Rozhodnutia vo veci 124/2018/NF týkajúcej sa odmietnutia Európskej komisie poskytnúť prístup verejnosti k dokumentom v súvislosti s projektom TETRA o priedušnici pripravenej metódou tkanivového inžinierstva z autológnych kmeňových buniek, financovanom z prostriedkov EÚ

Rozhodnutie
Prípad 124/2018/NF - **Otvorené dňa** 18/01/2018 - **Rozhodnutie z dňa** 14/03/2018 - **Dotknutý orgán** Európska komisia (Nezistil sa žiadny nesprávny úradný postup) |

Vec sa týkala odmietnutia Európskej komisie poskytnúť prístup verejnosti k dokumentom o stave klinického výskumného projektu s názvom „TETRA“, ktorý financovala EÚ. Cieľom projektu TETRA je vykonávanie klinického skúšania v súvislosti s inovatívnym prístupom k tracheálnej náhrade.

Požadované dokumenty obsahujú informácie o prípravnej fáze klinického skúšania. Komisia odmietla zverejniť dokumenty s tvrdením, že by to malo nepriaznivý vplyv na obchodné záujmy účastníkov projektu TETRA, ako aj na súkromie a integritu niektorých účastníkov projektu TETRA a osôb externe participujúcich na projekte. Sťažovateľ protestoval proti rozhodnutiu Komisie na základe škandálu v súvislosti s podvodom a pochybeniami v oblasti výskumu, ku ktorému došlo v prípade iného výskumného projektu v oblasti tracheálnych implantátov.

Ombudsmanka po preskúmaní dokumentov a po stretnutí s Komisiou konštatovala, že zo strany Komisie nedošlo k nesprávnemu úradnému postupu. Vzhľadom na to, že skúšanie v rámci projektu TETRA sa ešte nezačalo a nezačne sa ani v blízkej budúcnosti a že v obsahu správ o stave, ak by sa zverejnil, by sa neriešili žiadne obavy týkajúce sa verejného zdravia, ani by tieto správy neprispeli k verejnému prospechu, ombudsmanka je názoru, že neexistuje prevažujúci verejný záujem na zverejnení správ o stave projektu TETRA.

Background to the complaint
1. On 1 July 2017, the complainant, a science journalist, requested that the European Commission give him public access [1] to documents concerning the status of the ‘TETRA’ project. [2] TETRA, short for ‘Autologous Stem Cell Seeded Tissue Engineered Trachea’ [3] , is a project funded under the EU’s Horizon 2020 research and innovation funding programme. [4] It concerns clinical research on regenerative medicine and aims to conduct a phase II clinical trial on an innovative approach to tracheal replacement, which involves repopulating a trachea 'scaffold' with a patient’s own stem cells. The tracheal replacement is designed to

be a one-off curative treatment for patients with severe structural airway disease.

2. Against the background of a research fraud and misconduct scandal, which concerned a doctor who worked on an earlier tracheal clinical trial carried out under a different research project, the TETRA project has received a certain level of public attention.

3. On 11 September 2017, the Commission replied to the complainant's request and refused to provide him with any access to the three project status reports. It argued that disclosure of the documents would undermine (i) the **commercial interests** [5] of the TETRA project participants and (ii) the **privacy and integrity** [6] of some TETRA participants and individuals external to the project.

4. The complainant asked the Commission to review [7] its decision.

5. On 3 January 2018, the Commission confirmed its decision not to give any access to the three status reports:

- Document 1: Deliverable 6.2 – 6-month report on INSPIRE and TETRA clinical trials status, dated 24 June 2016, Ref No Ares(2016)4879315 - 30/08/2016;

¤ Document 2: Deliverable 6.3 – 12-month report on INSPIRE and TETRA clinical trials status, dated 31 December 2016, Ref No Ares(2016)7158144 - 23/12/2016; and

¤ Document 3: Deliverable 6.4 – 18-month report on INSPIRE and TETRA clinical trials status, dated 28 June 2017, Ref No Ares(2017)3245873 - 28/06/2017.

