FOI 23/089

2nd March 2023

Dear

Thank you for your FOI request dated 2nd February 2023, where you requested:

• An update to our previous response for FOI 22/982, including reporting figures on Yellow Card reports where a COVID-19 vaccine was the suspect drug and there was a serious reaction or fatal outcome reported and the postcode was reported to be within Northern Ireland.

• Additionally, that these reports be broken down by age and COVID-19 vaccine brand.

Firstly, it is important to note 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. 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.

Where fewer than 5 reports have been received for a specific month, age and vaccination breakdown, we have concealed this number in order to comply with data protection laws and protect reporter confidentiality given the additional factor of geographic breakdown requested. Please note the same applies across the entirety of your request where the number of reports is fewer than 5. This falls under Section 40 and 41 of the FOIA and as outlined in our Privacy Policy Privacy Policy | Making medicines and medical devices safer (mhra.gov.uk), the MHRA will not share the identity of anyone submitting a Yellow Card report with any person outside the MHRA without their explicit consent, unless we are required or permitted to do so by law. As this is personal data in relation to an individuals' health, this would be of detriment to them and may damage the engagement with the scheme. The Policy also states that we may receive requests for Yellow Card report data under the Freedom of Information Act. While we are legally obliged to provide some of the requested information, we only provide high-level summary information with all person-identifiable data excluded.

The information supplied in this response relies on the reporter providing a postcode which starts with 'BT' in the original Yellow Card. If the postcode is incorrectly provided or incomplete, or if the reporter has provided an email address in place of a postal address, the Yellow Card will not be included in this data. As the data has been extracted using available postal addresses only, it may not reflect the true number of ADR reports following COVID-19 vaccinations reported from Northern Ireland. It is important to note that the number of reports received for Northern Ireland does not directly equate to the number of people who may have experienced adverse reactions and therefore cannot be used to determine the incidence of reactions.

As of 3rd February 2023, we have not received any reports for COVID-19 Vaccine Novavax from a reporter with a postcode starting 'BT.'

When breaking down the number of reports from Northern Ireland for each COVID-19 vaccine by month, and age group, only 4 age group and month combinations displayed values of 5 or above meaning the majority of the table would be censored data. As such we have instead provided the total reports from Northern Ireland split by age group and vaccine brand only in Table 1 in order to be helpful.

Table 1: Number of UK ADR reports from Northern Ireland received from 1st September 2022 up to and including 3rd February 2023 broken down by age group and vaccine brand

Age group	COVID-19 Vaccine Pfizer/BioNTech monovalent	COVID-19 Vaccine Pfizer/BioNTech bivalent	COVID-19 Vaccine AstraZeneca	COVID-19 Vaccine Moderna monovalent	COVID-19 Vaccine Moderna bivalent	COVID-19 Vaccine Brand Unspecified
0-19	0	0	0	0	*	0
20-39	17	7	*	*	*	0
40-59	19	10	9	5	11	*
60-79	15	12	*	*	10	*
80+	5	*	6	5	*	*
Unknown	9	7	*	0	*	*

With regard to the number of serious or non-serious reports received per COVID-19 vaccine, this data is displayed in Table 2. A Yellow Card report is considered serious according to two criteria; firstly, a reported reaction can be considered serious according to our medical dictionary. Secondly, whether the original reporter considers the report to be serious whereby they can select based on 6 criteria1.

Please also note that one report may contain more than one brand of COVID-19 vaccine. For example, someone may report their reactions to both their initial and booster vaccinations within the same report.

Table 2: Number of UK ADR reports from Northern Ireland received for a COVID-19 vaccine by seriousness from 1st September 2022 up to and including 3rd February 2023

Vaccine	**Non-Serious**	**Serious (incl. fatal)**
Monovalent COVID-19 Vaccine Pfizer/BioNTech	8	57
Bivalent COVID-19 Vaccine Pfizer/BioNTech	9	29
COVID-19 Vaccine AstraZeneca	*	12

Monovalent COVID-19 Vaccine Moderna	*	146

Finally, between 1st September 2022 up to and including 3rd February 2023 the MHRA have not received any reports with a fatal outcome for bivalent COVID-19 vaccines Pfizer/BioNTech and Moderna. For all other COVID-19 vaccines the number of reports including a fatal outcome were fewer than 5 and as such we are unable to provide a breakdown.

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,

Vigilance and Risk Management of Medicines Division