

Report on the European Ombudsman's inspection of documents concerning Own-Initiative Inquiry OI/8/2015/JAS involving the European Commission

Correspondence - 21/09/2015

Case OI/8/2015/JAS - **Opened on** 26/05/2015 - **Decision on** 12/07/2016 - **Institutions concerned** European Parliament (No further inquiries justified) | Council of the European Union (No further inquiries justified) | European Commission (No further inquiries justified) |

Institution or body concerned: European Commission

Date and time: 16 September 2015, 9.30-14:30

Location: Brussels, DG SANTE

Inspection carried out by :

- Mr Fergal Ó Regan, Head of Complaints and Inquiries Unit 2
- Mr Jan Stadler, Complaints and Inquiries Unit 2

Introductory and procedural aspects

The Ombudsman representatives introduced themselves, thanked all services [1] for their cooperation and then set out the objective and purpose of the present inspection within the context of the Ombudsman's own-initiative inquiry on trilogues.

They then outlined the legal framework which applies to the Ombudsman's services when they carry out inspections and informed the Commission staff present that if they identified any documents to be confidential, the applicable rules provide that no access may be granted to those documents [2] . The Ombudsman representatives further explained that a report on the inspection would be prepared, sent to the Commission and published on the Ombudsman's website.

Objective of the inspection

The objective of the inspection was to inspect the Commission's file on the trilogues concerning the Clinical Trials Regulation [3] .



The inspection of the file

The Commission representatives provided full access to the Ombudsman representatives to the documents in the above-mentioned file.

At the beginning of the inspection, the Commission representatives provided general information about the Clinical Trials Regulation. The Commission representatives also explained the structure and nature of the files provided to the Ombudsman representatives.

The Ombudsman representatives then proceeded to a thorough inspection of the documents provided by the Commission in order to get a better understanding of the different types of documentation usually produced in connection with trilogues.

The contents of the files that were inspected were as follows:

Documents tabled for trilogue sessions:

- Technical meeting, 26/06/13
- Invitation to the tech meeting of 26/06 from the EP ENVI [4] secretariat sent on 19 June and Council confirmation (conf.)
- ENVI Committee report + consolidated report (not req.)

- Technical meeting, 12/07/13
- Invitation from the EP ENVI secretariat with details on the agenda (conf.)

- Political trilogue, 06/11/13
- Draft agenda
- Index to the agenda prepared by EP
- 4CT [5] prepared by Council, Version of 31 October 2013 (not req.)
- Consolidated version received on 22 November (not req.)

- Technical meeting, 07/11/13
- Agenda prepared and sent by the EP ENVI secretariat
- EP compromise on clinical trials with low interventional risk (conf.)

- Technical meeting, 11/11/13
- Draft agenda prepared and sent by the EP ENVI secretariat
- EP proposal on Article 29 (conf.)

- Political trilogue, 13/11/13
- Invitation from the EP ENVI secretariat (conf.)
- Draft agenda

- Technical meeting, 15/11/13
- Invitation from the EP ENVI secretariat (conf.)



- Draft agenda
- EP proposal on Article 72 (conf.)
- EP proposal on Article 28(2a) (conf.)
- Compromise on Article 72 drafted by Commission (conf.)
- EP compromise proposal on Article 78(3) and Recital 20a (conf.)
- Council compromise proposal: Working Document No 4 - informed consent and cluster trials, Art 28-29 (conf.)

- Technical meeting, 22/11/13
- Draft agenda
- Compromise proposal by EP on Article 78(2) and Recital 52 (conf.)

- Technical meeting, 29/11/13
- Invitation from the EP ENVI secretariat (conf.)
- Draft agenda
- 4CT prepared by Council, Version 26 and 27 November 2013 (not req.)
- Annotated 4CT drafted and sent by the EP ENVI secretariat, Version of 28 November 2013 (not req.)
- Informal EP working documents on the annexes (not req.)
- Proposal by Presidency on Article 2(3), working document nr 6 (conf.)
- Presidency compromise, working document nr 7 (conf.)
- EP compromise proposal on Article 34(3) and Article 39a (conf.)

- Political trilogue, 04/12/13
- Draft agenda
- 4CT, Version of 2 December 2013 (conf.)
- Presidency compromise on Article 8(3) (conf.)

- Technical meeting, 06/12/13
- Email from EP with details on the agenda (conf.)
- Sections of the 4CT as amended during the last technical meeting (not req.)
- Presidency proposal on Article 93, 78a and 91 (conf.)
- Email with a proposal from EP on Article 2(30a) (conf.)
- Email with a proposal from EP on Article 73 (conf.)

- Political trilogue, 12/12/13
- Draft agenda
- EP compromise amendment on incapacitated subjects (conf.)
- Commission proposal on vulnerable populations (conf.)
- Email from Commission on patients involvement (conf.)
- Council compromises drafted for the last trilogue (conf.)

- Technical meeting, 13/12/13
- 4CT prepared by Council, Version of 13 December 2013 (not req.)
- Recitals of the 4CT prepared by DG SANTE [6] (not req.)



- Sections of 4CT prepared by EP, Version of 13 December 2013 (not req.)
- Technical meeting, 16/12/13
- 4CT prepared by EP, Version of 16 December 2013, including comments on recitals from the Commission (conf.)
- Emails on fine tuning of the recitals (conf.)

Internal reporting:

- Report of the trilogue of 07/11/2013 prepared by SG [7] and circulated internally in DG SANTE (conf.)
- Report of the trilogue of 13/11/2013 prepared by SG (conf.)
- SG report of the trilogue of 13/11/2013 circulated internally in SANTE (conf.)
- Report of the trilogue of 04/11/2013 prepared by SG (conf.)
- Intra-DG SANTE report on the outcome of the trilogue of 12/12/2013 (conf.)
- Report of the trilogue of 12/12/2013 prepared by SG (conf.)