The Commission clarified that it understood the scope of the access request to be limited to those parts of the documents that concern the TETRA project. The parts concerning only the INSPIRE project thus fell outside the scope of the access request and were not addressed in the Commission's decision. The Commission otherwise maintained, and expanded on, its reasoning for refusing to release the documents.

6. Dissatisfied with the Commission's decision, the complainant turned to the Ombudsman in January 2018.

The inquiry

7. The Ombudsman opened an inquiry into the complainant's allegation that the Commission was wrong to refuse public access to the documents concerning the status of the TETRA project.

8. The Ombudsman inspected the documents at issue and met with the Commission to discuss the case. The Ombudsman also obtained copies of the TETRA grant agreement and of the Commission's responses to the complainant's related requests for information on the TETRA project and his earlier request to be given access to the TETRA grant application. The Ombudsman's decision takes into account all the information obtained.

9. The Ombudsman reviewed the documents at issue against the requirements of EU access

to documents rules, with a view to assessing whether the Commission was justified in not disclosing the three reports on the status of the TETRA project.
The Commission's refusal to grant public access to TETRA status reports

Arguments made by the Commission and the complainant

10. The complainant requested access to the TETRA status reports in relation to his online blog coverage of tracheal clinical trials and a research scandal that occurred in the context of an earlier, different clinical trial. The complainant did not, otherwise, formulate any specific arguments as to why the documents at issue should, in his view, be released under EU access to documents rules. The complainant stated that he wished to obtain specific information on the TETRA project, in particular the status of potential ethics evaluations, the project stage, and how much funding the EU had already paid to the TETRA consortium.

11. The Commission argued that it could not release the requested documents given that their disclosure would undermine (i) the **commercial interests** [8] of the TETRA project participants and (ii) the **privacy and integrity** [9] of some TETRA participants and individuals external to the project.

12. Regarding the TETRA project participants' commercial interests, the Commission argued that there was a real and non-hypothetical risk that public access to the documents would undermine the commercial interests, including intellectual property, of the TETRA consortium. The TETRA clinical trial not yet having been launched, the documents contain information on the consortium's preparatory work, that is, on both work already performed under the TETRA project, as well as on works, studies, reviews and the clinical trial to be undertaken. The Commission contended that the information set out in the documents thus constitutes inside knowledge of the TETRA consortium, which reflects its specific intellectual property, know-how, trade secrets, methodologies and potential inventions. Disclosure of the preparatory activities - which include the project milestones, detailed operational aspects of the project implementation, the timetable of planned activities, and information about regulatory and ethical approvals and permits to be obtained - would adversely affect the TETRA consortium's competitive market position by giving an unfair advantage to its (potential) competitors and by potentially causing reputational damage to the consortium and individuals linked to it.

13. The Commission added that the documents in question, which are project deliverables, are confidential under the Horizon 2020 grant agreement signed between the Commission and the TETRA consortium. [10] It also stated its view that Article 339 Treaty on the Functioning of the European Union - which requires staff members of the EU institutions to refrain from disclosing information of the kind covered by the obligation of professional secrecy, in particular information about undertakings, their business relations or their cost components - is applicable in this case and prevents disclosure of the documents.

14. The Commission stated that the complainant had not put forward any overriding public interest for disclosing the documents. Neither had the Commission itself been able to

identify any public interest capable of overriding the protection of the commercial interests at issue. While the Commission is aware of a particular interest from some individuals regarding the TETRA project, given a research fraud and misconduct scandal in the same field of research, the TETRA clinical trial has not yet started. In light of the project's preliminary stage, the Commission is of the view that there is no public interest that could override the protection of the TETRA consortium's commercial interests and thus justify disclosing the confidential project deliverables.

15. Regarding the **protection of privacy and the integrity of the individual** , the Commission stated that the documents contain personal data of individuals involved in, or linked to, the TETRA project, such as their names, functions, contact data and opinions. It argued that **the complainant had failed to establish the necessity** [11] **of a transfer** of that personal data, which consequently cannot be disclosed.

16. The Commission considered that it could not give any meaningful partial access to the documents, without undermining the protected interests. It concluded that the documents are, in their entirety, covered by the exceptions for the protection of commercial interest and the privacy and integrity of the individual.

