Medicines & Healthcare products Regulatory Agency

MHRA
Regulating Medicines and Medical Devices

[redacted]

MHRA
10 South Colonnade
Canary Wharf
London
E14 4PU
United Kingdom

www.gov.uk/mhra

27th September 2023

Dear [redacted]

FOI 23/296 Internal Review

I am writing in response to your request for a review of the Medicines and Healthcare products Regulatory Agency's ('the Agency') reply to your FOI request (23/296).

The purpose of this review is to determine whether the Agency dealt properly and fairly with your request under the Freedom of Information Act (FOIA). In particular, it will examine the reasons why any information may have been withheld from you.

Your original request and the Agency's response are annexed. In your request for a review you stated the following:

> Dear Lou,
>
> Thanks for your reply. It was indeed helpful in terms of my next steps
>
> I would like to seek an internal review of FOI 23/296 and for you to provide an explanation of the reasons for delays in handling this particular request to the internal reviewer, for inclusion alongside their review.
>
> If I have understood your reply correctly, you will progress the IR? Or should I respond to the relevant email and make that request directly myself? Please advise?
>
> The new request I will submit myself using the clarified request you have suggested, which sounds fine to me.
>
> Many thanks and kind regards
> [redacted]

Correspondence between yourself and our FOI Manager explaining the key parts of your request for an internal review are set out below:

22nd August email from requester:

Thank you for your offer of further advice with the attached response. The response asks me to clarify my request, which I will try and do, but I have also addressed some of the reasons given for not being able to fulfil my request.

I am requesting all the reports being given to the government from the MHRA and the advice on the matter, referred to by the Senior Coroner [redacted] in the linked Daily Mail report. He said "there are reports being given to the Government from the MHRA and there is advice on the matter".

I listed the causes, Brain Stem Infarction, acute Intracerebral Haemorrhage and VITT, to identify the case and so the reports and advice on the matter I was asking to be disclosed. Reports and advice implies the MHRA may have looked at data, carried out or proposed studies and analyses, directly or indirectly, to look at why/how the AZ vaccine might have caused the three conditions that brought on [redacted] fatal ADR. I say all to be sure nothing of relevance is missed in fulfilling the request.

I am not asking if the MHRA has looked into all deaths that happened as a result of these three causes so my request does not need "to include any and all Yellow Card data concerning these events".

The MHRA must know what reports and advice it has given to the government in relation to this one case? So I do not understand how the MHRA is unclear which reports and advice I mean or unable to identify what information I am asking for without further description from me? I also cannot see how disclosing the data would pose problems in terms of the breadth or scope of the request or it covering "more information than we can retrieve within the 24-hour 'appropriate limit' in FOIA".

30th August email from requester:

Thank you for your swift reply. You're right, I am dissatisfied with the response and I want the data I have requested to be disclosed. However I'm a little unclear from your reply below whether, in order to achieve that, I'm better off requesting an internal review of the MHRA's response or resubmitting it as a clarified request or maybe both?

You have rightly understood I am only asking for information that concerns the specific case mentioned in the Daily Mail article, so any reports, data, analyses or advice provided by the MHRA to any government departments about this specific case.

So I don't see that the scope of the information originally asked for is relevant, except in the context of misinterpretation and I will be frank with you. I believe my original request was deliberately misinterpreted by the MHRA, which on the back of a 60+ day delay in responding and a complaint to the ICO, suggests a reluctance to disclose. Surely breaching the principle of the Freedom of Information Act, that the presumption is in favour of disclosure? The ICO website does say "people have a right to know about the activities of public authorities, unless there is a good reason for them not to." Someone's death, and highly likely other deaths, was caused by a drug approved for emergency use by the regulator. What greater reason is there to know?

It also flies in the face of the MHRA's professed desire for greater transparency, as endorsed by June Raine's sworn testimony at the Infected Blood Inquiry that the regulatory system operates "in a climate of openness and transparency, putting patients' interests at the heart, to do everything to ensure that the regulator has a part to play in making sure this doesn't happen again."

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Consideration of the issues

In your original request you asked for disclosure of all data, studies and analyses carried out by the MHRA to examine causes of such deaths as a consequence of the AstraZeneca Covid 19 Vaccination and the "reports being given to the government from the MHRA", to which the Senior Coroner [redacted] refers in the above quote. [In reference to the Daily Mail article.]

