Your email of 30 January - FOI 24/124 (Part 1) and Internal Review of FOI 24/001 (Part 2)

MHRA Customer Services <MHRACustomerServices@mhra.gov.uk>
Thu 08/02/2024 08:50
To [redacted]
Cc:MHRA Customer Services <MHRACustomerServices@mhra.gov.uk>
2 attachments (1 MB)
FOI 23/876 - FOIA request - Commission on Human Medicines; FOI 24-001 reply.pdf;
Dear [redacted]

Thank you for your email of 30 January 2024. In your email, you raised two points, and I'd like to respond to each one in turn. There is quite a lot of explanation below, and I've separated this initial response to your email into two sections, one for each of the two points you mentioned. This is because we will need to deal with the two points you have raised in your email separately under the provisions of the Freedom of Information Act legislation.

Your email of 30 January 2024 referred to the response that had been issued to your previous request FOI 24/001 and said:

> *"Thank you for your reply. However it does not answer my questions.*
>
> *I would like copies of the committee minutes. I see you expect to publish them in 2024, but it appears the committee have already been meeting for some time.* [Point 1]
>
> *The link you sent me describes the report process but it does not contain the final report. Please could you send me a copy of the report. If it is not ready yet please could you let me know when it will be ready and send me a copy then. If a draft is available that would be good if you could send me that."* [Point 2]

I should first explain that the Freedom of Information Act grants access to the recorded information held by a public authority in response to requests made, and in addition to this, there is also a formal process through which a requester may seek an 'internal review' of a previous response that has been issued to them. You raised two different points in your email of 30 January 2024; as one contains a new request for information, and the second is a point raised in respect of the link provided to you in the previous response to FOI 24/001, I will set out discussion of each point out separately.

POINT 1: (This is a new request, with reference number FOI 24/124)

> ***"I would like copies of the committee minutes. I see you expect to publish them in 2024, but it appears the committee have already been meeting for some time."***

This refers to the response we provided to you for your previous request, FOI 24/001, but it goes on to ask for different information to that request. In FOI 24/001 you had asked why the Vaccine Safety Surveillance Expert Working Group had stopped meeting and I've copied the question from that request here:

> *"Please could you explain why the committee suddenly stopped meeting – or whether it was renamed etc and is still meeting under a different label"*

We responded to this in FOI 24/001, explaining that:

> *"In August 2020, a second Working Group was formed with a different remit and comprised of a wider range of expertise – this time to advise the MHRA on the benefits and risks of the COVID-19 vaccines in development. The minutes of all Benefit Risk EWG meetings are intended for future publication, and we are working to commence a schedule of proactive publication in 2024."*

I will first give some further explanation to add to this response for clarity. In FOI 24/001, you were asking about the Vaccine Safety Surveillance Expert Working Group. There were 4 meetings of this Expert Working Group, and we had provided these to you in response to another previous request – FOI 23/876. I've attached a copy of that response to my email, which includes copies of all 4 meetings. These were the only meetings held for the Safety Surveillance Expert Working Group.

When you asked your further question in FOI 24/001, where you asked why this "*committee*" (the Vaccine Safety Surveillance Expert Working Group) had stopped meeting, I do think that we could have included a link to the final report of the 'Commission on Human Medicines Expert Working Group on COVID-19 vaccine safety surveillance' (the full title of the Vaccine Safety Surveillance Expert Working Group), which was published on 21 February 2021.

I have provided the link to this final report below; this contains further explanation that the purpose of the Vaccine Safety Surveillance Expert Working Group was specifically to determine the overarching approach that would be taken forward for vigilance and safety monitoring:

> *In May 2020, the Commission on Human Medicines established an Expert Working Group (EWG) to advise the Medicines and Healthcare products Regulatory Agency (MHRA) on its safety monitoring strategy for COVID-19 vaccine(s).*
>
> *The EWG held four meetings from May to October 2020, during which it considered proposals and methodologies for MHRA-led vigilance activities.*
>
> *Based on this advice, the MHRA has developed, and now has in place, a four-stranded approach to vigilance, which is summarised in this report.*
>
> https://www.gov.uk/government/publications/report-of-the-commission-on-human-medicines-expert-working-group-on-covid-19-vaccine-safety-surveillance

As the published report explains, the role of the Vaccine Safety Surveillance Expert Working Group was to consider proposals and advise on the overarching vigilance and safety monitoring strategy, and to set out how this four stranded approach to vigilance would be taken forward. There were no further meetings of the Vaccine Safety Surveillance Expert Working Group after this approach was determined.

