Raccomandazione sulla modalità con cui la Commissione europea ha gestito una richiesta di accesso del pubblico ai documenti concernenti la qualità delle mascherine mediche distribuite durante la pandemia di COVID-19 (caso 790/2021/MIG)

Raccomandazione
Caso 790/2021/MIG - **Aperto(a) il** 30/04/2021 - **Raccomandazione su** 05/11/2021 - **Decisione del** 25/05/2022 - **Istituzioni interessate** Commissione europea (Riscontrati estremi di cattiva amministrazione) | Commissione europea (Raccomandazione accettata dall'istituzione) |

Il denunciante ha chiesto l'accesso pubblico ai documenti relativi a 1,5 milioni di mascherine mediche che la Commissione aveva acquistato in una fase iniziale della pandemia di COVID-19 e che non soddisfacevano gli standard di qualità richiesti. La Commissione ha individuato in totale 134 documenti e, pur avendo impiegato dieci mesi per fornire una risposta definitiva al denunciante, ha concesso un ampio accesso pubblico. Il denunciante ha contestato il rifiuto della Commissione di concedere l'accesso a (parti di) 12 documenti e, in particolare, il suo ricorso alla necessità di tutelare gli interessi commerciali del fabbricante interessato.

Il Mediatore ha ritenuto che le informazioni in questione non potessero ragionevolmente essere considerate sensibili sotto il profilo commerciale ai sensi delle norme dell'Unione europea in materia di accesso del pubblico ai documenti. Ha inoltre sottolineato che, pur ammettendo che la Commissione possa ragionevolmente invocare l'esenzione per la tutela degli interessi commerciali, le informazioni in questione riguardano prodotti che l'UE ha acquistato utilizzando il denaro dei contribuenti per proteggere la salute pubblica durante la più grave crisi sanitaria mondiale da oltre un secolo. Dato che sono sorti problemi con le mascherine acquistate, il Mediatore ritiene che vi sia un forte interesse pubblico a sapere quali misure siano state adottate per garantire che non fossero messe in circolazione e utilizzate mascherine difettose.

Il Mediatore ha pertanto ritenuto che il rifiuto di accesso del pubblico da parte della Commissione in questo caso costituisse cattiva amministrazione. Ha raccomandato alla Commissione di riconsiderare la sua posizione al fine di concedere un accesso notevolmente maggiore, se non integrale, ai documenti in questione.

Made in accordance with Article 4(1) of the Statute of the European Ombudsman [1]

Background to the complaint

1. In spring 2020, to help tackle the COVID-19 pandemic, the European Commission purchased ten million medical masks via the Emergency Support Instrument [2] . The medical masks were to be distributed to healthcare workers in the participating 17 Member States and the United Kingdom.

2. After the Commission had sent on the first batch of 1.5 million masks to participating countries, some national authorities raised concerns about the quality of the masks, saying they did not meet the required standard. The Commission then suspended the delivery of the masks, stating that it was looking into the matter. [3] The Commission also stated that it had followed all control measures when purchasing the masks, and that it had verified that they were usable. It ultimately turned out that the masks were of poor quality and the trader agreed to mitigating measures.

3. In June 2020, the complainant, a journalist, asked [4] the Commission to give public access to

"[a]ll e-mails, including attachments, between the Commission and Member States about the shipment of medical masks delivered to 17 Member States and the UK to protect healthcare workers against the coronavirus, as part of the Emergency Support Instrument."

4. The Commission identified 134 documents. It granted full access to three documents, partial access to 95 documents and refused access to 36 documents in their entirety. In refusing access, the Commission relied on a number of exceptions provided for under the EU's rules on public access to documents, including the need to protect commercial interests [5] .

5. In November 2020, the complainant asked the Commission to review its decision to refuse access (by making a 'confirmatory application').

6. The Commission then granted the complainant wider access. However, it maintained that access to (parts of) a number of documents had to be refused to protect the public interest as regards public security [6] and to protect personal data [7] . The Commission also denied access to three documents in their entirety and to parts of nine documents based on the need to protect the commercial interests of the manufacturer concerned. In that regard, the Commission held that there was no public interest that could override the need to protect those commercial interests.