> I refer to this quote from the report in the Daily Mail Psychologist, 32, died from complications of the AstraZeneca Covid vaccine, inquest rules | Daily Mail Online
>
> '[redacted] said: 'My understanding is that this condition is rare. Causes are being examined by the MHRA (Medicines and Healthcare products Regulatory Agency). [...] 'It is being looked at and there are reports being given to the Government from the MHRA and there is advice on the matter.'"
>
> In relation to the three causes of death as a consequence of the AstraZeneca Covid 19 Vaccination mentioned in the Daily Mail report:
>
> 1. Brain Stem Infarction
> 2. Acute Intracerebral Haemorrhage
> 3. Vaccine Induced Thrombosis and Thrombocytopenia
>
> I request disclosure of all data, studies and analyses carried out by the MHRA to examine causes of such deaths as a consequence of the AstraZeneca Covid 19 Vaccination and the "reports being given to the government from the MHRA", to which the Senior Coroner [redacted] refers in the above quote.

This information was refused under section 1(3) of the FOIA which states access to information held by public authorities is subject to the following provisions:

> (3)Where a public authority—
>
> (a)reasonably requires further information in order to identify and locate the information requested, and
>
> (b)has informed the applicant of that requirement,

The response requested clarification in order to determine what information was being requested in regard to two aspects:

1. Whether the request related to 'all data, studies and analyses carried out by the MHRA to examine cause of death'
2. What reports the Senior Coroner [redacted] is referring to from the Daily Mail article link provided.

In subsequent correspondence with our FOI Manager you have clarified that your request does not relate to all deaths associated with the three causes of death detailed in your original request but is limited to the one specific case described in the Daily Mail article. As stated in your emails of the 22 August 2023 and 30 August 2023:

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22 August 2023 "*I am not asking if the MHRA has looked into all deaths that happened as a result of these three causes so my request does not need "to include any and all Yellow Card data concerning these events". The MHRA must know what reports and advice it has given to the government in relation to this one case*?"

30 August 2023: *"You have rightly understood I am only asking for information that concerns the specific case mentioned in the Daily Mail article, so any reports, data, analyses or advice provided by the MHRA to any government departments about this specific case."*

The concern you have raised is that your request was deliberately misinterpreted. In this internal review I have considered the scope and interpretation of your original request and looked to answer the following questions:

- Whether the request clearly described the information, so that information relevant to the request could be identified?
- If it did not, which points were unclear?
- Was there more than one possible interpretation of the request?
- How broad was the potential scope of the request?
- Was it correct to ask the request to provide further details to clarify the request?

In addition, I will provide explanation regarding the delays experienced in the handling of your FOI request.

You have also requested an additional point be included in the internal review as described in your email of 7 September 2023:

> With regard to the Internal Review of FOI 23/296, as per your email, I do have a further point I wish to include, which is this:
>
> In the response to FOI 23/296 the MHRA states:
>
> "Firstly, we should explain that the MHRA conducts safety analyses which include adverse events with a fatal outcome. You have requested disclosure of studies and analyses carried out by the MHRA to examine causes of deaths from brain stem infarction, acute intracerebral haemorrhage and vaccine-induced thrombsosis and thrombocytopenia. **However, this is not part of the MHRA's role** (my emphasis). The MHRA evaluates a range of safety data to assess the likelihood of an overall association between a medicinal product and an adverse event, regardless of whether the event has a fatal outcome or not."
>
> However in this document, it makes clear that, amongst other activities, part of the MHRA's Proactive vigilance for COVID-19 vaccines involves **Formal Epidemiological Studies** (my emphasis).
> These studies are one of the four main strands of its proactive vigilance. The document gives an example: "Examples of such studies undertaken by the MHRA in the past include the association between human papillomavirus (HPV) vaccine and chronic fatigue syndrome and the safety of pertussis vaccine in pregnancy (pertussis and HPV."
>
> I would therefore think that carrying out the "studies and analyses...to examine causes of deaths from brain stem infarction, acute intracerebral haemorrhage and vaccine-induced thrombsosis and thrombocytopenia" I referred to in my request are precisely the sort of formal epidemiological studies the MHRA claims to be doing, so very much part of their role? It seems to me, from the coroner's quote where he says "causes are being examined by the MHRA", that he too understood this.

I think this point needs to be fully addressed along with the other points I raised, especially in light of this news from Germany, which I'm afraid very much corresponds with my experience of FOI responses from the MHRA. You can perhaps understand why I draw the sort of conclusions my comment about the delay to the original response suggest.

Was the information clearly described in the request?

