GOV.UK

FOI release

Freedom of Information request on Yellow Card data relating to COVID-19 vaccinations (FOI 21/1109)

Published 26 May 2022

This publication is available at https://www.gov.uk/government/publications/freedom-of-information-responses-from-the-mhra-week-commencing-1-november-2021/freedom-of-information-request-on-yellow-card-data-relating-to-covid-19-vaccinations-foi-211109

FOI 21/1109

3rd November 2021

Dear,

Thank you for your email correspondence received on 9th August 2021 requesting information on Yellow Card data relating to COVID-19 vaccinations. You will have received a response from our colleagues on 11th October detailing that some of your request has been logged as a Freedom of Information (FOI) request.

Under the FOI act, we will be responding to the below questions from your correspondence:

1. For how many of these 1,490 deaths does MHRA have permission to follow up and how many has MHRA followed up?
2. For how many of these 1,490 deaths does MHRA have the date of vaccination and date of death or date of onset of the event leading to death?
3. Please could you provide a copy of the MHRA's SOP for monitoring COVID-19 vaccine suspected ADRs, and indicate how follow-up of deaths and, if done, other AESIs, is conducted and in what timeframes?
4. Please provide a report on the investigations performed and results obtained under these pharmacovigilance plans to monitor VAED and VAERD in Pfizer and AstraZeneca Vaccines.
5. Have Pfizer and AstraZeneca provided further information on VAED and VAERD?
6. Please can you confirm that each of these yellow card reports of individuals with post vaccination myocarditis and pericarditis have been followed up and for how long?
7. In addition, please can you confirm how many of these individuals have recovered fully and the status of those who have not fully recovered?
8. The most common cause of sudden death is a cardiovascular event. Have these deaths with unspecified reason been followed up to establish the likely cause?
9. Since drawing these unusual reports to the attention of the MHRA, have these individuals been followed up?
10. For how many of these 1,490 deaths does MHRA have permission to follow up and how many has MHRA followed up?

To submit a Yellow Card report, we require certain personal information. We ask for the reporter's name and contact details so that we can get in touch if we need more information on their case. This information is outlined in our Privacy Policy which can be viewed via this link Yellow Card Scheme - MHRA. Therefore, the MHRA does not need to seek permission to follow up once a report has been submitted.

Although we hold information on whether a Yellow Card report has been followed up, this information is not easily extractable and therefore the requests for information within your correspondence would fall under Section 12 of the FOI Act. Section 12 of the FOI Act specifies that a public authority may refuse requests where the cost of dealing with the request would exceed the appropriate limit, which for central government is set at £600. This represents the estimated cost of one person spending 24 working hours in determining whether the department holds the information, locating, retrieving, and extracting the information. We consider that extracting the number of fatal reports that have been followed up will take longer than 24 working hours to complete.

It is important to note that as with any serious suspected ADR, reports with a fatal outcome are fully evaluated by the MHRA to consider whether the medicine or vaccine may have caused the event or whether the event and fatal outcome were likely to be purely coincidental and due to underlying illness. To ensure the comprehensive assessment of fatal reports, we follow-up all fatalities which contain missing information that would aid MHRA assessment where permission has been provided to do so for further information.

1. For how many of these 1,490 deaths does MHRA have the date of vaccination and date of death or date of onset of the event leading to death?

Although date of vaccination, date of death or reaction start date (onset) are fields within the Yellow Card form, they are not mandatory fields. Therefore, this information is not always provided by the reporter and any data provided will be incomplete when looking at the number of reports received. We can confirm that as of 13th October 2021 the MHRA have received 1,684 reports with a fatal outcome. Of these 1,684 fatal reports, 1,438 reports have provided vaccination date and 1,582 have provided a date of death or reaction start date for the reaction leading to a fatal outcome. Please be assured that any additional information received via follow up information or post-mortem reports, relating to the date of death are included for full assessment.

1. Please could you provide a copy of the MHRA's SOP for monitoring COVID-19 vaccine suspected ADRs, and indicate how follow-up of deaths and, if done, other AESIs, is conducted and in what timeframes?

The safety monitoring processes used by the MHRA do not differ according to whether the vaccine is for emergency use or under normal approval, although for COVID-19 vaccines we have outlined a specific surveillance strategy in light of the large numbers of people being vaccinated over a short space of time, the COVID-19 Vaccine Surveillance Strategy. Information about on MHRA processes for monitoring the safety of medicines and vaccines is available at Yellow Card Scheme - MHRA. Guidance on pharmacovigilance procedures operated by the MHRA in accordance with current Regulations is available at Guidance on pharmacovigilance procedures - GOV.UK (www.gov.uk).

