Medicines & Healthcare products Regulatory Agency

MHRA
Regulating Medicines and Medical Devices

[redacted]

MHRA

10 South Colonnade
Canary Wharf
London
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United Kingdom

www.gov.uk/mhra

20 March 2024

Dear [redacted]

RE: FOI 24/203

Thank you for your information request, dated 21 February 2024, where you asked for information on COVID-19 vaccines and deaths. Please find responses below:

1. *How many deaths has MHRA ruled to be caused by the mRNA covid-19 vaccines?*
2. *How many deaths has MHRA ruled to be caused by the adenovirus-vector vaccines?*

The MHRA does not hold information on the number of patients that have a COVID-19 vaccine listed as a cause of death on their death certificate, as this falls outside of our remit. The MHRA does not determine causality of individual reports, and this includes reports of fatalities. You may wish to contact the Office for National Statistics (ONS) here FOI.Team@ons.gov.uk as they may hold this information.

The MHRA holds information on suspected adverse reactions and runs the Yellow Card scheme, which collects and monitors information on suspected safety concerns involving healthcare products. The scheme relies on voluntary reporting from the public as well as from healthcare professionals. There are also legal requirements for pharmaceutical companies to report to us. Reports of adverse reactions to COVID-19 vaccines can be found via COVID-19 vaccine reports published on the Yellow Card website. The reports contain interactive graphs and tables designed so users can filter the data to view the information that is of most interest to them.

3. *How many autopsies were carried out on the reported deaths in the Yellow card system?*

The MHRA does not hold this information. Whilst we request a copy of the postmortem findings if one has been performed, these are not always provided, and we would only be

aware of these if a Yellow Card is reported to us. Coroners are encouraged to report to us if they consider a medicinal product was a contributing factor to the death of a patient, but this is not a mandatory requirement.

In addition, there is no specific flag within our systems that highlights when such information has been received. Retrieving such information would require a manual review of every report with a fatal outcome, which based on previous sampling exercises would fall under the scope of Section 12 (1) of the FOIA.

4. *How many deaths linked to the vaccines are still under investigation?*

In order to respond to this part of your request we would require some clarification as it is unclear if you are referring to assessments carried out by the MHRA on adverse reaction reports received, or investigations into deaths carried out by coroners. As above, the MHRA does not hold information on investigations by coroners.

If you are referring to assessments made by the MHRA, it is important to be aware that while Yellow Card reports with a fatal outcome are reviewed by MHRA assessors to determine which additional information will be requested from the reporter, in the assessment of a safety issue, Yellow Card reports are evaluated cumulatively, alongside other information and evidence. Causality is not assigned to individual reports, nor is an assessment recorded for individual reports. All the information is assessed on a continual basis to see whether a new side effect is identified, or the safety profile has changed. In addition, we also apply statistical techniques which can tell us if we are seeing disproportionately more cases than we would expect to see based on what is known about background rates of illness in the absence of vaccination. If it is considered that a medicine may be causing the side effect, we will look at the risk of the side effects in relation to its benefits to consider whether regulatory action is needed.

Further information on past analysis of reports with a fatal outcome and specific safety topics can be found in our now archived Coronavirus vaccine - summary of Yellow Card reporting - GOV.UK (www.gov.uk).

5. *How many deaths linked to the vaccine have completed investigations?*

Please see response to question 4.

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,

Medicines & Healthcare products Regulatory Agency

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Regulating Medicines and Medical Devices

FOI Team,
Safety and Surveillance

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If you have a query about the information provided, please reply to this email

Please remember to quote the reference number above in any future communications.

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