# Decision in case 1402/2014/DK on the European Medicines Agency's action

Decision
**Case** 1402/2014/DK - **Opened on** 10/09/2014 - **Decision on** 21/11/2016 - **Institution concerned** European Medicines Agency ( Settled by the institution ) |

**Decision**

in case 1402/2014/DK on the European Medicines Agency's action

*The case concerned the European Medicines Agency's decision to refuse the complainant's request for public access to the Agency's public consultation on the publication of and access to clinical trial data. The Agency refused access thereto twice on the grounds that its draft 'Policy on publication of clinical data for medicinal products for human use' had not yet been adopted.*

*The Ombudsman inquired into the issue and found that the Agency, in the meantime, adopted the policy and published it in October 2014.The decision-making process had thus clearly ended. Accordingly, the Ombudsman requested the Agency to consider granting the complainant access to the requested documents.*

*In response, the Agency provided the Ombudsman and complainant with the requested documents. The Ombudsman found that the European Medicines Agency had thus settled the matter complained about.*

**The background to the complaint**

**1.** In May 2014, the complainant made a request, in accordance with Regulation 1049/2001 [1] [Link], for access to documents held by the European Medicines Agency (the Agency) relating to its public consultation on the publication of and access to clinical trial data. He requested access to all relevant correspondence and submissions, made in the ambit of the public consultation, by any pharmaceutical industry association or the Commission

**2.** The Agency refused granting access to the requested documents on the grounds that the disclosure of the documents would seriously undermine the institution's decision-making process [2] . It explained that it was still finalising its ' *policy on proactive publication on clinical data* ' and as such, disclosure would indeed seriously undermine its ongoing decision-making

process. The Agency also stated that there was no overriding public interest in disclosure

**3.** In his request for a review of that refusal, a so-called “confirmatory application”, the complainant argued that the Agency could not simply assert, but actually had to show that the exception it invoked applied to the case at hand. More specifically, the complainant disagreed that the Agency relied on the notion that disclosure of the requested documents would “seriously undermine” its decision-making process. He noted that the documents to which he requested access to were not purely internal documents, but rather communications between the Agency, pharmaceutical associations and the European Commission. Moreover, there was an overriding public interest as the Agency's correspondence with the Commission was clearly a significant factor in the newly proposed policy. The affected stakeholders should have access to this correspondence for the sake of transparency.

**4.** In its decision on the complainant's confirmatory application, the Agency reiterated its previous position and refused to grant access to the requested documents. It stated that the requested documents played a key role in the development of its new policy and that their release would place unnecessary and targeted external pressure on its services. The disclosure of the requested documents could have complicated the final steps in the adoption of the Policy. The Agency disagreed that there was an overriding public interest for disclosure given that its public consultations were open and transparent. Furthermore, it received over 1000 submissions, making it practically impossible for it to share them with stakeholders and to obtain their comments thereon. Finally, the Agency noted that it was in the public interest to adopt the Policy as soon as possible. Disclosing the requested documents, at the time, would negatively affect that objective.

**5.** The complainant then turned to the Ombudsman with the present complaint.

**The inquiry**

**6.** The Ombudsman opened an inquiry into the following allegation and claim.

**Allegation:**

The European Medicines Agency failed to grant public access to documents relating to its " *public consultation* " on publication of and access to clinical trial data.

**Claim:**

**7.** The Agency should grant public access to the requested documents.

**8.** In the course of the inquiry, the Ombudsman received the opinion of the Agency and subsequently, the complainant's observations on it. The Ombudsman then asked the Agency to reconsider its decision.

# Allegation that the Agency wrongly refused to give public access to documents

Arguments presented to the Ombudsman

**9.** In its opinion, the Agency first noted that the Policy was adopted under the procedure set out in Article 80 of Regulation 726/2004 [3] [Link] which requires that the transparency measures, such as the Policy, be adopted by the Management Board on the basis of a proposal by the Executive Director and with the agreement of the European Commission. It thus sets out a procedure that involves a clear and specific decision-making process within the meaning of Article 4(3) of Regulation 1049/2001. The public consultation on the draft Policy was part of this procedure, which was ongoing at the time of the complainant's request.

**10.** The Agency further noted that its decision on the confirmatory application clearly stated the arguments in support of the applicability of the exception provided for in Article 4(3), first paragraph of Regulation 1049/ 2001. These arguments justify the refusal to disclose the requested documents at the time of the request due to the on-going decision making procedure and show that disclosure would have had a substantial impact on the on-going decision making process and would have seriously undermined it.

