EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

Mr Jim Murray
OpenMedicineEU

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21 July 2014
EMA/434352/2014
Procedure Management & Business Support Division

Dear Mr Murray,

Subject: Publication of and Access to Clinical Trial Data - ASK – 3429 - **Rejection letter to the requester- confirmatory application**

Thank you for your confirmatory application of 30 June 2014 appealing against the refusal of the European Medicines Agency (the Agency) to grant access to the documents concerning Agency's public consultation on publication of and access to clinical trial data concluded on 30th September 2013, in particular:

- All submissions or correspondence in written form to or from any pharmaceutical industry association, together with notes of submissions or comments received in any other form from any pharmaceutical industry association, between 31st May 2013 and 22nd May 2014.
- All correspondence from 31st May 2013 to 22nd May 2014 between the agency and the European Commission relating to the publication or prospective publication of, and access to, clinical trial data, including but not confined to any submission or correspondence in relation to the public consultation described above.

Your confirmatory application has been handled in accordance with Article 8(1) of Regulation (EC) No 1049/2001 regarding public access to European Parliament, Council and Commission documents (the Regulation)[1], and Article 7(1) of the Rules for the Implementation of Regulation (EC) No 1049/2001 on access to EMEA documents (the Agency rules)[2]. Moreover, it has been assessed pursuant to Article 4 of the Regulation, Article 3 of the Agency rules and the European Medicines Agency policy on access to documents related to medicinal products for human and veterinary use (the Agency policy)[3].

The Agency has conducted an individual assessment of your confirmatory application and hereby confirms the initial refusal of 13 June 2014 against disclosure of the above mentioned documents.

The documents you requested come under the exceptions set out in the Regulation and the Agency rules and therefore cannot be released. In particular, the exception applicable is in accordance with Article 4.3. 1st paragraph, whereby access to a document, produced, received or in possession of the

1 OJ L 145, 31.5.2001, p. 43–48
2 EMEA/MB/203359/2006 Rev 1 Adopted
3 EMA/110196/2006 of 30 November 2010

Agency shall be refused if disclosure of the document would seriously undermine the decision-making process.

The Agency is currently finalising the draft of the Policy for proactive publication of clinical trial data. The Management Board has endorsed this policy at its meeting on 12 June 2014. The Management Board of the Agency has postponed the formal adoption of the Policy on publication of clinical trial data to its 2 October 2014 meeting. If adopted, the Policy will be published on the Agency's website and become effective. At that stage, the Agency will also publish information concerning the feedback received to the public consultation on the draft of the EMA Policy for proactive publication of clinical trial data.

Therefore, as of today, the above procedure is still on-going. Even though the Agency's public consultation on publication of and access to clinical trial data was concluded on 30th September 2013, the information contained in the requested documents plays an important role in the finalization of the Policy. This includes all submissions or correspondence in written form to or from any pharmaceutical industry association, as well as all correspondence from 31st May 2013 to 22nd May 2014 between the Agency and the European Commission relating to the policy.

The disclosure of such information prior to the finalization of the Policy may lead to unnecessary external pressure from various stakeholders that might compromise the final steps of the process and all Agency's efforts made in the last 12 months to strike a balance between proactive data disclosure, the absolute need to protect personal data and the concerns relating to the protection of commercially confidential information. In conclusion, the Agency maintains its position that the disclosure of the documents that you have requested will undermine the related decision-making process.

In your confirmatory application, you state that "The agency is independent in the exercise of its functions". The Agency is indeed independent in the exercise of its functions. However, the Policy is based on Article 80 of Regulation (EC) 726/2004. The said Article clearly requires the Agency to obtain the agreement of the European Commission to the adoption of transparency measures based on this Article.

In accordance with Article 4.3. 1st paragraph of the Regulation, the Agency refuses access to the requested documents.

The Agency has also conducted an assessment of your request with a view to identifying the presence of an overriding public interest in disclosing copies of the requested documents. It has not been possible, however, to ascertain the presence of such an interest that could override the protection of the interests identified above.

The Agency does not agree with the claim in your confirmatory application that the disclosure of the requested documents is justified by the "enormous public interest" and "overriding public interest in there being a proper and full consultation on such an issue before the final decision". The Agency strongly believes that the public consultation on the Policy that was conducted was open and transparent. Your claims that the consultation was "not a proper one" are neither based on facts nor substantiated.

Your claim that individual stakeholders did not have the opportunity in good time to see, and challenge (or support) the submissions of all the other stakeholders does not demonstrate that the consultation was "not a proper one". The Agency received over 1000 responses to the public consultation. It is practically impossible for the Agency to share these responses with all stakeholders and to seek their comments on the initial submissions. Such process would require very substantial administrative and time resources and would effectively render the adoption of the Policy impossible. As you acknowledge in your letter, the Agency organised a number of targeted consultations during which the Policy was

discussed in detail and stakeholders were informed of and consulted on the outcome of the public consultation.

Moreover, it is in the public interest for the Policy to be adopted as soon as possible. As discussed above, the disclosure of the requested documents prior to the final adoption of the policy may lead to unnecessary external pressure from various stakeholders that might compromise the whole process.

Therefore we confirm the refusal to grant access to the documents requested as long as the policy is not adopted.

This decision terminates the procedure before the Agency. Should you wish to avail yourself of the remedies available under Union law against this decision, please be informed that you can bring a complaint before the European Ombudsman, pursuant to Article 228 of the Treaty on the Functioning of the European Union (TFEU). In the alternative, you can institute legal proceedings before the General Court of the European Union in accordance with Article 263 of the TFEU.

Yours sincerely,