Fw: FOI 23/150

MHRA Customer Services <MHRACustomerServices@mhra.gov.uk>
Sat 16/03/2024 19:09
To [redacted]

From: MHRA Customer Services <MHRACustomerServices@mhra.gov.uk>
Sent: 11 March 2024 15:01
To: [redacted]>
Subject: FOI 23/150

FOI 24/150

Dear [redacted]

We are writing in response to your email of 12 February 2024. We recently issued a detailed response to a different request from you (FOI 24/117), and we will refer to that response below.

The wording of your email of 12 February 2024 is here:

> *"I refer to the attached response received from the MHRA yesterday, which follows a Freedom of Information Act request I made in my personal capacity on 30th January 2024.*
>
> *As you are aware from the request, Dr Tess Lawrie had raised concerns regarding the large number of potential side effects reported to the Yellow Card scheme during the first 6 months of Covid-19 vaccine roll out, and the very well known and documented under-reporting of potential side effects. In response to Dr Lawrie, you appear to attribute these large numbers of reported ADRs to "high public awareness of the Yellow Card scheme and the reporting of suspected reactions" and as you are also aware I requested evidence of this claim from that period (i.e. up to 22 July 2021).*
>
> *In your attached response you confirm that "the MHRA do not hold a specific document for disclosure that could be provided in response to [my] request" to support your claim, which I read as you being unable to support your claim. If this is not the case please confirm.*
>
> *What I find particularly worrying is where you state (emphasis added): "The statement made by the MHRA concerning high public awareness of the Yellow Card scheme and the reporting of suspected reactions was **inferred from the number of Yellow Cards received reporting suspected side effects to the COVID-19 vaccines**."*
>
> *If my understanding is correct, the MHRA is inferring (guessing) that the reason there is high public awareness of the Yellow Card scheme and the reporting of suspected reactions is because there was a (much) higher than usual reporting of suspected side effects to the Covid-19 vaccines. Surely, as a regulator, the immediate response to a much higher reporting of vaccine side effects would be to investigate the cause of this, rather than guess that it is due to a higher public awareness of the scheme for reporting! As you have confirmed that you have no evidence to support the claim of high public awareness of the reporting scheme or the reporting of suspected reactions resulting from the awareness, I expect that you MUST investigate the actual event, i.e. the much higher reporting of suspected side effects and therefore the quality,*

safety and efficacy of the product(s). Has this been carried out, and if so, what are your findings?

Returning to your response, you further claim that reporting rates for the Covid-19 vaccinations via the Yellow Card scheme was higher than for other medicines throughout the pandemic because the MHRA worked to "ensure that people knew how to report suspected side effects to the Yellow Card scheme." You then list how you claim this was achieved, for example via social media campaigns, a Drug Safety Update, a press release, and embedded information about the scheme within healthcare professionals training materials, plus the encouragement of the general public to report any suspected side effects to the MHRA on televised press briefings. Please provide the evidence you have to support your claim that these examples actually led to an increased level of reporting. I already am aware of your inference of increased awareness from increased reporting, so there is no need to provide this as a rationale or as evidence. I am particularly interested to receive information on the press release (singular) and televised press briefings you refer to, please provide evidence of all of these up to the date 22 July 2021.

Finally, you refer to product information and PHE materials containing information on reporting side effects to the MHRA, however the former at least has been a requirement in all product information for at least 10 years and therefore is unlikely to lead to an increase in reporting rates. With regards to the latter example, the PHE materials, please provide evidence supporting your claim, other than inference.

These additional requests, where necessary can be treated as a new FOIA request.

Although I am writing in my personal capacity here, I am a seasoned regulatory affairs professional of 25 years, and the above actions and position of the MHRA only erodes my faith in your ability to carry out your role as regulator and gateway to the UK market for novel products. I hope you can restore my faith in your organisation."

We are refusing FOI 24/150 under section 12(4)(d) of the FOIA; this allows public authorities to aggregate requests made by one or more persons made within a period of 60 consecutive working days for the same or similar information. This includes two other requests made within this period and also notes that time was also spent in preparing a detailed response to FOI 24/117. That request required significant clarification, and the response sought to provide a great deal of advice and assistance; we also note that the amount of information sought in that request was potentially so broad that the response advised that, depending on the correct interpretation of particular questions, the scope of the information sought would create a significant burden. (In respect of the latter point, we also note that you have submitted a number of other enquiries to the MHRA in recent months.)

In terms of providing advice and assistance on how to narrow future requests, we refer to the advice and assistance provided for FOI 24/117. While it is not entirely clear what specific information you are seeking in your new question "*I expect that you MUST investigate the actual event, i.e. the much higher reporting of suspected side effects and therefore the quality, safety and efficacy of the product(s). Has this been carried out, and if so, what are your findings?"*, this appears to cross-over with the types of safety information also sought in FOI 24/117 and we refer you to the advice and assistance it contains. We do not wish to refuse future requests solely on the grounds of the burden that compliance would create, and we therefore mention our general advice here, that a requester should allow one request or enquiry to be dealt with and completed before submitting further requests on related subjects.