17. At the meeting with the Ombudsman, the Commission provided further information on the status of the TETRA project. TETRA aims at conducting a **phase II** clinical trial, building on the experience to be gathered from a **phase I** clinical trial that is part of another (non-EU funded) project, called INSPIRE. Clinical trials have consecutive phases, each of which must be authorised by the Competent Authorities in the Member States and launched only once the previous phase has been completed successfully. This means that the authorisations for the TETRA clinical trial could be requested only once the INSPIRE clinical trial has been successfully finished. Only then could the clinical trial of the TETRA project be authorised by the relevant Member State authorities to begin. The INSPIRE project has been delayed since December 2016, so it is not currently possible for the TETRA participants to request authorisation for the phase II clinical trial provided for in the TETRA grant agreement. The TETRA clinical trial is therefore not imminent.

18. The duration of the TETRA project is 48 months and it will end on 31 December 2019. The current delay to the INSPIRE project therefore makes the prospects for the commencement and completion of the TETRA project uncertain.

19. As a means of reinforced monitoring of the situation, the Commission requested the TETRA project participants to provide it with 6-months status reports (that is, the documents requested by the complainant).

20. The Commission pointed out that it had already provided the complainant with information on the TETRA project, both in its decisions on his access requests and in reply to requests for information. Among other things, it informed the complainant:

· that the scientific research involved in TETRA is pursuing a different method than the one developed by the doctor who has been subject to misconduct investigations,

· that the TETRA clinical trial is dependent on the successful completion of the INSPIRE project,

· that the TETRA project has not yet undergone any ethics reviews other than the ethics assessment at the grant proposal evaluation stage, and

· that the EU has so far made an advance payment of €2,617,740.38 to the TETRA project coordinator.

The Ombudsman's assessment

General comments

21. Clinical trials are scientifically controlled studies undertaken in humans to establish or confirm the safety and effectiveness of " *investigational* " medicinal products. [12] Interventional clinical trials on medicinal products that are carried out in the EU and the European Economic Area are subject to EU clinical trial rules. Before any clinical trial can start, it needs to receive regulatory approval from the national authorities where the trial sites are situated and favourable opinions of the ethics committees. Clinical trials are commonly classified into four consecutive phases: phase I - first-in-human studies, dose escalation, tolerability/safety studies; phase II - proof-of-concept, early efficacy studies; phase III - confirmation of efficacy; and phase IV - 'post-approval' studies. An individual trial may encompass one or several of the four phases. Each trial phase can be launched only once the previous phase has been completed successfully. Public information on phase II to IV clinical trials is available on the EU Clinical Trials Register.

22. TETRA is a project in the area of regenerative medicine. Regenerative medicine is the process of creating living, functional tissues to repair or replace tissue or organ function lost due to age, disease, damage or congenital defects. Research in the area of regenerative medicine is innovative and unconventional in nature.

23. The EU's Horizon 2020 research and innovation funding programme seeks to facilitate the funding for clinical research on regenerative medicine, amongst many other areas of research, thus helping translate basic knowledge on regenerative medicine into in-patient research. [13]

24. The Horizon 2020 rules for participation [14] set out specific confidentiality rules for documents submitted in the context of a project funded under Horizon 2020, such as TETRA. The level of confidentiality of deliverables and reports that consortia submit to the Commission is specified in every grant agreement. Consortia thus have assurance that all innovative ideas and results generated in the project will remain confidential until they are disclosed in certain mandatory publications, communication activities or intellectual property applications. The Horizon 2020 confidentiality rules are in line with EU access to documents

rules, given that they provide that confidentiality of project documents ceases to exist if so required under EU law, such as Regulation 1049/2001 on public access to documents. [15]

25. Therefore, if the Commission receives a request for public access to such documents, it carries out an individual assessment of the documents. It also did so in this case.

26. The Ombudsman acknowledges the public concerns triggered by a research scandal regarding a specific doctor involved in an earlier tracheal clinical trial. Understandably, the complainant, who has covered that scandal on his blog, was interested in obtaining further information on the TETRA project, which involves a clinical trial in the same field of research.

