Medicines & Healthcare products
Regulatory Agency

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[redacted]

4 April 2024

FOI 24/233

Dear [redacted],

Thank you for your Freedom of Information (FOI) request dated 06 March 2024 where you asked,

"I would like to request the data/statistics that show how many people have died shortly after a vaccine or booster, say within 48 hours of having one of the vaccines. I cannot see this data anywhere. I have asked the ONS and NHS however, I have been directed to you as you are the ones who hold the information."

The MHRA does not hold the complete information on patients who have died shortly after a vaccine or booster, or within 48 hours of having one of the vaccines. However, in accordance with Section 16 of the FOIA, concerning the provision of advice and assistance to those requesting information under FOI we have provided some further information below which you may find useful.

Whilst we cannot provide the complete information on the number of patients who have died shortly after a vaccine or booster, we can provide information around suspected side effects to the COVID-19 vaccines, along with their outcomes, that have been reported to us via the Yellow Card scheme.

The MHRA runs the Yellow Card scheme, which collects and monitors information on suspected safety concerns involving healthcare products, like a side effect with a medicine or an adverse medical device incident. The scheme relies on voluntary reporting of problems to a healthcare product by the public (including patients, parents, and carer givers) as well as from healthcare professionals. There is also a legal obligation for pharmaceutical companies to report to us.

Whilst anyone can report their suspicions of a safety concern or incident, a reported reaction does not necessarily mean it has been caused by the vaccine, only that the reporter had a suspicion it may have. The number of reports received via the Yellow

Card scheme does not directly equate to the number of people who suffer adverse reactions and therefore cannot be used to determine the incidence of a particular side effect or outcome.

For patients that have a COVID-19 vaccine listed as a cause of death on their death certificate, we do believe that the Office for National Statistics (ONS) may hold this information and can be contacted here FOI.Team@ons.gov.uk as you might be aware.

I can confirm that the MHRA have received 2,655 spontaneous suspected Adverse Drug Reaction (ADR) reports with a fatal outcome, in association with all COVID-19 vaccines between 01/01/2021 to 28/02/2024. I can confirm that of these reports, 450 reported the onset time of the adverse drug reaction that was considered to cause the fatality, to be within 48 hours of vaccine administration. It is important to note that vaccine administration dates and reaction dates are not mandatory fields, therefore this information is not always provided by the reporter.

Vaccination and surveillance of large populations means that, by chance, some people will experience and report a new illness or events, sadly including deaths in the days and weeks after vaccination. Usage of the COVID-19 vaccines has increased over the course of the vaccine campaigns and as such, so has reporting of fatal events with a temporal association with vaccination. However, an ADR report associated with a fatal outcome does not mean that the vaccine caused the death of the individual. The MHRA do not determine causality of individual reports, and this includes reports of fatalities.

When considering Yellow Card data, it is important to be aware of the following points:

- A reported reaction does not necessarily mean it has been caused by the vaccine, only that the reporter had a suspicion it may have. Each year, millions of doses of vaccinations are given in the UK alone, and when any vaccine is administered to large numbers of people, some recipients will inevitably experience illness following vaccination. The fact that symptoms occur after use of a vaccine or medicine, and are reported via the Yellow Card Scheme, does not in itself mean that they are proven to have been caused by it. Underlying or concurrent illnesses may be responsible and such events can also be coincidental.

- It is important to note that the number of reports received via the Yellow Card scheme does not directly equate to the number of people who suffer adverse reactions and therefore cannot be used to determine the incidence of a reaction or compare the safety profile of different vaccines. ADR reporting rates are influenced by the seriousness of ADRs, their ease of recognition, the extent of use of a particular medicine, and may be stimulated by promotion and publicity about a drug. Reporting tends to be highest for newly introduced

medicines during the first one to two years on the market and then falls over time.

You may be interested to know that the MHRA have published the ADR data we hold for the COVID-19 vaccines in the form of interactive Drug Analysis Profiles (iDAPs) which can be accessed by following the link https://yellowcard.mhra.gov.uk/idaps. These iDAPs provide a summary of the all the adverse reactions that have been reported in associated with COVID-19 vaccines and list the number of fatal reports. Please note the most recent COVID-19 vaccine in use are not currently published but will be shortly. It is important to note that this information does not represent an overview of the potential side effects associated with the vaccines therefore the product information should be reviewed for each vaccine for this information.

I hope the information provided is helpful.

Yours sincerely,

FOI Team,
Safety and Surveillance Group

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, 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 Wycliffe House
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