In our response to FOI 24/117, we also explained:

"We have included directions to some of the ICO's guidance at the end of this email, which advises how to make effective requests for information. We appreciate that this

guidance does not quite cover the way you are submitting requests for information alongside general correspondence, but we hope it will be useful nonetheless – the underlying principle of FOIA is that the clearer a request for recorded information is, the less likelihood that a public authority will need to come back to the requester to ask for clarification of the information that is being requested. It is a requirement for a valid request that a clear description of the information sought is provided by the requester. In addition, your own questions are punctuated by 'if necessary' and 'if it helps' – so it would be very helpful if you could review the ICO's guidance with a view to being a little clearer in whether you wish to submit an FOIA request or not.

We note that this issue also arises in your concurrent request, FOI 24/150, and we will write to you about this request separately."

The ICO's guidance to public authorities is that where it is not clear whether a requester wishes an informal response or not, we should contact them:

"The best way round this is usually to speak to the applicant, explain to them how the Act works, and find out what they want."

We will therefore set out an explanation here. A concern specific to the present request is that, while you appear to be dissatisfied with the response you received to a previous response FOI 24/099, we cannot see that you have stated that you are exercising your right of appeal (details of which were included in the response issued to you). Instead, you have chosen to pursue your concerns about the response through further correspondence from your private email address and you have then stated that these *"additional questions"* can be dealt with under the FOI legislation "*where necessary*".

In terms of the FOIA, all questions asked in your email of 12 February 2024 are focused on the response issued for FOI 24/099. This is particularly the case where further correspondence about a response repeats some of the questions asked in the previous request and seeks further confirmation of the response issued. This is most apparent where you ask:

In your attached response you confirm that "the MHRA do not hold a specific document for disclosure that could be provided in response to [my] request" to support your claim, which I read as you being unable to support your claim. If this is not the case please confirm.

This refers specifically to the response previously issued to you for FOI 23/099. We would therefore additionally advise that, in previous cases, the ICO has encouraged us to recognise emails similar to your own of 12 February 2024 as seeking an internal review of the previous request. We have checked that your rights of appeal were included in that response, and we are unsure why you have not chosen to pursue the option to seek a review of that decision if you have concerns. (We should also note that, as the question above seeks a view or opinion rather than recorded information, it is not a valid request under the FOIA in its own right.)

It is the purpose of an internal review to determine if the original response was handled appropriately and, if the FOIA was not appropriately applied, to amend the decision. In terminology also used in your other request FOI 24/117, you have stated, "*These additional requests, where necessary can be treated as a new FOIA request."*, however, the questions you have now asked, indicating that they should be taken forward as new requests, are ones that should be more appropriately considered in line with our FOI complaints process, as an internal review of the response issued to FOI 24/099. This would be the appropriate mechanism to deal with a complaint received about a response that has been issued and would allow the points you have raised in respect of the previous response to be considered, as set out in your appeal rights.

In preparing this response, we note that you have submitted numerous enquiries and other correspondence to the MHRA, including requests and enquiries from several different email addresses. We would therefore again draw your attention to the Information Commissioner's guidance on making effective requests for information. We note that while still useful, the link we included in FOI 24/117 has been updated and the guidance we originally directed you to now appears on a different page of the ICO's website. We include both links here:

https://ico.org.uk/for-the-public/official-information/how-to-write-an-effective-request-for-information/

https://ico.org.uk/for-the-public/official-information/preparing-and-submitting-your-information-request/

The ICO's 'Top Tips' and guidance on 'Protecting public money' are now available here:

https://ico.org.uk/for-the-public/official-information/

While we would consider a new request, we advise that you may wish to consider if you would prefer that we first conduct an internal review of the response to FOI 24/099. If you wish us to conduct an internal review of FOI 24/099, please confirm this to us and we will take this forward.

Yours sincerely

MHRA Customer Experience Centre
Communications and engagement team
Medicines and Healthcare products Regulatory Agency
10 South Colonnade, Canary Wharf, London E14 4PU

Appeal rights

If you are dissatisfied with the handling of your request, you can ask us to conduct an internal review. Internal review requests should be submitted within two months of the date you receive this response and addressed to: info@mhra.gov.uk

If you remain dissatisfied with the outcome of the internal review, you have the right to apply directly to the Information Commissioner for a decision. Please bear in mind that the Information Commissioner will not normally review our handling of a request unless the requester has first asked us to conduct an internal review.

The Information Commissioner can be contacted through their online webform at: https://ico.org.uk/make-a-complaint/foi-and-eir-complaints/foi-and-eir-complaints/

Or in writing to: Information Commissioner's Office, Wycliffe House, Water Lane, Wilmslow, Cheshire, SK9 5AF

From: [redacted]
Sent: Monday, February 12, 2024 1:20 PM
To: [redacted]
Cc: [redacted]>
Subject: FOI 24/099 - request-1078483-9fc5bc17@whatdotheyknow.com - Follow Up

Dear [redacted]

I refer to the attached response received from the MHRA yesterday, which follows a Freedom of Information Act request I made in my personal capacity on 30th January 2024.