In order to determine how clearly your request for information has been described I have reviewed the wording in your original request. From this I note there are two sources of ambiguity around the description of the information requested; firstly is use of a media report as the basis for your request. Your request relates to a Daily Mail article and focuses on a quote from a coroner which refers to 'this matter'. However, the reporting relied upon in this article doesn't give a clear enough description of recorded information that may be held by the MHRA. In the Daily Mail report, 'this matter' also doesn't clearly refer to the specific case, or to 'the condition' (which might involve other cases). At one point in the article, it refers to all three conditions the request listed and at other points just 'vaccine induced thrombosis'.

The second point to consider is the wording of the request itself, your request listed the three causes given in the article and then asked for 'disclosure of all data, studies and analyses carried out by the MHRA to examine causes of **such deaths** as a consequence of the Astrazeneca Covid19 vaccination…". Using the plural in this sentence can objectively be interpreted as referring to more than one case.

Interpretation of the request for 'all data, studies and analyses carried out by the MHRA' in relation to all cases related to the three causes of death listed, as they may have occurred across more than one case, or just as the three that occurred in a single case significantly impacts the interpretation of the scope of the request. It is correct that requests for 'all data' can often be very broad and likely to need significant retrieval which may then exceed the limit set out in section 12 of the FOIA.

Based upon these three factors I believe there is evidence of lack of clarity and therefore more than one possible interpretation of your request.

ICO guidance on this matter is available below:

https://ico.org.uk/for-organisations/foi-eir-and-access-to-information/freedom-of-information-and-environmental-information-regulations/interpreting-and-clarifying-requests/

The guidance states:

- *"Sometimes a request may have more than one possible interpretation." "In this situation, you must go back to the requester to ask them to clarify which interpretation is correct."*
- *"How should we handle an unclear request?*
  If the request is not sufficiently clear to enable you to locate or identify the requested information, then your duty to provide advice and assistance will be triggered. You must go back to the requester to ask for further clarification."
- *"The requester cannot reasonably be expected to have a detailed knowledge of: the way in which you organise and structure your records; or*
  the terminology you use to describe and classify your information internally. You must therefore make allowances for this when reading requests."
- *"If you are unclear what the requester is asking for then you must ask them for further clarification."*

- *"Sometimes you may receive an unclear or ambiguous request where you reasonably require further information in order to identify and locate the requested information. This will trigger your duty to provide advice and assistance. You must contact the requester as soon as possible, but within the 20 working days to ask for clarification."*

I therefore believe it was reasonable for the MHRA to request further clarification on your request. The guidance states that there should be no expectation of detailed knowledge of an organisation's ways of working or how information is classified. The response from MHRA did provide further detail regarding examination of causes of death and what fell within the remit of the MHRA in order to assist with the clarification required for your request.
In your clarified request there is a clear difference in language used which no longer describes the three causes of death from the Daily Mail article but talks about the specific case you are interested in receiving information about.

Your further point for inclusion in this internal review related to the MHRA's role in examining cause of death and an apparent contradiction between the explanation provided in your FOI response and what is stated in the MHRA's COVID-19 vaccine safety surveillance strategy. You are correct in stating that the MHRA undertakes formal epidemiological studies on an ad-hoc basis should the need arise based on other vigilance activities in order to confirm and quantify the association of a suspected rare side effect to a medicine or vaccine. This is however done at a population level and not for individual cases. The response to your FOI request correctly stated that the MHRA's role is to assess the association of an adverse event to a medicine or vaccine, however it is not the MHRA's role to assign cause of death in relation to suspected adverse events following any medicinal product.

Delays in FOI request handling at MHRA

The requirements around information refused under section 1(3) of the FOIA states that any request for clarification should be sent to the submitter as soon as possible and within the 20-working day timeframe. Unfortunately, this was not the case in your request and the FOI Manager has provided information below regarding delays experienced in the handling of FOIs at the MHRA.

> The Information Commissioner's recent Practice Recommendation to the MHRA sets out in some detail that there have been delays in the handling of FOI requests and that a backlog of delayed requests subsequently occurred. If you are not already aware of the Practice Recommendation, the summary and full report are available here:
>
> https://ico.org.uk/action-weve-taken/information-notices/
>
> https://ico.org.uk/media/action-weve-taken/practice-recommendations/4026124/mhra-pr.pdf
>
> Request FOI 23/296 has been one of a regrettable number of requests delayed in the period considered by the Practice Recommendation. While it is noted that your correspondence regarding this internal review asked for the reasons for the delay to this particular request to be explained, the reasons apply to this and other requests at this time.
>
> The 'devolved' system of handling FOI requests at the MHRA, where requests are responded to by multiple teams across a public authority, first requires sufficient resource and an appropriate system at a central point to monitor the progress of each request and advise colleagues (in advance) of statutory deadlines and then also advise if these have been missed. The ICO's Practice Recommendation highlights the issues and gives advice here when it suggests *"MHRA should analyse and review its current request handling procedures to*

ensure that it has adequate long term resources in the right areas. Its systems and procedures need to be able to cope with sustained increased volumes. For example introduce a case management system or consider a dedicated FOI request handling areas which is separate to general enquiries and other correspondence."