The Commission's refusal to release the documents

Regarding the protection of commercial interests

27. Any restrictions on the public right of access to documents held by EU public bodies must go no further than is strictly necessary to protect defined interests. These interests, which are set out in EU rules on public access to documents, include the need to protect the public interest regarding privacy and personal data and the need to protect commercial interests. Some exceptions protecting certain interests, among them commercial interests, do not apply where there is an overriding public interest in the disclosure of the document in question. Whenever the Commission gets a request for public access to documents, it must ask itself two questions. First, do the documents contain information which would, if disclosed to the public, undermine one of the protected interests? The risk of the interest being undermined must be reasonably foreseeable and must not be purely hypothetical. [16] Second, if so and where applicable, does the public interest in disclosure of the documents outweigh that protected interest? [17]

28. The Ombudsman's handling of access to documents complaints concerning ongoing research projects, such as TETRA, may be limited to an inspection of the documents at issue. However, given the importance of the complainant's motives for requesting access to the TETRA status reports and the concerns he has raised, the Ombudsman not only inspected the documents at issue but also took the additional step of meeting with the Commission to discuss the context.

29. Having reviewed the content of the TETRA status reports, and taking into account the information provided by the Commission, the Ombudsman is of the view that it is at least reasonably foreseeable that public disclosure of the documents would undermine the commercial interests of the TETRA consortium.

30. The Ombudsman agrees that the TETRA status reports contain commercially sensitive information, in relation to the preparation of the planned clinical trial, which may be of value to competitors and which the TETRA consortium may not wish to be known to their competitors. It is important to emphasise, in this regard, that the documents at issue are not clinical trial reports, that is reports on the safety and the efficacy of a medicine, but reports

describing the activities carried out, or to be carried out, by the project partners in *preparation* of a clinical trial. The information contained in the status reports thus reflects the TETRA consortium's particular expertise [18] in organising a clinical trial in its research area.

31. Even if a status report contains commercially sensitive information, that information will still have to be released if there is an overriding public interest in disclosure. This only applies, however, where disclosure of the documents could, because of their content, effectively address the public interest at issue.

32. The Ombudsman's view is that where the information in the documents in question has clear health implications, as is typically the case with information on the efficacy or the safety of a medicine covered in clinical trial reports, the overriding public interest provision is very likely to be engaged.

33. However, the Ombudsman emphasises again that the documents at issue in this case are not clinical trial reports, but reports on the preparatory phase of a clinical trial.

34. The Commission has told the Ombudsman that the TETRA clinical trial is not imminent. Rather, it is still in its preparatory phase. It is uncertain even whether the TETRA clinical trial is going to take place. As the Commission has explained, and as is clear from publicly available information [19] , the TETRA project (a planned phase II clinical trial) relies on results to be obtained from a phase I clinical trial to be carried out under the INSPIRE project. The INSPIRE project was suspended in December 2016. So far no patients have been recruited for, or treated on, the INSPIRE trial. It is thus not currently possible for the participants in the TETRA project to request authorisation for the phase II clinical trial.

35. Against this background, the Ombudsman notes that the content of the status reports does not address any public health concerns or public benefits. This is because the documents simply describe the activities undertaken, or to be undertaken, by the TETRA consortium in preparation of the clinical trial. They do not contain any kind of risk-benefit assessment in relation to the planned clinical trial, nor do they reveal information of relevance to the assessment of the safety and efficacy of interventional medicine.

36. The Ombudsman therefore finds that there is no overriding public interest in the disclosure of these documents and concludes that the Commission was entitled to use the commercial interests exception to protect the commercial interests of the TETRA consortium and refuse disclosure of the requested documents.

Regarding the protection of the privacy and integrity of the individual

37. Public access to documents containing personal data can be granted only if doing so is in accordance with EU data protection rules [20] . [21] EU data protection rules provide that "' *personal data' shall mean any information relating to an identified or identifiable natural person hereinafter referred to as data subject [...]* " [22] . The TETRA status reports contain names, functions, contact data and opinions of individuals involved in, or linked to, the TETRA

project. The documents thus contain personal data of those persons.

38. The Ombudsman notes that the complainant has put forward no reasons why he needs that specific personal data, as EU data protection rules would require.