A separate Expert Working Group, the Benefit Risk Expert Working Group, was set up in August 2020 to provide ongoing advice specifically in respect of the benefits and risks of the COVID-19 vaccines in development, and this forms part of the overarching vigilance and safety monitoring safety strategy that was put in place through the work of the Vaccine Safety Surveillance Expert Working Group.

I hope that this gives a little more clarity about the respective roles of the two Expert Working Groups.

To now return to the point you raised in your email of 30 January 2024, *"I would like copies of the committee minutes. I see you expect to publish them in 2024, but it appears the committee have already been meeting for some time*".

I would like to explain that, if you mean the minutes of the Vaccine Benefit Expert Working Group that we had referred to in the response to FOI 24/001, then as stated in that response, the intention to publish that we mentioned refers to the publication of all minutes of the Vaccine Benefit Expert Working Group from the first meeting in August 2020. For clarity, we are not intending to publish *only* meetings held from 2024 onwards; we have an intent to publish *all* previous meetings from the first meeting in August 2020 onwards.

I hope that this explains the situation more clearly. It means that, for a request for the Vaccine Benefit-Risk Expert Working Group meeting minutes, we are refusing this request in advance of the scheduled publication. This is because section 22(1) of the FOIA exempts information from disclosure in response to a request if that information is already intended for future publication.

Section 22 states that:

> "Information is exempt if, at the time when the public authority receives a request for it:
>
> (a) the information is held by the public authority with a view to its publication, by the authority or any other person, at some future date (whether determined or not),
>
> (b) the information was already held with a view to such publication at the time when the request for information was made, and
>
> (c) it is reasonable in all the circumstances that the information should be withheld from disclosure until the date referred to in paragraph (a)."

Prior to receipt of your email of 30 January 2024, the decision had already been made to publish the minutes of this EWG. Therefore, we consider that points a, b and c above apply in the context of the information you have requested.

As Section 22 is a qualified exemption, we have considered whether the public interest in maintaining the exemption is greater than public interest in disclosing the requested information. We do appreciate that there is a strong public interest in disclosure of the COVID-19 VBR EWG minutes, and this has informed our decision to publish the minutes for the widest public benefit. However, on this occasion, we consider that the greatest public interest lies in maintaining the proposal to publish these minutes, and our view is that the public interest therefore favours maintaining the section 22 exemption. Under section 22 a date for publication does not need to be set; however, I can advise that we are working now to begin a schedule of publication in the coming months.

POINT 2: (Internal review of our previous response FOI 24/001)

The second point in your email of 30 January 2024 concerned the link provided in response to your previous request FOI 24/001:

> *"The link you sent me describes the report process but it does not contain the final report. Please could you send me a copy of the report. If it is not ready yet please could you let me know when it will be ready and send me a copy then. If a draft is available that would be good if you could send me that"*

This point concerns whether the previous response to your request FOI 24/001 provided the information that you had asked for in that request. In short, your request FOI 24/001 asked for a particular report, and you have said that the link that was provided to you did not include the report itself.

When someone receives one of our responses and contacts us to say that they think that we haven't provided the correct information, or that we have made an error with a previous response, we need to deal with this as an 'internal review'. The purpose of the internal review procedure is to provide a fair, thorough and independent review of the handling of your request under the Freedom of Information Act 2000.

I provide an acknowledgement here that we will deal with Point 2 of your email of 30 January 2024 as an internal review of the response issued to FOI 24/001. We follow the Cabinet Office FOI Code of Practice and the Information Commissioner's guidance that an internal review should be completed within 20 working days if possible, and within 40 days at most. We will therefore seek to respond to an internal review for Point 2 concerning FOI 24/001 by 27 February 2024 and will write to you if an extension is required.

I am sorry that this has been a long email, so just to confirm at the end , the internal review of Point 2 will not consider Point 1 of your email any further. As I've explained above for Point 1, we are intending to publish all Vaccine Benefit-Risk Expert Working Group minutes from August 2020 onwards, and this means that section 22(1) applies to the information at this time.

Yours sincerely

[redacted]

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MHRA Customer Experience Centre
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From: [redacted]
Sent: Tuesday, January 30, 2024 1:20 PM
To: MHRA Customer Services MHRACustomerServices@mhra.gov.uk
Subject: IR FOI 24/001 - Commission on Human Medicines

Dear MHRA

Thank you for your reply. However it does not answer my questions.

I would like copies of the committee minutes. I see you expect to publish them in 2024, but it appears the committee have already been meeting for some time.

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Kind regards