**11.** Moreover, the General Court recognized in the MasterCard judgment [4] [Link] that the protection of the decision-making process from targeted external pressure may constitute a legitimate ground for restricting access to documents relating to the decision-making process [5] [Link]. The Agency's decision established the reality of the negative impact of the potential disclosure of the requested documents and set out the arguments demonstrating the risk that the disclosure would have certainly lead to external targeted pressure that would have seriously undermined the decision-making process. This risk was not hypothetical. The Agency's decision was thus in line with the findings of the General Court in the MasterCard judgment.

**12.** Finally, the Agency also considered that there was no overriding public interest in the disclosure of the requested documents at the time of the request.

**13.** In his observations, the complainant underlined that the Policy had been adopted and published. There could thus no longer be any reason why access to the requested documents could not be provided. The new Policy concerns issues of great importance for the public. The adoption of the Policy has been a matter of a strong debate, in which the industry strongly represented its views. The outcome attracted attention from transparency groups and evoked interest from the Ombudsman. Under such circumstances, it cannot be accepted that access is not granted to the requested documents.

## Further developments

**14.** In light of the complainant's observations, in September 2015, the Ombudsman requested the Agency to reconsider its decision not to release the requested documents.

**15.** On 15 October 2015, the Agency replied to the Ombudsman's request and stated that the exception invoked earlier for the protection of the decision-making process no longer applied because the decision-making process has been concluded and the Policy was adopted. As the complainant was still interested in receiving the documents requested, the Agency was in the process of finalising the identification of all concerned documents so as to make a new assessment of the request. In addition, as the complainant requested access to *"all submission and correspondence"* with different stakeholders, the Agency needed to consult the third-party originators, in accordance with Article 4(4) of Regulation 1049/2001 [6] [Link].

**16.** On 30 November 2015, the Agency sent a copy of its letter sent to the complainant in which it disclosed the first batch of the requested documents. On 16 December 2015, the Agency provided both the complainant and the Ombudsman with the second batch of the requested documents. As such, the Agency has disclosed all the requested documents, with only certain parts redacted therein for the protection of personal data.

**17.** By letter of 8 January 2016, the Ombudsman asked the complainant to submit observations on the Agency's replies. The complainant has not submitted observations.

The Ombudsman's assessment

**18.** The Ombudsman welcomes the fact that the Agency reconsidered its initial decision and decided to disclose all the requested documents to the complainant. The Ombudsman sees the Agency's reconsideration as a further indication that it supports transparency in the EU public administration.

**19.** In view of the above, and the fact that the complainant did not consider it necessary to comment on the Agency's release of the documents requested, the Ombudsman considers that the Agency has taken the necessary steps to settle this complaint.

**20.** However, the Ombudsman considers that it would have been good administrative practice if the Agency had, when it carried out the public consultation, informed the potential contributors of the fact that their contributions could be made public. The Ombudsman will therefore make a suggestion for improvement below.

**Conclusion**

On the basis of the inquiry into this complaint, the Ombudsman closes it with the following conclusion:

**The European Medicines Agency has settled the matter.**

The complainant and the Agency will be informed of this decision.

**Suggestions for improvement**

**The Agency should, when carrying out public consultation on any topic, inform potential contributors of the fact that their contributions will, in principle, be made public.**

Emily O'Reilly

European Ombudsman

Strasbourg, 21/11/2016

[1] [Link] Regulation 1049/2001 of the European Parliament and of the Council regarding public access to European Parliament, Council and Commission documents, OJ 2001 L 145, p. 43.

[2] [Link] Article 4(3), first indent, of Regulation 1049/2001 provides that " *Access to a document, drawn up by an institution for internal use or received by an institution, which relates to a matter where the decision has not been taken by the institution, shall be refused if disclosure of the document would seriously undermine the institution's decision-making process, unless there is an overriding public interest in disclosure.* "

[3] [Link] Regulation (EC) No 726/2004 of the European Parliament and of the Council of 31 March 2004 laying down Community procedures for the authorisation and supervision of medicinal products for human and veterinary use and establishing a European Medicines Agency (OJ L136, 30.04.2004, p.1.)

[4] [Link] Case T-516/11, *MasterCard vs Commission* , judgment of 9 September 2014, not yet reported.

[5] [Link] Idem, paragraph 71.

[6] [Link] Article 4(4) of Regulation 1049/2001 provides that: " *As regards third-party documents, the institution shall consult the third party with a view to assessing whether an exception in paragraph 1 or 2 is applicable, unless it is clear that the document shall or shall not be*

*disclosed.* "

[7] [Link] The check list will be relevant also for draft Recommendations and for proposed Solutions.