FOI 23/507

Dear

Thank you for your email of 6 July 2023 regarding the research letter entitled ‘Batch-dependent safety of the BNT162b2 mRNA COVID-19 vaccine’ by Schmeling and colleagues where you where you requested the following:

1. Assuming the MHRA are aware of Schmelling et al., 2023 and the conclusion drawn that "the results suggest the existence of a batch-dependent safety signal for the BNT162b2 vaccine, and more studies are warranted to explore this preliminary observation and its consequences," please provide a copy of all internal and external communications relating to this topic and any actions taken by the MHRA as a result of becoming aware of it.

2. If the MHRA are aware of any similar batch-dependent Suspected Adverse Events findings, whether carried within the MHRA or via any other source, please provide details of these and any actions taken by the MHRA.

The MHRA’s ongoing safety monitoring of COVID-19 vaccines has not identified any batch related safety concerns and no regulatory action has been taken for individual batches of these vaccines. Therefore, the MHRA does not hold the information requested.

The safety of COVID-19 vaccines is continuously monitored; should a new safety issue be confirmed we will act promptly to inform patients and healthcare professionals and take appropriate steps to mitigate any identified risk and protect public health.

If you disagree with how we have interpreted the Freedom of Information Act 2000 in answering your request, you can ask for an internal review. Please reply to this email, within two months of this reply, specifying that you would like an Internal Review to be carried out.

If you were to remain dissatisfied with the outcome of the internal review, you would 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 your request unless you have first contacted us to conduct an internal review. The Information Commissioner can be contacted at:

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

Yours sincerely

MHRA Customer Experience Centre
Communications and engagement team
Medicines and Healthcare products Regulatory Agency
10 South Colonnade, Canary Wharf, London E14 4PU Telephone 020 3080 6000

FURTHER MHRA RESPONSE
INTERNAL REVIEW DECISION
10 OCTOBER 2023

Dear

Internal review of FOI 23/507

I am writing in response to your request of 12 September 2023 for an internal review of the Medicines and Healthcare products Regulatory Agency's ('the Agency') response to your FOI request FOI 23/507.

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).

I will first set out the history of the request.

Request history
On 6 July 2023 you made the following request for information:

> *Dear Medicines and Healthcare Products Regulatory Agency (MHRA),*
> *A Research Letter by Schmelling et al. was accepted on 26 March 2023 by the European Journal of Clinical Investigation (Schmelling et al., 2023)[1]. Assuming the MHRA are aware of Schmelling et al., 2023 and the conclusion drawn that "the results suggest the existence of a batch-dependent safety signal for the BNT162b2 vaccine, and more studies are warranted to explore this preliminary observation and its consequences," please provide a copy of all internal and external communications relating to this topic and any actions taken by the MHRA as a result of becoming aware of it.*
> *If the MHRA are aware of any similar batch-dependent Suspected Adverse Events findings, whether carried within the MHRA or via any other source, please provide details of these and any actions taken by the MHRA.*
> *[1] Schmeling M, Manniche V, Hansen PR. Batch- dependent safety of the BNT162b2 mRNA COVID- 19 vaccine. Eur J Clin Invest. 2023;00:e13998. doi:10.1111/eci.13998*

The Agency responded to your request on 8 August 2023 as follows:

> *FOI 23/507*
> *Thank you for your email of 6 July 2023 regarding the research letter entitled 'Batch-dependent safety of the BNT162b2 mRNA COVID-19 vaccine' by Schmeling and colleagues where you where you requested the following:*
> *1. Assuming the MHRA are aware of Schmelling et al., 2023 and the conclusion drawn that "the results suggest the existence of a batch-dependent safety signal for the BNT162b2 vaccine, and more studies are warranted to explore this preliminary observation and its consequences," please provide a copy of all internal and external communications relating to this topic and any actions taken by the MHRA as a result of becoming aware of it.*
> *2. If the MHRA are aware of any similar batch-dependent Suspected Adverse Events findings, whether carried within the MHRA or via any other source, please provide details of these and any actions taken by the MHRA.*
> *The MHRA's ongoing safety monitoring of COVID-19 vaccines has not identified any batch related safety concerns and no regulatory action has been taken for individual batches of these vaccines. Therefore, the MHRA does not hold the information requested.*
> *The safety of COVID-19 vaccines is continuously monitored; should a new safety issue be confirmed we will act promptly to inform patients and healthcare professionals and take appropriate steps to mitigate any identified risk and protect public health.*

