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

Correspondence - 20/11/2015
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 Parliament

Date and time: 19 November 2015, 15:00-17:00

Location: Brussels, SQM 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 Parliament 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 Parliament and published on the Ombudsman's website.

Objective of the inspection

The objective of the inspection was to inspect the Parliament's file on the trilogues concerning

the Clinical Trials Regulation [3] .

The inspection of the file

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

At the beginning of the inspection, the Parliament representatives provided general information about the legislative process leading to the adoption of the Clinical Trials Regulation. The Parliament 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 Parliament 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 internal Parliament documents:
- Trilogue, 06/11/2013
- Feedback note from the first trilogue (conf.)

- Shadows meeting, 13/11/2013
- List of issues for the Shadows meeting (conf.)
- Background document: Outcome of the discussion held at technical level on Article 29 (conf.)

- Trilogue, 13/11/2013
- Feedback note from the second trilogue (conf.)

- Shadows meeting, 27/11/2013
- Agenda for the Shadows meeting (conf.)

- Trilogue & Shadows meeting, 04/12/2013
- Agenda for the Shadows meeting and the trilogue (conf.)
- Background document: Overview of timelines, by the ENVI [5] Secretariat (conf.)
- Background document: Overview of timelines, by the Rapporteur's office (conf.)
- Background document: Overview of timelines, by the Presidency (conf.)
- Feedback note from the third trilogue (conf.)

- Shadows meeting, 11/12/2013
- Agenda for the Shadows meeting (conf.)

- Trilogue, 12/12/2013
- Feedback note from the fourth trilogue (conf.)

- ENVI meeting, 14/11/2013
- Excerpt from the minutes of meeting; Update by the Chair on trilogues

- ENVI meeting, 27-28/11/2013
- Excerpt from the minutes of meeting ; Update by the Chair on trilogues

- ENVI meeting, 16-17/12/2013
- Excerpt from the minutes of meeting ; Update by the Chair on trilogues

The Parliament 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 [6] . This is without prejudice to the right of citizens to request public access to these documents in accordance with Regulation 1049/2001 [7] .

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

The meeting then ended.

Brussels, 20 November 2015

Mr Jan Stadler Legal Officer (case handler)

Ms Rosita Agnew Head of Strategic Inquiries

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

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

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

[7] 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.