GRI

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fiches:

- GRI fiche S(2013) 610/2 (conf.)
- GRI fiche SI(2013) 703 (conf.)
- GRI fiche SP(2014) 294 (conf.)

Other documents:

- Summary of the meeting of 26 June prepared by the Irish presidency (conf.)
- Email confirmation by the Council on participation to the technical meeting of 12 July 2013 (conf.)
- Email confirmation by Commission on participation to the technical meeting of 12 July 2013 and reply from EP secretariat (conf.)
- Email from ENVI secretariat with a proposal for trilogue dates and details on the scope of the pre-trilogues technical meetings (conf.)
- Email from Commission to ENVI secretariat with questions on the amendments voted by EP and reply from EP (conf.)
- Email from Commission to ENVI secretariat with comments on the proposed dates of meetings and reply from EP (conf.)
- Follow-up email prepared by EP ENVI secretariat on meeting dates (conf.)
- Email exchanges between EP ENVI secretariat and Council secretariat (conf.)
- Email from ENVI secretariat confirming the dates of the trilogues and reply from Council (conf.)
- Possible agenda points for the 1st and 2nd trilogue prepared by Council secretariat (conf.)
- List of participants to the trilogue of 06/11/2013 from Council (conf.)



- Draft Agenda of the trilogue of 06/11/2013 drafted and sent by the EP ENVI (conf.)
- Email from Council on the agenda of the trilogue of 06/11/2013 (conf.)
- Email from ENVI secretariat with the EP participants to the trilogue of 06/11/2013 and reply from Council (conf.)
- Email from Commission to Council secretariat informing of mistakes in the 4CT and reply from Council (conf.)
- Email with details of the trilogue of 06/11/2013 and EP participants prepared and sent by the EP ENVI secretariat (conf.)
- Emails between SANTE and ENVI secretariat on timelines for assessments (conf.)
- Email with comments on the agenda of the technical meeting of 07/11/2013 sent by Council (conf.)
- Email between SANTE and ENVI secretariat on the agenda of the technical meeting of 07/11/2013 (conf.)
- Informal suggestion from SANTE to ENVI secretariat and rapporteur on Article 4 and Article 8 (conf.)
- Emails between Council secretariat and EP secretariat on the agenda for the meeting on 11 November 2013 (conf.)
- Emails between Council secretariat and EP secretariat on the meeting of 15 November 2013 (conf.)
- Email from SANTE to the EP secretariat on the proposal on access to documents legislation (conf.)
- Email from Council to EP on the possible agenda points for the technical meeting of 22/11/2013 (conf.)
- Informal email from SANTE to ENVI secretariat and rapporteur office on the compromise amendment on Article 78(2) (conf.)
- Informal email from SANTE to ENVI secretariat and rapporteur office on standards for the voluntary sharing of raw data (conf.)
- Informal email from SANTE to ENVI secretariat and rapporteur office on the definition of CSR (conf.)
- Emails between ENVI secretariat and Council Secretariat on the agenda of the meeting of 29/11/2013 (conf.)
- Informal email from ENVI secretariat to SANTE on the annexes to the proposal and reply from SANTE (conf.)
- Informal emails ENVI secretariat-SANTE on the date of application of the Regulation (conf.)
- Rapporteur office forwarded to SANTE an email the rapporteur has sent to the Presidency (conf.)
- Informal email from the rapporteur office to SANTE on Article 72(3) and replies (conf.)
- Exchanges SANTE/Council/ENVI secretariat on the wording of recital 5 (conf.)
- Email from Council secretariat informing that some factual mistakes have been detected (conf.)

In a brief discussion following the inspection of the files, the Ombudsman representatives were able to obtain clarification on certain aspects of the documents provided.

The Ombudsman representatives asked for and obtained copies of the documents provided by



the Commission [9] .

The Commission staff stated that, for the purposes of the inspection, the documents marked above as 'conf.' were confidential. The applicable rules provide that no access may be granted to those documents by the Ombudsman [10] . This is without prejudice to the right of citizens to request public access to these documents in accordance with Regulation 1049/2001 [11] .

Finally, the Ombudsman's services expressed their gratitude for the good cooperation of all three institutions involved and present.

The meeting then ended.

Brussels, 21 September 2015

Mr Jan Stadler Legal Officer (case handler)

Mr Fergal Ó Regan Head of Unit

[1] A representative each from the Council of the EU and from the European Parliament attended along with their colleagues from the Commission.

[2] Articles 13(3) and 14(2) of the European Ombudsman's Implementing Provisions.

[3] Regulation (EU) No 536/2014 of the European Parliament and of the Council of 16 April 2014 on clinical trials on medicinal products for human use, and repealing Directive 2001/20/EC; OJ 2014 L 158, p. 1.

[4] European Parliament Committee on Environment, Public Health and Food Safety.

[5] Four-column table.

[6] Directorate-General for Health and Food Safety.

[7] Secretariat-General.

[8] Inter-institutional relations group.

[9] The Ombudsman did not request copies of certain documents, indicated in the list as 'not req.', since these documents were readily available from other sources, will be obtained either from the Parliament or the Council or were otherwise not required for the inquiry.



[10] Articles 13(3) and 14(2) of the European Ombudsman's Implementing Provisions.

[11] Regulation (EC) No 1049/2001 of the European Parliament and of the Council of 30 May 2001 regarding public access to European Parliament, Council and Commission documents, OJ 2001 L 145, p. 43.