On 12 September 2023, you sought a review of this response:

> *Dear Medicines and Healthcare Products Regulatory Agency,*
> *Please pass this on to the person who conducts Freedom of Information reviews.*
> *I am writing to request an internal review of Medicines and Healthcare Products Regulatory Agency's handling of my FOI request 'Communications and Actions following Batch Specific Safety Signals'.*
> *The MHRA has not responded to the request, whereby it is asked for any internal or external communications regarding its knowledge of batch-dependent safety signals. The request was not to determine if the MHRA has identified batch related safety concerns via its ongoing safety monitoring of COVID-19 vaccines. (However, this*
> *does raise an important question and a new question will be introduced today regarding this topic.) In relation to this internal review, however, please determine whether the MHRA has responded adequately to points 1 and 2 raised in the initial request (FOI 23/507) as it appears it has not.*
> *A complete history of my FOI request and all correspondence is available on the Internet at this address: https://www.whatdotheyknow.com/request/c...*
> *Issues on review*

The internal review considered:
· Whether the MHRA adequately answered the request regarding any internal or external correspondence relating to the issue
· Whether the MHRA adequately disclosed any actions relating to the issue
· Whether the MHRA was aware of other batch related issues and provision of details of these issues and any MHRA actions

Consideration of the issues
I will address each of these points in turn:

With respect to the disclosure of all MHRA internal and external correspondence relating to the topic, it was unclear what “the topic” was in the request as this could have been interpreted as relating to either the Schmelling et al publication or the topic of batch related safety signals for the vaccine. The request also relied upon a number of assumptions of the MHRAs knowledge which also made interpretation of the request difficult.

In accordance with section 1 (3) of the FOIA, the MHRA could have requested clarity on the request asking for our “awareness” of the publication and batch related issues, as this is not in itself a request for information and might have allowed the MHRA to provide a more refined answer for the enquirer, and clarity could also have been sought on what the main topic in question was in the request so that the relevant data could be provided

However, the MHRA response has been accurate in stating that there were no actions taken with respect to batch issues of the type you refer to, as no internal or regulatory actions have been taken with respect to batch specific safety concerns. Therefore the MHRA does not hold information on actions in respect of batch-dependant safety issues.

The MHRA could have been helpful in provided more context for the response, noting that our analysis of the batch data takes into account that not all batches of the COVID-19 vaccines are the same size, and some batches may have had more wastage than other batches or be distributed more widely outside of the UK, along with a variety of other factors that might impact reporting rates with different batches.

3. Conclusions
This internal review has identified that the original response lack clarity on what the exact topic was that the request related to. There could have been a request made for more refinement on what was meant by “awareness” in the request and also what the main topic of interest was as this is open to interpretation. This would have allowed the MHRA to understand the scope of the request and provide a response in line with this.

Broadly the MHRA has responded adequately to the request for information on any actions the MHRA has taken in relation to batch related safety concerns, in that there was no relevant information to disclose. However, the MHRA could have provided helpful context as to how batch related safety data is analysed.

I also note that you have submitted a further FOI (FOI 23/672) regarding the MHRAs signal detection processes for batch related safety concerns, which you alluded to in your request for internal review on 12 September 2023.

I hope that this review is useful for you and has further explained our position on the information you requested.

I would invite you to provide a more refined request for information in line with the advice outlined above so that we can fully understand the request being made.

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

Medicines and Healthcare products Regulatory Agency