Medicines & Healthcare products Regulatory Agency

MHRA
Regulating Medicines and Medical Devices

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MHRA

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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