The MHRA endeavour to follow up all Yellow Card reports relating to AESIs or fatal outcomes as soon as possible following receipt.

1. Please provide a report on the investigations performed and results obtained under these pharmacovigilance plans to monitor VAED and VAERD in Pfizer and AstraZeneca Vaccines.

In response to your request for analysis of the data in relation to vaccine associated enhanced disease (VAED) and vaccine associated enhanced respiratory disease (VAERD), VAED and VAERD are an identified potential risk for both Pfizer and AstraZeneca COVID-19 vaccines and are therefore kept under close review. We can confirm that no new concerns about VAED and VAERD have been identified from the ongoing monitoring of this potential risk to date. Analysis of Yellow Card data, as

well as data from other sources, is an ongoing process as evidence is accumulated, including effects associated with VAED and VAERD with the use of the Pfizer and AstraZeneca vaccines. We can confirm that our ongoing assessment of cases has not identified a link to disease enhancement. Should any new concerns be identified about the potential risk of VAED and VAERD, these would be documented and taken to the Vaccine Benefit-Risk Expert Advisory Group for independent advice.

1. Have Pfizer and AstraZeneca provided further information on VAED and VAERD?

The MHRA receive regular information from all companies that hold an authorisation for a COVID-19 vaccine with regards to the ongoing safety monitoring of these products. This information includes Summary Safety Reports provided by the companies which include an overview of data on AESIs and safety concerns including VAED and VAERD. The MHRA meet regularly with companies to discuss any issues of concern or potential issues and have not identified any new signals from ongoing discussions.

1. Please can you confirm that each of these yellow card reports of individuals with post vaccination myocarditis and pericarditis have been followed up and for how long?

As mentioned above, the MHRA endeavour to follow up all Yellow Card reports relating to AESIs or fatal outcomes as soon as possible following receipt. As per question 1, although we hold information on whether a Yellow Card report has been followed up, this information is not easily extractable and therefore the requests for information within your correspondence would fall under Section 12 of the FOI Act. We consider that extracting the number of reports that have been followed up will take longer than 24 working hours to complete. We can confirm that current processes mean that all cases of myocarditis and pericarditis in young adults are followed up. In addition to this we have made some technical updates to our online and App Yellow Card forms to include more extensive questions to include details that would assist with the assessment of these reports, specifically when a reporter selects myocarditis or pericarditis as a suspected adverse drug reaction (ADR). This is to ensure relevant information for assessment is collected within the initial report submission to reduce the chance of missing information that might require retrospective follow up.

1. In addition, please can you confirm how many of these individuals have recovered fully and the status of those who have not fully recovered?

The MHRA has undertaken a thorough review of both UK and international reports of suspected myocarditis and pericarditis following vaccination against COVID-19. These reports are extremely rare, and the events are typically mild with individuals usually recovering within a short time with standard treatment and rest.

For information on the number of patients who have recovered fully and the status of those who have not fully recovered, we can confirm that we hold this information however as we intend to publish the data we consider that your request is covered by Section 22 of the Freedom of Information Act (information intended for future publication) and the information you have asked for is therefore exempt from disclosure. Section 22 is a qualified exemption which means we have considered whether there is a greater public interest in releasing the information requested or withholding it. We recognise there is strong interest in seeing this data and accept it should not be withheld however wish to publish this information alongside appropriate context and assessment.

1. The most common cause of sudden death is a cardiovascular event. Have these deaths with unspecified reason been followed up to establish the likely cause?

Although we hold information relating to follow up for reports of death unexplained, this information is not easily extractable and therefore the requests for information within your correspondence would fall under Section 12 of the FOI Act. We consider that extracting the number of reports that have been followed up for reports of death with unspecified reason will take longer than 24 working hours to complete. It is important to note the MHRA routinely follows up on all fatal cases which are reported through the Yellow Card scheme, and if a post-mortem is not provided then this request for the information is made where appropriate.

1. Since drawing these unusual reports to the attention of the MHRA, have these individuals been followed up?

We can confirm that the reports that you have highlighted have already been reviewed and continue to be part of our ongoing review and assessment process. As we have mentioned, the MHRA takes all reports of adverse reactions with the utmost seriousness, including those reporting fatal events in patients who have received a COVID-19 vaccine. Where these events are reported to us, we follow up to find out full details of the events and the cause of death and, where applicable, further information of any post-mortem findings. We also monitor deaths rates over time and the information is thoroughly analysed for patterns or evidence which might suggest a causal link between the vaccination and the death. We can confirm that our follow up approach for reports with a fatal outcome has not changed since the start of the vaccination campaign and all reports are followed up as described.

I hope the information provided is helpful, but 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