Medicines & Healthcare products Regulatory Agency

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[redacted]

28th March 2024

Our Ref: FOI 24/217

Dear [redacted]

Thank you for your Freedom of Information request dated 1st March 2024, where you requested details of all Yellow Card reports concerning COVID-19 vaccinations for Guernsey in the Channel Islands, including the number of fatalities.

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 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).

Further to your query, we have conducted a search of our database for all ADR reports for the available COVID-19 vaccines, where the reporter postal code is in Guernsey (GY-). I can confirm that the MHRA have received a total of **426** spontaneous suspected ADR reports relating to a COVID-19 vaccine from Guernsey, up to and including 19th March 2024. A total of **8** reports include a fatal outcome. Please find the attached Vaccine Analysis Print (VAP) for details of the reported reactions to this vaccine, as well as the enclosed information sheet for guidelines on how to interpret the VAP. More information relating to the fatal reports can also be found within right-hand column of the Vaccine Analysis Print (VAP). 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.

It is also important to note that the data included within this FOI response has been extracted based on reporter postal code. Therefore, the accuracy of this data relies on the postcode being correctly provided by the reporter in the original Yellow Card. The provision of postal addresses is not required to submit a valid report; reporters are required only to provide a contactable address which can be either an email address or postal address. If reporters only provided an email address, these will not have been included in this analysis. As the data has been extracted using available postal addresses only, it may not reflect the true incidence of reporting following COVID-19 vaccinations from Guernsey.

Furthermore, please see Figure 1 below which shows the number of ADR reports concerning the available COVID-19 vaccines from Guernsey, broken down by the respective patient age group. To note, patient age is not a mandatory field when submitting a Yellow Card report. The MHRA requires only one patient identifier to be present in order for a report to be deemed valid. This can include patient age, patient sex and patient initials. Please also see Figure 2 which shows the number of reports received each year broken down by quarter.

Figure 1: All UK spontaneous suspected ADR reports relating to a COVID-19 vaccine and a reporter postal code in Guernsey, up to and including 19/03/2024, broken down by patient age group.

Age Group	Number of Reports
1-10	1
11-20	14
21-30	59
31-40	79
41-50	75
51-60	76
61-70	44
71-80	24
81-90	10
91-100	4
Unknown	40

Figure 2: All UK spontaneous suspected ADR reports relating to a COVID-19 vaccineand a reporter postal code in Guernsey, up to and including 19/03/2024, broken down by year and quarter received.

Year	Quarter	Number of Reports
2020	Q4	4
2021	Q1	94
	Q2	101
	Q3	102
	Q4	63
2022	Q1	30
	Q2	6
	Q3	3
	Q4	12
2023	Q1	1
	Q2	1
	Q3	2

	Q4	5
2024	Q1	2

When considering the attached spontaneous ADR 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 been. Each year, millions of doses of routine 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 also 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. ADR reporting rates are influenced by the seriousness of ADRs, their ease of recognition, the extent of use of a particular vaccine, and may be stimulated by promotion and publicity about a vaccine. Reporting tends to be highest for newly introduced medicines during the first one to two years on the market and then falls over time. For these reasons the enclosed data should not be used as a basis for determining incidence of side effects.

Please be aware that the VAP provided should not be used as a list of side effects to the available COVID-19 vaccines, nor should this data to be used to estimate the frequency of side effects or to compare the safety profile of different vaccines. All established undesirable effects for the available COVID-19 vaccines can be found in the Summary of Product Characteristics (SmPC) for healthcare professionals and the Patient Information leaflet (PIL), both of which can be found on the MHRA products website.

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

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
Wycliffe House
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