FOI 23/272 – Yellow Card reports for COVID-19 vaccines for Jersey, Guernsey and associated islands

MHRA RESPONSE 11 May 2023

Thank you for your email dated 11 April 2023, where you asked for information on the following:

- All Yellow card reports from COVID-19 Vaccinations for the whole of the Channel Islands (Jersey, Guernsey and associated 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 may or may not be aware, 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 23rd April 2023, I can confirm that the MHRA have received 851 spontaneous suspected Adverse Drug Reaction (ADR) reports associated with COVID-19 vaccinations reported from the whole of the Channel Islands including Jersey, Guernsey and associated islands; twelve of which concern a fatal outcome.

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.

Please find below Tables 1 and 2 which show the breakdown of the reports by sex, and by age. To note, we are unable to provide data where the number of reports is less than 5 to ensure patients or reporters cannot be identified according to exemptions under Section 40 and 41 of the FOIA.

Table 1: UK spontaneous suspected ADR reports categorised by sex, received up to and including 23rd April 2023, from the whole of the Channel Islands in association with COVID-19 vaccines.

Sex	Number of suspected ADR reports
Female	599
Male	212
Unknown	40

Table 2: UK spontaneous suspected ADR reports categorised by age, received up to and including 23rd April 2023, from the whole of the Channel Islands in association with COVID-19 vaccines.

Sex	Number of suspected ADR reports
0-19	25*
20-29	85
30-39	144
40-49	171
50-59	153
60-69	94
70-79	64
80-89	18
90-99	8
Unknown	89

(*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 ^.

Table 3: UK spontaneous suspected ADR reports categorised by SOC, received up to and including 23rd April 2023, from the whole of the Channel Islands in association with COVID-19 vaccines.

SOC	Number of suspected ADR reports
Blood and lymphatic system disorders	51
Cardiac disorders	73
Ear and labyrinth disorders	41
Endocrine disorders	^
Eye disorders	61
Gastrointestinal disorders	189
General disorders and administration	419
site conditions	
Immune system disorders	12
Infections and infestations	72
Injury, poisoning and procedural	33
complications	
Investigations	33

Metabolism and nutrition disorders	18
Musculoskeletal and connective tissue disorders	248
Neoplasms benign, malignant and unspecified (incl cysts and polyps)	٨
Nervous system disorders	360
Pregnancy, puerperium and perinatal conditions	٨
Psychiatric disorders	47
Renal and urinary disorders	7
Reproductive system and breast disorders	78
Respiratory, thoracic and mediastinal disorders	105
Skin and subcutaneous tissue disorders	119
Social circumstances	٨
Surgical and medical procedures	6
Vascular disorders	56

Regarding the 12 reports with a fatal outcome, these were from the following SOCs: Cardiac disorders, Respiratory, thoracic and mediastinal disorders, General disorders and administration site conditions, Infections and infestations, Nervous system disorders, and Pregnancy, puerperium and perinatal conditions.

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 <u>information for healthcare professionals and the</u> 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, in December 2022, the MHRA published <u>COVID-19 Vaccine</u> <u>reports</u>, 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

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