Medicines & Healthcare products Regulatory Agency

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www.gov.uk/mhra

[redacted]

28th March 2024

Dear [redacted]

FOI 24/220 - Northern Ireland COVID-19 Vaccine Reports

Thank you for your Freedom of Information (FOI) request dated 3rd March 2024 where you asked for the exact same data and format that we previously provided you with in response to FOI 23/246.

Please see below your requested information in **bold** with our response to each of the questions raised.

Please note, the information supplied in this response relies on the reporter providing a postcode which starts with 'BT' in the original Yellow Card report. 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 Adverse Drug Reaction (ADR) reports following COVID-19 vaccinations reported from Northern Ireland.

When considering the spontaneous ADR data within this response and attached, 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.

1) From the beginning of the rollout until present date please provide the number of deaths reported to the MHRA yellow card system from Northern Ireland broken down by vaccine manufacturers.

In response to this request, please refer to **Table 1** (below) which shows the number of spontaneous suspected ADR reports from Northern Ireland for the available COVID-19 vaccines where there was a fatal outcome, up to and including the 20th March 2024.

Table 1: The number of ADR Reports from Northern Ireland with a fatal outcome, up to and including 20/03/2024, broken down by vaccine manufacturers.

Vaccine	Number of Fatal Reports
COVID-19 Vaccine Pfizer/BioNTech monovalent	16
COVID-19 Vaccine Pfizer/BioNTech bivalent	0
COVID-19 Vaccine AstraZeneca	39
COVID-19 Vaccine Moderna monovalent	1
COVID-19 Vaccine Moderna bivalent	0
COVID-19 Vaccine Brand Unspecified	2

To note, previously reports containing fewer than 5 reports were marked with an asterisk and not disclosed in order to comply with data protection laws and protect reporter confidentiality given the additional factor of geographic breakdown. However, after seeking advice from the Information Commissioner's Office (ICO) we are now able to provide this data without restrictions.

2) From the beginning of the rollout until present date please provide the total number of serious and non-serious reports from Northern Ireland.

I can confirm that the MHRA has received a total of 5166 serious (including fatal outcomes) and 1601 non-serious UK spontaneous ADR reports for the COVID-19 vaccines from Northern Ireland up to and including 20th March 2024.

3)a. Furthermore, please can you provide the serious adverse reports broken down by vaccine manufacturers.

3)b. Can you also confirm from the serious reports, how many were hospitalised.

Medicines & Healthcare products Regulatory Agency

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 the 6 serious criteria[1] available. Please see **Table 2** (below) which shows the number of ADR reports that are serious as well as the number considered serious due to the selection of hospitalisation or prolonged inpatient hospitalisation.

Table 2: Number of ADR reports from Northern Ireland received for a COVID-19 vaccine up to and including 20/03/2024, broken down by vaccine manufacturers.

Vaccine	Serious (incl. fatal)	Hospitalised
COVID-19 Vaccine Pfizer/BioNTech monovalent	2368	153
COVID-19 Vaccine Pfizer/BioNTech bivalent	38	6
COVID-19 Vaccine AstraZeneca	2548	219
COVID-19 Vaccine Moderna monovalent	152	21
COVID-19 Vaccine Moderna bivalent	24	2
COVID-19 Vaccine Brand Unspecified	36	9

* Please 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.

4)a. Please provide the excel spread sheets again broken down by vaccine manufacturers and age groups.

4)b. Furthermore, can the excel spread sheets be split by non-serious and serious. This meaning I will receive two separate spreads of excel spread sheets.

As requested, please find the attached Excel spreadsheet containing the requested information. These tables are organised by month and age group, labelled as **Tables 3a-8a**. Additionally, there are two sets of tables categorised by seriousness; **Tables 3b-8b** for serious reports and **Tables 3c-8c** for non-serious reports.

5) The coroner's office for NI have only investigated and confirmed 3 deaths caused by the vaccines. Can you confirm that our coroner's office should be investigating each and every suspected death reported to yourselves (MHRA) via the yellow card reporting system.

[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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Regulatory Agency

The reporting of deaths to a coroner and criteria for investigation is not within the remit of the MHRA. Further information regarding this question should be directed to the Coroner's Office.

Please note, if you plan on sharing this data more widely, or publishing this data, please can you provide us with a copy prior to publication to ensure the correct interpretation and confidentiality of the data provided.

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
Medicines and Healthcare products Regulatory Agency

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, 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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