

This is a confirmatory application to appeal the refusal of access to documents in the case ASK – 3429. The refusal was conveyed by way of a message from the agency reference EMA/345677/2014, carrying the date 13th June 2014 but first received by me in a readable form on 16th June.

The request was made under Regulation (EC) No 1049/2001 (“the regulation”) and Article 4.3 of that regulation was cited as the basis of the refusal.

The arguments in support of my appeal are as follows:

1. Under Article 4.1 of the regulation “*Any citizen of the Union, and any natural or legal person residing or having its registered office in a Member state, has a right of access to documents of the institutions, subject to the principles, conditions and limits defined in this Regulation*”.
2. I assert my right of access to the requested documents, under Article 4.1 of the regulation.
3. Under Article 15 of the Consolidated version of the Treaty on the Functioning of the European Union “*...the Union's institutions, bodies, offices and agencies shall conduct their work as openly as possible*”.

4. In this instance the agency asserts that the case meets the terms of the exception provided under Article 4.3 of the regulation. Given the rights under Article 4.1, I say that it is for the agency to prove that the exception applies in this case. The exception cannot simply be asserted. Access is a right; refusal is an exception that must be validated.

5. To be valid, the exception must meet two, independent conditions;

a) The requested documents must relate to a matter

“where the decision has not been taken by the institution”

AND

b) if disclosure of the document would seriously undermine the institution's decision-making process.

(Even then, access must be provided if there is an overriding public interest in disclosure.)

6. Conditions a) and b) are independent and must each be met if a refusal is to be justified.

7. Under condition b) refusal may be justified if disclosure would “seriously undermine” the

institution's decision-making process. To claim that disclosure in this instance would seriously undermine the decision making of the agency is to claim that it would be much more than merely an inconvenience or embarrassment, but rather that it would be significantly damaging to the agency in the performance of its functions. This is a very large claim that needs justification on the part of the agency.

8. The agency has not justified, and has not said anything to justify, the claim that disclosure in this case would seriously undermine or damage decision making in the agency.
9. The following factors are also relevant in considering whether the refusal is justified:
 - a) My request does not refer to purely internal documents of the agency. I requested access to communications between the agency and the pharmaceutical associations, and between the agency and the European Commission. How could disclosure of these communications seriously undermine the decision making of the agency?
 - b) Even if, as I do not concede, disclosure of some of the requested documents would seriously undermine decision-making, this could not in itself justify a blanket refusal to release any of the requested documents.

- c) My request covered a period in which agency published, in a “targeted” consultation, new and more specific proposals on transparency arising from an earlier and wider consultation on the issue. To many, the new proposals, including the addition of certain terms of use, seemed to change the overall direction or effect of the agency’s policy from what had previously seemed to be the case. Among those who expressed concern was Glenis Willmott MEP and the Ombudsman. In response to an enquiry from the Ombudsman, the Executive Director of the agency said *inter alia* that one of the contributing factors to its latest proposals was the “ *...Commission’s clear message that we also have to assure compliance with national and international obligations ...including but not confined to TRIPS and copyright laws...* ”. Since the message from the Commission was clearly a significant factor in the proposed new policy, the agency should not have refused access to that message and related communications. Indeed, the principles of transparency behind regulation 1049/2001 and the terms of the regulation itself would seem to require publication of the basis for the new policy when that new policy was published for (targeted) consultation.
- d) I should add here in passing that a number of participants at the meetings for the recent targeted consultation were given to understand

that the agency was “under pressure” from the Commission in this matter, or at any rate that the views of the Commission had been particularly influential in this case. This is all the more reason for transparency in relation to communications between an independent agency and the European Commission.

