FOI 23/001

1st February 2023

Dear

Yellow Card reports for COVID-19 vaccines for Guernsey

Thank you for your email dated 2nd January 2023, where you asked for information on the following:

• All Yellow card reports from COVID-19 Vaccinations for Guernsey in the Channel Islands

• The number of suspected fatalities, in addition to the type of adverse reaction. Any other data you may have (i.e., age demographic, date reported etc.) would be much appreciated.

As you are aware from previous FOIs, the MHRA works closely with the UK devolved administrations as well as the governments of the Channel Islands. All individuals receiving a vaccine are encouraged to report side effects to COVID-19 vaccines to the Yellow Card Scheme by the governments in these territories.

Following a search of our database up to and including 11th January 2023, I can confirm that the MHRA have received 415 spontaneous suspected Adverse Drug Reaction (ADR) reports associated with COVID-19 vaccinations reported from Guernsey. Further to your request, of these 415 reports, 8 reports concern a fatal outcome suspected to be associated with the COVID-19 vaccine administration.

The accuracy of this data relies on the postcode being correctly provided by the reporter in the original Yellow Card. Additionally, the provision of postal addresses is not required to submit a report; reporters are required only to provide a contactable address which can be either an email address or postal address. If reporters only provide an email address, these will not have been included in this analysis.

Since your previous response we have made changes to the way in which we provide data on spontaneous ADR reports. We implemented changes in policy which further strengthens our duty to protect patients and reporters to the Yellow Card scheme. Therefore, we are unable to provide data where the number of reports is less than 5, as such some of the breakdowns requested in your response have unfortunately not been fulfilled. We have however tried to be helpful and provide data where the restrictions allow or provided slightly less granular information to complete your request.

Please find below Tables 1 and 2 which show the breakdown of the reports by sex, and by age.

Table 1: UK spontaneous suspected ADR reports categorised by sex, received up to and including 11th January 2023, from Guernsey in association with COVID-19 vaccines.

Sex	**Number of suspected ADR reports**
Female	293
Male	106
Unknown	16

Table 2: UK spontaneous suspected ADR reports categorised by age, received up to and including 11th January 2023, from Guernsey in association with COVID-19 vaccines.

Sex	Number of suspected ADR reports
0-19	12*
20-29	53
30-39	75
40-49	79
50-59	68
60-69	47
70-79	27
80-89	9
90-99	5
Unknown	40

(*This age group is a merged age group of 0-9 and 11-19, in order to prevent patient/reporter identification in line with our duty of confidentiality to patients and reporters.)

Please find below a breakdown of the ADR reports by System Organ Class (SOC). Please note that an individual report can contain multiple reactions and as such the total in the table below will not equal the number of individual reports. Where there are less than 5 reports, numbers have been replaced with a ^ in order to prevent patient/reporter identification in line with our duty of confidentiality to patients and reporters.

Table 3: UK spontaneous suspected ADR reports categorised by SOC, received up to and including 11th January 2023, from Guernsey in association with COVID-19 vaccines.

SOC	Number of suspected ADR reports
Blood and lymphatic system disorders	22
Cardiac disorders	55
Ear and labyrinth disorders	18
Eye disorders	27
Gastrointestinal disorders	85
General disorders and administration site conditions	209
Immune system disorders	^
Infections and infestations	35
Injury, poisoning and procedural complications	16
Investigations	16
Metabolism and nutrition disorders	6
Musculoskeletal and connective tissue disorders	113
Neoplasms benign, malignant and unspecified (incl cysts and polyps)	^
Nervous system disorders	183
Pregnancy, puerperium and perinatal conditions	^
Psychiatric disorders	20
Renal and urinary disorders	^
Reproductive system and breast disorders	34
Respiratory, thoracic and mediastinal disorders	54
Skin and subcutaneous tissue disorders	53
Surgical and medical procedures	^

Vascular disorders	23

Regarding the 8 reports with a fatal outcome, these were from the following SOCs: Cardiac disorders, Respiratory, thoracic and mediastinal disorders, General disorders and administration site conditions and Nervous system disorders.

This information does not represent an overview of the potential side effects associated with the vaccines. A list of the recognised adverse effects of the COVID-19 vaccines is provided in the information for healthcare professionals and the recipient information. Conclusions on the safety and risks of the vaccines cannot be made on the data shown in the report alone. When viewing the data provided, you should remember that:

• 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.

• 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.

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

As you may know the Coronavirus vaccine – summary of Yellow Card reporting, is available here which includes summaries of our assessment so far on particular safety topics surrounding the COVID-19 vaccinations. The MHRA has revised the format of the Summary of Yellow Card reporting to focus on the COVID-19 vaccines administered from the beginning of the Autumn 2022 booster campaign. Any new assessments or safety issues regarding vaccines used in the primary and initial booster campaigns will also be included in this record, however previous and known information on these vaccines will remain available as a record only and can be viewed on the government website (Coronavirus (COVID-19) vaccines adverse reactions - GOV.UK (www.gov.uk)).

Additionally, in December 2022 the MHRA published COVID-19 Vaccine reports which contain interactive charts and tables displaying data for all COVID-19 vaccines.

I hope the information provided is helpful, but 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