

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

Correspondence - 18/01/2018

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: Council of the European Union

Date and time: 20 November 2015, 10:00-13:30

Location: Brussels, Justus Lipsius building

Inspection carried out by :

- Ms Rosita Agnew, Head of Strategic Inquiries
- Mr Jan Stadler, Inquiry Coordination Unit

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 Council 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 Council and published on the Ombudsman's website.

Objective of the inspection

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

The inspection of the file



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

At the beginning of the inspection, the Council representatives provided general information about the legislative process leading to the adoption of the Clinical Trials Regulation. The Council 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 Council in order to get a better understanding of the different types of documentation usually produced in connection with trilogues.

As most of the documents tabled for the individual trilogue meetings had already been obtained during the inspection of the Commission's file [4] , the Ombudsman services asked only for, and obtained copies of, the following documents tabled during the meetings:

- Follow-up to the technical meeting of 16 December 2013
- DS [5] 2089/13 - Article 78
- Email exchange between Council and Commission on abovementioned document (conf.)

The Council's services further provided the following internal Council documents [6] :

- Summary of the meeting of 26 June prepared by the Irish presidency dated 26 June 2013 (conf.)
- Copy of an email of 9/12/2013 of the rapporteur office sent to the Presidency (conf.)
- Working Party of 26 September 2013
- Working documents CTR [7] -32 and CTR-33
- Working Party of 2 & 3 October 2013
- Presidency Flash 11 (conf.)
- Document 13463/13
- Working documents CTR-14 REV 3, CTR-15 REV 4, CTR-25 REV 1, CTR-26 REV 1, CTR-28 REV 1, CTR-31, CTR-34, CTR-35, CTR-36, CTR-37
- DS 1692/13 + ADD 1
- DS 1796/13, DS 1801/13 + ADD 1 + ADD 1 REV 1, DS 1807/13
- Working Party of 14 October 2013
- Presidency Flash 13 (conf.)
- Document 13463/1/13 REV 1
- Working documents CTR-15 REV 5, CTR-23, CTR-25 REV 2, CTR-34 REV 1, CTR-39, CTR-42, CTR-43
- DS 1819/13, DS 1821/13, DS 1822/13, DS 1828/13, DS 1829/13, DS 1838/13, DS 1839/13, DS 1840/13, DS 1841/13, DS 1842/13, DS 1843/13, DS 1844/13, DS 1845/13, DS 1846/13, DS 1848/13, DS 1851/13
- Working Party of 21 & 22 October 2013
- Presidency Flash 16 and 17 (conf.)
- 13463/2/13 REV 2



- Working documents CTR-40, CTR-41, CTR-42, CTR-43, CTR-43 REV 1, CTR-44, CTR-45, CTR-46, CTR-47, CTR-48
- DS 1822/1/13 REV 1
- DS 1796/13 ADD 1, DS 1796/13 ADD 1 REV 1, DS 1822/2/13 REV 2, DS 1867/13, DS 1869/13 + ADD 1, DS 1880/13, DS 1881/13, DS 1882/13
- Working Party of 28 October 2013
- Presidency Flash 18 (conf.)
- Document 13463/3/13 REV 3
- Working documents CTR-49, CTR-50, CTR-50 REV 1, CTR-51, CTR-52
- DS 1895/13, DS 1896/13, DS 1897/13, DS 1898/13, DS 1900/13
- COREPER [8] of 30 October 2013
- Document 15245/13 : Presidency Note to COREPER of 29 October 2013 - Preparation of the first informal trilogue
- Working Party of 8 November 2013
- Presidency Flash 19 (conf.)
- Working documents CTR-51, CTR-53, CTR-53 REV 1, CTR-53 REV 2, CTR-54, CTR-54 REV 1
- CTR-55 (not req.)
- DS 1923/13
- DS 1834/13
- DS 1834/13 ADD 1, 2, 3, 4, 5, 5 REV 1, 6, 7, 8 :4-columns document (not req.)
- Working Party of 12 November 2013
- Presidency Flash 21 (conf.)
- Working document CTR-56
- Working Party of 18 November 2013
- Presidency Flash 22 (conf.)
- Working documents CTR-57, CTR-57 REV 1
- Working Party of 25 November 2013
- Presidency Flash 23 (conf.)
- Working documents CTR-58, CTR-59, CTR-60
- COREPER of 29 November 2013
- Document 16636/13 + COR 1: Presidency Note to COREPER of 27 November 2013 - Preparation of the third informal trilogue
- Working Party of 3 December 2013
- Presidency Flash 25 (conf.)
- Working documents CTR-61, CTR-62, CTR-63, CTR-63 REV 1, CTR-64, CTR-65, CTR-66, CTR-67, CTR-68, CTR-69, CTR-70, CTR-71, CTR-72
- DS 2015/13
- COREPER of 4 December 2013
- Document 15720/13 : Presidency Note to COREPER of 3 December 2013 - Preparation of the third informal trilogue
- DS 2034/13
- Working Party of 6 December 2013
- Working documents CTR-63 REV 2, CTR-64 REV 1, CTR-65 REV 1, CTR-67 REV 1 (not req.)
- CTR-73



- CTR-74 (not req.)
- CTR-75
- DS 2040/13
- COREPER of 12 December 2013
- Documents 17414/13 + ADD 1 to 8: Presidency Note to COREPER of 9 December 2013 - Preparation of the fourth informal trilogue
- COREPER of 20 December 2013
- Documents 17865/13 + COR 1
- Document 17863/1/13 REV 1
- DS 2089/13 (Article 78)
- Document 17866/13

The Council 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 [9] . This is without prejudice to the right of citizens to request public access to these documents in accordance with Regulation 1049/2001 [10] .

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

The meeting then ended.

Brussels, 25 November 2015

Mr Jan Stadler Legal Officer (case handler)

Ms Rosita Agnew Head of Strategic Inquiries

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

[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] Please see the relevant inspection report.

[5] Document de Séance.



[6] The Ombudsman did not consider it necessary to request copies of certain documents, indicated in the list as 'not req.', since these documents were not required for the inquiry, already contained within other documents or otherwise readily available from other sources. Some documents were not obtained in their entirety as they are publicly available on the Council register.

[7] Clinical Trials Regulation.

[8] Committee of Permanent Representatives.

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

[10] 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.