39. The Ombudsman thus finds that the Commission was justified in refusing access to the personal data.

No meaningful partial access

40. The Ombudsman also accepts the Commission's view that it could not give any meaningful partial access to the TETRA status reports. The Ombudsman thus concludes that the Commission was entitled not to release the TETRA status reports.

The Commission's provision of information to the complainant

41. Lastly, the Ombudsman is satisfied that the Commission has provided the complainant with information on the TETRA project on several occasions in 2016 and 2017. By providing some of the information directly in its decisions on the complainant's related access to documents requests, the Commission has shown itself to be citizen-friendly and not excessively secretive.

Conclusion

Based on the inquiry, the Ombudsman closes this case with the following conclusion [23] :

There was no maladministration by the European Commission in handling the complainant's request for public access to documents on the status of the TETRA project.

The complainant and the European Commission will be informed of this decision **.**

Emily O'Reilly

European Ombudsman

Strasbourg, 14/03/2018

[1] The EU's public access to documents rules are set out in Regulation 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.

[2] The Commission registered the complainant's request on 18 July 2017, after the complainant had provided it with his postal address.

[3] Information on the TETRA project is available here: https://cordis.europa.eu/project/rcn/198788_en.html

and on the project website: http://www.tetra-h2020.eu/

[4] TETRA is funded under the programme “H2020-EU.3.1. - SOCIETAL CHALLENGES - Health, demographic change and well-being”, established with Council Decision 2013/743/EU, OJ 2013 L 347, p. 965. See here: http://cordis.europa.eu/programme/rcn/664237_en.html

[5] Article 4(2), first indent, of Regulation 1049/2001.

[6] Article 4(1)(b) of Regulation 1049/2001 in conjunction with Articles 2(a) and 8(b) of Regulation 45/2001 of the European Parliament and of the Council of 18 December 2000 on the protection of individuals with regard to the processing of personal data by the Community institutions and bodies and on the free movement of such data, OJ 2001 L 8, p. 1.

[7] He made a so-called ‘confirmatory application’ under Article 7(2) of Regulation 1049/2001.

[8] Article 4(2), first indent, of Regulation 1049/2001.

[9] Article 4(1)(b) of Regulation 1049/2001 in conjunction with Articles 2(a) and 8(b) of Regulation 45/2001.

[10] The Commission referred to the judgment of the General Court of 12 May 2015, *Technicon v Commission* , T-480/11, ECLI:EU:T:2015:272, para 58.

[11] As required under Article 8(b) of Regulation 45/2001.

[12] See Article 2(a) of Directive 2001/20/EC of the European Parliament and of the Council of 4 April 2001 on the approximation of the laws, regulations and administrative provisions of the Member States

relating to the implementation of good clinical practice in the conduct of clinical trials on medicinal

products for human use, OJ 2001 L 121, p. 34 and Article 2(2) of Regulation 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.

[13] See: https://cordis.europa.eu/programme/rcn/665186_en.html

[14] Regulation 1290/2013 of the European Parliament and of the Council of 11 December 2013 laying down the rules for participation and dissemination in "Horizon 2020 - the Framework Programme for Research and Innovation (2014-2020)" and repealing Regulation

(EC) No 1906/2006, OJ 2013 L 347, p. 81.

[15] Article 36(1) of the Horizon 2020 model grant agreement.

[16] See, for example, judgment of the Court of 21 July 2011, *Sweden* v *MyTravel and Commission* , C¤506/08 P, EU:C:2011:496, para 76 and the case-law cited.

[17] See, for example, judgment of the Court of 1 July 2008, *Sweden and Turco* v *Council* , C¤39/05 P and C¤52/05 P, EU:C:2008:374, para 45.

[18] See judgment of the General Court of 9 September 2014, *MasterCard and Others* v *Commission* , T¤516/11, EU:T:2014:759, para 84.

[19] See:
http://data.parliament.uk/writtenevidence/committeeevidence.svc/evidencedocument/science-and-techn
;
http://data.parliament.uk/writtenevidence/committeeevidence.svc/evidencedocument/science-and-techn

[20] Regulation 45/2001.

[21] Judgement of the Court of 29 June 2010, *Commission v Bavarian Lager* , C-28/08 P, ECLI:EU:C:2010:378.

[22] Article 2(a) of Regulation 45/2001.