Medicines & Healthcare products Regulatory Agency

MHRA
Regulating Medicines and Medical Devices

[redacted]

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2nd May 2023

Dear [redacted]

FOI 23/246

Thank you of your email dated 3rd April 2023, where you kindly clarified your request which was:

- An update to your previous request, FOI 23/089, of the number of reports from Northern Ireland with a fatal outcome following COVID-19 vaccination, with the data broken down by brand.
- An update to your previous request, FOI 23/089, of the number of reports from Northern Ireland following COVID-19 vaccination, with the data broken down by brand, month, and patient age.

I hope that you find the information below and attached helpful and that it sufficiently answers your query.

Table 1: Number of UK ADR reports from Northern Ireland for the COVID-19 vaccines where there was a fatal outcome up to and including 29th March 2023.

Vaccine	Fatal
COVID-19 Vaccine Pfizer/BioNTech monovalent	14
COVID-19 Vaccine Pfizer/BioNTech bivalent	0
COVID-19 Vaccine AstraZeneca	37
COVID-19 Vaccine Moderna monovalent	*
COVID-19 Vaccine Moderna bivalent	0
COVID-19 Vaccine Brand Unspecified	*

The information supplied in this response relies on the reporter providing a postcode which starts with 'BT' in the original Yellow Card. Furthermore, if the postcode is incorrectly provided, 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. ADR reporting rates are influenced by many aspects, including the extent of use.

Please see Tables 2 – 4 in the attached Excel spreadsheet showing reports from Northern Ireland for each COVID-19 vaccine broken down by month and age group. Please note that for COVID-19 Vaccine Pfizer/BioNTech bivalent, COVID-19 Vaccine Moderna bivalent, and where the brand of vaccine was not specified by the reporter, all categories display fewer than 5 reports. As such we have not provided this in table format.

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.

Table 5: Number of UK ADR reports from Northern Ireland received for a COVID-19 vaccine by seriousness up to and including 29th March 2023.

Vaccine	Non-Serious	Serious (incl. fatal)
COVID-19 Vaccine Pfizer/BioNTech monovalent	912	2339
COVID-19 Vaccine Pfizer/BioNTech bivalent	10	30
COVID-19 Vaccine AstraZeneca	598	2533
COVID-19 Vaccine Moderna monovalent	48	146
COVID-19 Vaccine Moderna bivalent	10	19
COVID-19 Vaccine Brand Unspecified	7	26

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 criteria[1]. Please note that cases where an ADR has a fatal outcome are included in the total number of serious cases. 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.

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 Group

[1] The seriousness criteria for ADR reporting were determined by a working group of the Council for International Organizations of Medical Sciences (CIOMS) and are defined as 6 possible categories which are documented on the Yellow Card. Reporters can select one or more of the following criteria by ticking the appropriate box on the Yellow Card. The criteria are: (1) patient died due to reaction (2) life threatening (3) resulted in hospitalisation or prolonged inpatient hospitalisation (4) congenital abnormality and (5) involved persistent or significant disability or incapacity or (6) if the reaction was deemed medically significant.

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The Information Commissioner's Office
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