There are no roles dedicated to dealing with FOI requests within the teams across the MHRA who have responsibility for handling FOI requests; these are dealt with by colleagues in addition to the core duties that they are required to perform for their dedicated roles. This has led to a backlog of requests within those teams within the MHRA who deal with larger numbers of requests.

As indicated in the ICO's Practice Recommendation, we are working to address these points and appropriately resource and support the handling of FOI requests to the MHRA.

Conclusion and recommendations

On the basis of this review, I conclude that the MHRA has met its obligations in handling your FOI request FOI 23/296, and that your request did require further clarification. The review notes here that the response advised that you contact the FOI Manager for further assistance, and that following this further discussion, this has led to the submission of a clarified request for information which is now being progressed separately to this review.

If you remain dissatisfied, you may ask the Information Commissioner (ICO) to make a decision on whether or not we have interpreted the FOIA correctly in dealing with the request and subsequent internal review. The ICO's address is:

The Information Commissioner's Office
Wycliffe House
Water Lane
Wilmslow
Cheshire
SK9 5AF

Yours sincerely

[redacted]

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Annex: FOI 23/296 correspondence

Dear [redacted]

FOI 23/296

Thank you for your email of 21 April 2023, where you requested disclosure of all data, studies and analyses carried out by the MHRA to examine causes of deaths from the following events as a consequence of the AstraZeneca Covid 19 Vaccination:

1. Brain Stem Infarction
2. Acute Intracerebral Haemorrhage
3. Vaccine Induced Thrombosis and Thrombocytopenia

and the "reports being given to the government from the MHRA", to which the Senior Coroner [redacted] eferred to in a Daily Mail article on 19 April 2023.

Firstly, we apologise for the delay in responding. However, we cannot respond to your request in its present wording as there are several parts where it is not clear what recorded information you are asking for. Under section 1(3) of the FOIA, we need to ask for your clarification of certain points, and we will indicate these below.

Firstly, we should explain that the MHRA conducts safety analyses which include adverse events with a fatal outcome. You have requested disclosure of studies and analyses carried out by the MHRA to *examine causes of deaths* from brain stem infarction, acute intracerebral haemorrhage and vaccine-induced thrombsosis and thrombocytopenia.

However, this is not part of the MHRA's role. The MHRA evaluates a range of safety data to assess the likelihood of an overall association between a medicinal product and an adverse event, regardless of whether the event has a fatal outcome or not. As part of these assessments, reports with a fatal outcome would be carefully evaluated in relation to determination of the public health impact of the safety concern. It is not the MHRA's role to assign cause of death in relation to suspected adverse events following any medicinal product. This is the case for both individual reports and aggregated data.

We would first ask if you could clarify if your request does intend to refer specifically to 'all data, studies and analyses carried out by the MHRA to examine cause of death' as this is not information that the MHRA would hold.

We would also like to seek clarification regarding the request for "*reports being given to the government from the MHRA*". It is not clear from your request what reports the Senior Coroner [redacted] is referring to and we cannot identify what information you are asking for without further description from you. We would be grateful if you could provide further details of these in order to progress your request.

We hope that the explanation we have provided above of the role of the MHRA and the work we undertake will help you to clarify your request.

We should also advise that in its present wording, if you do wish to continue with a new request using the terms "*all data, studies and analyses*" in relation to the above three events, this would be a very broad request, as it could be considered to include any and all Yellow Card data concerning these events as well as other assessments and analyses. Requests which ask for 'all information on' and

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‘all data held for’ can be so broad in scope that they may cover more information than we can retrieve within the 24-hour ‘appropriate limit’ in FOIA.

If you think it might be helpful to discuss your requests further, you are welcome to contact our FOI Manager Lou.Lander@mhra.gov.uk who will be able to give further advice about framing a new request.

We hope this explanation is useful, and we apologise that we did not contact you with these details sooner.

Yours sincerely,

FOI Team,