Medicines & Healthcare products Regulatory Agency

MHRA
Regulating Medicines and Medical Devices

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16 June 2023

FOI 22/1079

Dear Elizabeth Evans,

Thank you for your email of 31 October 2022 concerning our response to FOI 22/794. We are sorry to hear that you were not satisfied with our response. Please accept our apologies for the long delay in responding to your request.

In your further request you asked the following:

1) The specific criteria that [MHRA] have set which will trigger a formal epidemiological study, in the context of COVID-19 vaccine safety monitoring.
2) Any and all documents, emails, or minutes of meetings referring to rapid cycle analysis in the context of COVID-19 safety monitoring.
3) Any and all documents, emails, or minutes of meetings referring to targeted active monitoring in the context of COVID-19 safety
4) Any and all documents, emails, or minutes of meetings that you relied upon to decide how many of these fatal outcomes were caused by a COVID-19 vaccine.
5) The criteria that [MHRA] have set, regarding the number of reported COVID-19 vaccine-associated deaths to the Yellow Card system, that would prompt you to call for a halt of the COVID-19 vaccination program

The MHRA does hold some of the information requested. However, we have also determined that the information is exempt under Section 12 of the Freedom of Information Act and we cannot process these requests further without refinement. Section 12 of the Act allows public authorities to refuse requests where the cost of dealing with them 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. The following requests would require the use of a Discovery Search Tool. Based on experience in using this tool to perform Agency-wide searches for information, the time taken to set up and refine the search criteria then extract and review the results to identify relevant records would take in excess of 24 hours:

2) Any and all documents, emails, or minutes of meetings referring to rapid cycle analysis in the context of COVID-19 safety monitoring.
3) Any and all documents, emails, or minutes of meetings referring to targeted active monitoring in the context of COVID-19 safety.

Regarding question 1, there is no set criteria which would trigger a formal epidemiological study to investigate a safety concern with a COVID-19 vaccine, therefore the information is not held. However, as stated in the Report of the CHM Expert Working Group on COVID-19 vaccine Safety Surveillance, '*[epidemiological studies] will be undertaken on an ad hoc basis should the need arise based on other vigilance activities.'* Considerations for whether an epidemiological study will be undertaken by the MHRA include whether a signal has been suggested by spontaneous reporting or enhanced passive surveillance (eg observed versus expected analysis or rapid cycle analysis), feasibility for MHRA to conduct an epidemiological analysis for the safety concern (based on whether and how the outcome may be captured in healthcare records data available to MHRA), and whether a study is already being undertaken by another regulator or other organisation.

The MHRA also does not hold the information requested in question 4. While the MHRA carefully assesses Yellow Card reports with a fatal outcome to determine whether additional information is required to facilitate assessment of the link between a medicine and the reported adverse event, we do not assign causality (i.e. whether the patient's death was caused by the vaccine) at the level of individual reports. MHRA considers data from Yellow Card reports, along with relevant information from other sources in their overall assessment of whether there may be a causal link between a medicinal product and an adverse event. Should a new link between a medicine and a safety concern be confirmed, the MHRA will take regulatory action, such as updating product information to include a warning for patients and healthcare professionals.

Regarding question 5, please note that while the MHRA is the UK medicines regulator, responsible for ensuring that all medicinal products meet acceptable standards of quality, safety and efficacy at the time of first authorisation and thereafter through continued monitoring, decisions about vaccination policy are not within the MHRA's remit.

For a vaccine to be considered acceptably safe, the benefits, or expected benefits must be greater than the risks of known harmful reactions. It is important to note that most people receive vaccinations without having any serious side effects.

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,

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If you have a query about this email, please contact us. If you are unhappy with our decision, you may ask for it to be reviewed. That review will be undertaken by a senior member of the agency who has not previously been involved in your request. If you wish to pursue that option, please write to the Communications Directorate, 4-T, Medicines and Healthcare products Regulatory Agency (via this email address). After that, if you remain dissatisfied, you may ask the Information Commissioner at:

The Information Commissioner's Office
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