7. Dissatisfied with the outcome in relation to these twelve documents, the complainant turned to the Ombudsman in April 2021.

The inquiry

8. The Ombudsman opened an inquiry into the complaint that the Commission was wrong to refuse public access to (parts of) twelve documents based on the need to protect commercial interests.

9. In the course of the inquiry, the Ombudsman's inquiry team inspected the documents at

issue and held a meeting with representatives of the Commission. The inquiry team then drew up a meeting report which it shared with the complainant and, subsequently, received the complainant's comments on that report.

Arguments presented

At the review stage

10. The complainant questioned how, if it was the case that the delivery of poor quality masks had been unintentional and the mitigating response appropriate, disclosure of the documents would undermine the commercial interests of the manufacturer.

11. If, on the other hand, there had been ill intent, the complainant argued that there is an overriding public interest in knowing the identity of the manufacturer to prevent similar incidents in future.

12. The complainant also considered that there is an overriding public interest in knowing why the masks were initially considered to conform with the relevant standard, and what measures were taken.

13. The Commission said that the three non-disclosed documents contain information concerning an identified manufacturer, including control tests, quality inspection reports and other commercially sensitive information. The redacted parts of the remaining documents also contain details on the conformity of the masks with relevant standards, the mitigation measures proposed by the manufacturer and the manufacturer's commercial relations with other entities.

14. The Commission considered that disclosure of detailed information on the quality issues affecting the masks or the proposed mitigating measures could be used to harm the reputation of the manufacturer. This would affect the manufacturer's market position, thus undermining its commercial interest.

15. As regards a possible overriding public interest, the Commission said that the complainant had not demonstrated precisely how disclosure of the documents would contribute to protecting the public interest.

Before the Ombudsman

16. At the meeting with the inquiry team, the Commission said that the documents also contain information about its negotiations with the companies involved regarding the mitigating measures. Disclosure of that information would undermine the commercial relations of those entities.

17. The Commission maintained that there is no overriding public interest in disclosure. It said that the contractual rules governing the purchase of the masks were such as to protect the public interest in case of non-compliance with contractual obligations.

18. With regard to the generally high level of transparency ultimately provided by the Commission in the context of its vaccine negotiations with pharmaceutical companies, the Commission said that, in this case, the companies involved have not given their consent to disclosure of any information. The Commission added that it does not have a direct contract with the manufacturer of the masks and that it had thus not consulted it on the complainant's access request. It had consulted the distributor alone, who had not replied.

19. In his comments on the meeting report, the complainant argued that the Commission could not rely on the need to protect commercial interests, given that neither the distributor nor the manufacturer of the masks had objected to disclosure.

20. The complainant maintained that there is an overriding public interest in *"understanding why the defective masks were initially approved, and whether the masks were defective as a consequence of malintent or accident."*

The Ombudsman's assessment leading to a recommendation

21. While the Commission took ten months in total to reply to the complainant's access request, the Ombudsman acknowledges that the request concerned one of the busiest parts of the Commission at the time, namely DG SANTE. The Ombudsman further notes that the request concerned a significant number of documents and that extensive access was given. Twelve of the documents are at issue here.

22. The Ombudsman's inquiry team has inspected the documents. They include, among other things, information on the quality control of the masks, on their conformity with relevant standards, on the mitigating measures proposed by the manufacturer and on the business relations of the manufacturer with other entities.

23. EU institutions cannot rely on the need to protect commercial interests simply because information relates to a company and its business relations. The exception contained in the public access rules serves to protect commercially *sensitive* information, that is, information that, if disclosed, would undermine legitimate commercial interests of the company concerned, such as information relating to a its business strategy or its expertise. [8] When invoking this exemption, EU institutions have to explain how disclosure could *specifically and actually* undermine the legitimate commercial interests at stake. In addition, the risk that the suspected damage would occur must be *reasonably foreseeable and not purely hypothetical* . [9]

24. In this case, the Commission argued that disclosure of the withheld information would undermine the commercial interests of the manufacturer as it could be used to damage its

reputation and thus jeopardise its market position. The Ombudsman does not consider this sufficient to establish the existence of a legitimate and actual risk, as required by the EU's rules on public access to documents and the related case law.

