Medicines & Healthcare products Regulatory Agency

[redacted]

**MHRA**
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27th February 2024

**Our Ref: FOI 24/098**

Dear [redacted]

Thank you for your Freedom of Information (FOI) request dated 30th January 2024, where you requested:

- "*how many patients that had the Pfizer jab for COVID inc boosters the deaths since and causes.*"

Firstly, I feel it may be beneficial to provide some further context on the Yellow Card scheme. The Yellow Card Scheme is the UK system for collecting and monitoring information on suspected Adverse Drug Reactions (ADRs) and incidents in association with medicines, vaccines and medical devices. The Scheme is run by the Medicines and Healthcare products Regulatory Agency (MHRA) on behalf of the Commission on Human Medicines (CHM), and currently relies on voluntary reporting of suspected ADRs by health professionals and patients. It's vital to note that Yellow Card reports are made based on suspicion and are therefore not conclusive evidence that the medicine or vaccine caused the suspected reaction(s).

Please also be aware that the MHRA does not hold information on the number of patients that have Pfizer COVID-19 vaccines listed as a cause of death, as this falls outside of our remit. If you are interested in this information, I would advise you to contact the Office for National Statistics (ONS): Contact us - Office for National Statistics (ons.gov.uk).

We do hold data regarding suspected adverse reactions reported via the Yellow Card scheme for the Pfizer monovalent and bivalent COVID-19 vaccines. However, this data is exempt from release under Section 21 of the FOIA (Information accessible by other means), as this is already publicly available and can be found on our website via our COVID-19 Vaccine Reports, which allow users to view all adverse reactions reported for a particular vaccine. These reports can be filtered to display subsets of the data, such as those with a fatal outcome. Unfortunately, the Pfizer omicron booster vaccine is currently not available to view, but information on this and other booster vaccines will be available in the near future.

Therefore, we have conducted a search of our database for all fatal Pfizer COVID-19 omicron Adverse Drug Reaction (ADR) reports, as these are not currently published as part of our iDAPs. I can confirm that the MHRA have received a total of **18** UK spontaneous suspected ADR reports concerning Comirnaty Omicron XBB.1.5 or Comirnaty Original/Omicron BA.4-5 (available Pfizer omicron boosters) with a fatal outcome, up to and including 23rd February 2024.

Please find the attached Vaccine Analysis Print (VAP) for details of the reported reactions. The right-hand column also highlights the fatal terms included in each report for your reference. Please note that the total number of reactions in the table will not be equal to the total number of unique reports as one report may contain more than one reaction. The enclosed information sheet will also provide you with guidelines on how to interpret the VAP.

When considering the attached spontaneous adverse drug reaction (ADR) data, it is important to be aware of the following points:

- Reporters are asked to submit Yellow Card reports even if they only have a suspicion that the vaccine may have caused the adverse reaction. The existence of an adverse reaction report does not necessarily mean that the vaccine has caused the reaction.
- It may be difficult to tell the difference between something that has occurred naturally and an adverse reaction. Sometimes reactions can be part of the condition being treated rather than being caused by the vaccine.
- Many factors have to be considered when assessing whether a vaccine has caused a reported adverse reaction. When monitoring the safety of medicines and vaccines, MHRA staff carry out careful analysis of these factors.
- It is not possible to compare the safety of different vaccines by comparing the numbers presented in the vaccine reports. Reporting rates can be influenced by many factors including the seriousness of the adverse reactions, their ease of recognition and the extent of use of a particular vaccine. Reporting can also be stimulated by promotion and publicity about a product.

It is important to note that the VAP provided should not be used as a list of side effects to the available Pfizer COVID-19 vaccines. All established undesirable effects for these vaccines can be found listed in section 4.8 of the Summary of Product Characteristics (SmPC) and section 4 of the Patient Information Leaflet (PIL). Please see the following link for your reference: Product Information | Coronavirus (COVID-19) (mhra.gov.uk).

Furthermore, please be assured that the MHRA continuously monitors the safety of vaccines through a variety of pharmacovigilance processes including the Yellow Card scheme. As part of our signal detection processes all adverse reaction reports received by the Yellow Card scheme are assessed and cumulative information reviewed at regular intervals. Vaccines encompass a wide variety of products with different indications, different ingredients and different mechanisms of action and as such safety for each vaccine is considered individually rather than as a group.

Unfortunately, vaccination and surveillance of large populations means that, by chance, some people will experience and report a new illness or events in the days and weeks after vaccination. A high proportion of people vaccinated early in the vaccination campaign were very elderly, and/or had pre-existing medical conditions. Older age and chronic underlying illnesses make it more likely that coincidental adverse events including those with a fatal outcome will occur, especially given the millions of people vaccinated. The current UK guidance remains that the benefits outweigh the risks for the available COVID-19 vaccines.

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,
Safety and Surveillance Group

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