EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

Mr Jim Murray
OpenMedicineEU

jim@eujim.eu

13 June 2014
EMA/345677/2014
Procedure Management & Business Support Division

Dear Mr Murray,

Subject: Publication of and Access to Clinical Trial Data - ASK - 3429

- Rejection letter to the requester

Thank you for your correspondence dated 25 May 2014 in which you apply for the following documents in connection to your agency's public consultation on publication of and access to clinical trial data concluded on 30th September 2013:

- 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 request has been handled in accordance with Article 7 of Regulation (EC) No 1049/2001 regarding public access to European Parliament, Council and Commission documents (the Regulation)[1] and Article 6 of the Rules for the Implementation of Regulation (EC) No 1049/2001 on access to European Medicines Agency 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 regrets to inform you that 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 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 EMA policy for proactive publication of clinical trial data. The Management Board has endorsed this policy at its meeting on 12 June 2014. 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

Management Board reserved to adopt the policy by mid-July 2014. 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 and disclosure of the documents that you have requested will undermine the related decision-making process.

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

The Agency has not identified at this stage any overriding public interest justifying disclosure of the requested documents, and which would override the protection of the interest identified above.

You may submit a confirmatory application within 15 working days, in writing against this refusal to the European Medicines Agency. Should you wish to do so, you are kindly invited to provide your reasons against our decision to refuse access at this stage, or detail any other considerations in terms of overriding public interest, which you believe should be taken into account by the Agency in adopting a final decision.

Once your confirmatory application has been received, you will be informed of the outcome within 15 working days (extendable in exceptional circumstances), either granting you access to the documents or confirming refusal of access. In the latter case, you will also be informed of any further appeal routes open to you to consider.

The confirmatory application should be submitted using the on-line request form, available on the European Medicines Agency website, under the following location:

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

Please use the ASK Procedure Number mentioned in the subject line in any correspondence related to this request.

If you have any queries on the enclosed, please do not hesitate to contact the Access to Documents Coordinator for this request, [redacted], e-mail: [redacted].

Yours sincerely,

[redacted]

[redacted]
Legal Administrator
Legal Department