BONNOR Peter

From: Wathion Noel [redacted]
Sent: 07 May 2014 12:00
To: GRILL Gerhard
Cc: O REGAN Fergal Anthony; [redacted]
Subject: RE: Finalisation of an EMA policy on proactive publication of and access to clinical trial data
Attachments: 2014 05 - Finalisation of EMA policy on CT data - Mtgs with stakeholders....ppt; Redaction principles DRAFT.DOC; Terms of Use DRAFT.DOC; Agenda-Finalisation of EMA policy on CT data - 8 May 2014.pdf

Dear Mr Grill,

Thank you for your reply.
Let me try to clarify some issues.
We have sent the invitation directly to you and your Colleague because of your previous involvement in the discussions on this policy.
Indeed we should have sent the documents and apologies for the oversight.
In the meantime we have scheduled another stakeholder meeting next week Friday 16 May (from 9.00-13.00 hrs UK time).
The meeting tomorrow is with the European Industry Associations, the meeting on 16 May is with academia and medical journals. Yesterday we organised a TC with patients' organisations and healthcare professionals' organisations.
The data set used is each time the same (see attachments). We kindly ask you, since these are draft documents, for these documents not to be circulated.
The agenda for tomorrow's meeting is also enclosed. The agenda for next week still has to be finalised but will probably be identical unless issues arise from previous stakeholder consultation meetings.
Let me know if you want to attend tomorrow's meeting or next week's meeting.
If you have any further questions do not hesitate to contact me.
Kind Regards.

Noël Wathion
Chief Policy Adviser
Head of Stakeholders and Communication Division (ad interim)

Office 7-729 | Ext. 8592

From: GRILL Gerhard [redacted]
Sent: 07 May 2014 09:40
To: Wathion Noel
Cc: O REGAN Fergal Anthony
Subject: RE: Finalisation of an EMA policy on proactive publication of and access to clinical trial data

Dear Mr Wathion,

Thank you for the invitation that you sent on 1 May 2014 to Fergal and myself and the reminder that you sent yesterday. I presume that your invitation was addressed to the European Ombudsman as an institution, even though it was sent to Fergal and me directly.

We did not immediately react to your invitation as you had announced that you would send a draft agenda and supporting documents the following day (i.e., on 2 May) and further documents on Monday (i.e., on 5 May). However, we have not received any further information from you since then.

In these circumstances, I regret to have to inform you that the European Ombudsman is unfortunately not in a position to decide whether her Office should be represented at the meeting that EMA scheduled to take place tomorrow.

Best wishes,

European Ombudsman

Gerhard Grill
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From: Wathion Noel [redacted]
Sent: 06 May 2014 16:03
To: O REGAN Fergal Anthony; GRILL Gerhard
Subject: RE: Finalisation of an EMA policy on proactive publication of and access to clinical trial data

Dear Colleagues,

I refer to my email below.
I would very much appreciate if you could inform me if you are planning to attend this Thursday's meeting so that we can make the necessary arrangements.
KR,

Noël Wathion
Chief Policy Adviser
Head of Stakeholders and Communication Division (ad interim)

Office 7-729 | Ext. 8592

From: Wathion Noel
Sent: 01 May 2014 16:43
To: [redacted]
Cc: [redacted]
Subject: Finalisation of an EMA policy on proactive publication of and access to clinical trial data

Dear Colleagues,

As you will be aware the EMA is in the process of finalising its policy on proactive publication of and access to clinical trial data.
Following a public consultation on the draft policy undertaken last year, the EMA has reviewed all comments made.
Before presenting a revised draft to the EMA Management Board, whereby the Board will be invited to endorse the policy at its June meeting, the EMA has announced that it will undertake a targeted consultation with key stakeholders prior to finalisation of its policy.
Taking into account that the office of the European Ombudsman participated at our November 2012 workshop, and your support of the EMA's intention to further increase transparency of information on medicinal products, we would very much appreciate if you could attend next week's stakeholder meeting.
This meeting will take place on Thursday 8 May (3-6 pm UK time) at the EMA premises.
We acknowledge that this invitation comes quite late and we apologise for the short notice.
If it would not be possible for you to attend in person, we can also look at alternatives such as joining the meeting through Adobe Connect.
We will provide you tomorrow with the draft agenda and supporting documents. Other documents will be sent on Monday next week.
If you have any questions at this stage, please do not hesitate to contact me.
Kind Regards,

Noël Wathion

Chief Policy Adviser
Head of Stakeholders and Communication Division (ad interim)

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