- e) Apart from communication with the Commission it is probable that substantial elements of the new proposed policy, including the proposed terms of use and the interpretation of obligations under TRIPS and copyright law were also influenced by submissions from industry associations. There is, of course, nothing inherently wrong with this but in considering the proposed new policy there should be transparency about those submissions and clarity about the extent to which the proposed new policy reflected those submissions.
- f) A further relevant factor is that the new Head of Legal at the agency since July 2013 had played an important role at a senior level over many years in the development and elaboration of the industry’s views on TRIPs and intellectual property. In his new role in the agency he was required, with others, to evaluate submissions from the industry on these matters in developing the new proposed policy of the agency. I imply no impropriety on his part but there is an important matter of

public policy here: in the circumstances of this particular case, the refusal of the agency to disclose the documents requested may have adverse effects in terms of public trust in the agency.

10. The refusal in this case reflects a wider problem in the consultation procedures of the institutions. In general public consultations are wider and better than before, in my experience, but individual stakeholders rarely have the opportunity in good time to see, and challenge (or support) the submissions of all the other stakeholders. In these circumstances it is the institution alone that decides how much relative weight or value to give to each submission. This is the case in this particular instance: the agency says its latest policy is based on a particular view of obligations on intellectual property but will not say what that view is, or what submissions it received on the matter. How could the participants in the targeted consultation comment on the basis for the new policy when they did not know what that basis was?
11. It may be argued that some or even all of the documents that I have requested will be released later. This is irrelevant to the issue of the validity of the refusal. If, as I believe, disclosure in this case would not have undermined decision making in the agency, access should not have been refused when it

was refused. It is no argument to say “you will see them later”.

12. The above arguments may contain points of wider application but they are raised only in the context of the specific refusal of access in this particular case. They are factors that in my view counteract any claim that disclosure in this case would seriously undermine decision making in the agency. Non-disclosure may also undermine decision making if, as I believe may be the case here, it tends to undermine public trust or confidence.
13. The exception under section 4.3 may be invoked, *inter alia*, only before a decision is made. At the time of my request a decision had in effect been made – to publish a new and different set of policy proposals, containing provisions relating to matters such as intellectual property that had not previously appeared to be nearly so significant to the issue of transparency.
14. Refusal of access is subject to an exception in cases where there is an overriding public interest in disclosure. Although clearly not relying on this point alone, I think it may reasonably be argued that there is an overriding interest in public disclosure in this case. Taken together, much of the previous arguments make a case for an overriding public interest:

- a) The underlying policy in this instance is a matter of enormous public interest since it relates to access, for clinicians, scientists and citizens, to clinical trial reports on medicines after they have been approved for use in the EU. The evolution of policy on this issue and the basis for that evolving policy is also a matter of great public interest and should be disclosed before a final decision on that policy.

- b) The stakeholders included in the targeted consultation on the latest policy proposals were not told the basis for the apparent changes in the approach of the agency. A “clear message” from the Commission was mentioned but no further information given about the nature content or effect of that message. Without that information stakeholders could not offer a reasonable opinion on the apparent basis for the new policy proposals, and the consultation was therefore not a proper one. There is an overriding public interest in their being a proper and full consultation on such an issue before the final decision.

- c) The agency is independent in the exercise of its functions. In this case it is clear that the Commission significantly influenced the evolution of policy. There is nothing inherently wrong in this but an agency that values its independence and the perception of its independence should disclose clearly

communications from the Commission on policy issues.

d) Given the appointment of a new Head of Legal who had played a significant role at a senior level on the development of the industry's position on intellectual property rights, it is of overriding public interest for the agency to disclose fully all communications to and from industry associations on the matters at issue. This is not to imply any impropriety on the part of the Head of Legal, but rather to argue for public disclosure in the particular circumstances of this case, as a matter of good administration and as necessary step to preserve public trust and confidence in the agency.

I look forward to your response to this appeal.

Best wishes,

Jim Murray

29th June 2014

http://www.ema.europa.eu/ema/index.jsp?curl=pages/about_us/landing/ask_ema_landing_page.jsp&mid=WC0b01ac05806499f0

