Medicines & Healthcare products Regulatory Agency

D Jackson
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MHRA
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Canary Wharf
London
E14 4PU
United Kingdom

www.gov.uk/mhra

11th August 2022

MHRA reference: FOI 22/021 internal review

Dear Mr Jackson,

Firstly, I'd like to apologise for the length of time it has taken to provide a response to you. 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 ([22/021]).

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).

Your original request and the Agency's response are annexed.

On 9th February 2022, you stated in your request for this review:

" Please provide the following in relation to COVID 19 vaccines:

Procedures and policies relevant to the investigation of adverse reactions reported to the MHRA."

This question is relevant to workplace procedures and policies. However, no documents of this type have been provided. The links I have been referred to provide higher level descriptions of a broader process.

Such workplace documentation might contain, for example: responsibilities, reporting requirements, sign off's required, documentation to be completed, data handling policies, policies on contacting companies, patients, relatives etc.

In relation to my second question:

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"Templates used for reporting adverse reaction data and investigations of adverse reactions to stakeholders."

This has been more broadly interpreted as "how the MHRA communicates with stakeholders". Does the MHRA use any document templates e.g. Excel, Word, Powerpoint, database reports etc. to provide reporting in a standard format to stakeholders? If so, please provide those templates.

Please conduct an internal review of my request as I do not think I have received all of the information I have requested.

Following consideration, I have concluded that the Agency, whilst acting in good faith, did not respond to the request in full. We apologise for this and have now reconsidered our position. In response to the first part of your request, please find attached a document titled 'Monitoring and signal detection activities for ADR reports concerning the COVID 19 vaccine – June 2022' which reflects our current approach to these cases.

In response to the second part of your request, I can confirm that we don't hold any templates used for reporting adverse reaction data and investigations of adverse reactions to stakeholders. The only 'template' we have is the Yellow Card reporting form which is available at the following link: https://coronavirus yellowcard.mhra.gov.uk/

I hope you are content with this response. However, 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

MHRA FOI team

Medicines and Healthcare products Regulatory Agency

Medicines & Healthcare products Regulatory Agency

Annex: background correspondence

Original FOI:

Dear MHRA,

Please provide the following in relation to COVID 19 vaccines:

Procedures and policies relevant to the investigation of adverse reactions reported to the MHRA.

Templates used for reporting adverse reaction data and investigations of adverse reactions to stakeholders.

Yours faithfully,

D Jackson

We responded:

Dear D Jackson,

FOI 22/021 COVID 19 Adverse Reaction procedures, policies and templates

Thank you for your Freedom of Information request dated 6th January, where you asked for information on the following:

Please provide the following in relation to COVID 19 vaccines:
Procedures and policies relevant to the investigation of adverse reactions reported to the MHRA.
Templates used for reporting adverse reaction data and investigations of adverse reactions to stakeholders.

As with any vaccine or medicine, COVID 19 vaccines require continuous safety monitoring to ensure that the benefits in protecting people against COVID 19 outweigh any side effects or potential risks. Further information, specifically relating to the safety monitoring process for COVID 19 vaccines is outlined the COVID 19 Vaccine Surveillance Strategy. Please follow this link to the document: https://www.gov.uk/government/publications/report of the commission on human medicines expert working group on covid 19 vaccine safety surveillance/report of the commission on human medicines expert working group on covid 19 vaccine safety surveillance

Information on how the MHRA monitors the safety of all medicines and vaccines can be found via the following link. As described in the link, investigation of adverse drug reaction (ADR) reports, known as signal detection, is performed using specialised software. This software analyses all drug reaction combinations on the MHRA's database to identify

combinations that occur more frequently than would be expected compared to background rates. ‘Signals’ that meet defined criteria are then assessed by a multidisciplinary team of experts to determine the likelihood of a causal relationship between the drug and the reaction, and to determine if regulatory action is appropriate.

With regards to your second question, on how the MHRA communicates with stakeholders, this is also addressed in the second link provided above “How the MHRA monitors the safety of medicines”. As the document describes, where a new harm is identified, or new information about an existing side effect comes to light, the product information will be amended accordingly. Changes may also be communicated via the Drug Safety Update to alert clinicians of the new information: https://www.gov.uk/drug safety update.
With regards to communication specifically related to COVID 19 vaccine matters, you may already be aware that we are publishing a weekly summary of Yellow Card reporting which is available here: https://www.gov.uk/government/publications/coronavirus covid 19 vaccine adverse reactions/coronavirus vaccine summary of yellow card reporting

I hope the information provided is helpful.

If you are dissatisfied with the handling of your request, you have the right to ask for an internal review. Internal review requests should be submitted within two months of the date of this response; and can be addressed to this email address.

Yours sincerely,

FOI Team,

Vigilance and Risk Management of Medicines Division