25. Notably, the public is already aware that there have been quality issues with the first batch of 1.5 million masks. [10] While this information could potentially be used to harm the reputation of the manufacturer concerned, it is unclear how the redacted information, particularly on the specific mitigating measures, could be used to that end. Such a risk might materialise if no mitigating measures had been taken or if the measures proposed by the manufacturer were perceived as inappropriate or inadequate. However, the Ombudsman considers that, if details on the measures were disclosed, the public would be unlikely to take such a view.

26. It is, moreover, not clear to the Ombudsman that a company that delivers faulty products has a legitimate claim that the other party to the contract, in this case the Commission, must keep that secret.

27. The Ombudsman therefore finds that the Commission was not justified in refusing access based on the need to protect legitimate commercial interests.

28. Even if one were to accept that the Commission could reasonably invoke the exemption for the protection of commercial interests, it should be noted that this exemption can be overridden by a public interest that is deemed more important.

29. The Ombudsman considers that companies that conduct business with the EU administration, whether directly or indirectly, should expect that certain information is made publicly available. This includes their identity, and, where problems occur, information on those problems and the related measures to address them.

30. In this case, the information at issue concerns products which the EU purchased using taxpayers' money to protect public health during the most serious global health crisis in over a century. Given that there have been problems with the purchased masks, the Ombudsman considers that there is a strong public interest in knowing what steps have been taken to ensure that no faulty masks were brought into circulation and used.

31. In light of the above, the Ombudsman finds that the Commission's refusal to give full public access to the twelve documents at issue constituted maladministration. She therefore makes a corresponding recommendation below.

Recommendation

On the basis of the inquiry into this complaint, the Ombudsman makes the following recommendation to the Commission:

The Commission should reconsider its decision to refuse public access to (parts) of the twelve documents at issue based on the need to protect the manufacturer's commercial interests with a view to giving the complainant significantly increased, if not full, access to those documents.

The Commission and the complainant will be informed of this recommendation. In accordance with Article 4(2) of the Statute of the European Ombudsman, the Commission shall send a detailed opinion by 7 February 2022.

Emily O'Reilly European Ombudsman

Strasbourg, 05/11/2021

[1] Available at: https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=uriserv%3AOJ.L_.2021.253.01.0001.01.ENG&toc=OJ%

[2] For information on the Emergency Support Instrument, visit: https://ec.europa.eu/info/live-work-travel-eu/coronavirus-response/emergency-support-instrument_en .

[3] See Commission online press briefing: https://audiovisual.ec.europa.eu/en/video/I-190210 .

[4] Under Regulation 1049/2001 regarding public access to European Parliament, Council and Commission documents: https://eur-lex.europa.eu/legal-content/EN/ALL/?uri=celex%3A32001R1049 .

[5] In accordance with Article 4(2), 1st indent of Regulation 1049/2001.

[6] In accordance with Article (4)(1)(a), first indent of Regulation 1049/2001.

[7] In accordance with Article (4)(1)(b) of Regulation 1049/2001.

[8] See, for example, judgment of the General Court of 7 February 2018, *PTC Therapeutics International v EMA* , T-718/15:

https://curia.europa.eu/juris/document/document.jsf?text=&docid=199044&pageIndex=0&doclang=EN&
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[9] See, for example, judgment of the Court of 4 September 2018, *Cl ientEarth v Commission* , C¤57/16 P: https://curia.europa.eu/juris/document/document.jsf?text=&docid=205322&pageIndex=0&doclang=EN&
, paragraph 51.

[10] See, for example, https://euobserver.com/coronavirus/148374 .