of Health
DE	Arbeitskreis Medizinischer Ethik-Kommissionen in Deutschland e.V.
DE	Paul-Ehrlich Institut
DE	Federal Ministry of Health
DE	BFARM
DK	Danish Health and Medicines Authority
EE	Ethics Committee
EE	State Agency of Medicines
ES	AEMPS
FI	Finnish Medicines Agency
FI	National Committee on Medicinal Research Ethics
FR	ANSM
EL	EOF
IE	Health Information & Quality Authority
IE	Irish Medicines Board
IT	AIFA Italy
LT	SAM Latvia
NO	Norwegian Medicines Agency
PL	Ministry of Health
PT	National Ethics Committee for Clinical Research - CEIC
RO	CNESCM Asoc.Etic. Med.
SE	Ethics Committee
SE	Swedish NCA MPA
SK	State Institure for Grug Control
SV	JAZMP Agency for medicinal products and medical devices
UK	Health Research Authority
UK	MHRA
EMA	