Medicines & Healthcare products
Regulatory Agency

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www.gov.uk/mhra

[redacted]

2nd May 2024

Dear [redacted],

FOI 24/332 and FOI 24/333 - Northern Ireland COVID-19 Vaccine Reports

Thank you for your follow-up Freedom of Information (FOI) requests dated 5th April 2024. There are provisions under the FOIA that allow for the aggregation of requests of the same or similar information from a requestor within a 60-day time period. As such your requests have been aggregated and a single combined response has been provided in line with our previous response (FOI 24/220). Please note that we have not aggregated these requests with FOI 24/220 in this instance however as per the ICO guideline are eligible to do so given they were submitted within a 60-day time period; therefore, please note this for any future requests you submit. Please see below your requested information in **bold** with our response to each of the questions raised.

1) **Please provide a table containing the number of all serious ADRs from COVID-19 vaccines reported to the Yellow Card Scheme in Northern Ireland to date, broken down by age demographic (as per FOI 24/220), and now also broken down by both criteria and reporter type as follows.**

   By serious ADR criteria selected by the reporter:
   (1) death
   (2) life threatening
   (3) hospitalisation (new or prolonged)
   (4) congenital abnormality
   (5) persistent or significant disability or incapacity
   (6) reaction deemed medically significant

   By reporter type:
   (i) healthcare professional
   (ii) other (non-healthcare professional, e.g., patient, or their family/friends)

As requested, please find the attached Excel spreadsheet containing the requested information on all serious Adverse Drug Reaction (ADR) reports concerning COVID-19 vaccines from Northern Ireland. These tables are organised by month and age group, similar to the data previously provided to you in FOI 24/220. Tables 1-6 each concern a different COVID-19 vaccine brand and include breakdowns by

seriousness categories[1] (ordered alphabetically) and reporter type. Please note that where no tables have been provided for a certain seriousness criterion, we have not received any reports for the particular vaccine where the corresponding flag has been selected by the reporter.

For reference, 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 available. It is important to note that the aggregated number of reports within the seriousness tables provided will not equal the overall number of reports, given that reporters are able to select more than one of the 6 serious criteria.

As previously referenced, please keep in mind that 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.

2) Who is responsible for investigating serious ADRs reported through the Yellow Card Scheme?

All Yellow Card reports of suspected adverse reactions are evaluated, together with additional sources of evidence, by a team of safety experts comprising of physicians, pharmacists and scientists

[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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from the Safety and Surveillance group at the MHRA to assess the likelihood of a causal relationship between a drug or vaccine and any reported reactions.

Please see here, How we monitor the safety of medicines for further information.

3) Please provide the ages of all the deceased people who have been the subject of a suspected fatal ADR in Northern Ireland to date, as reported through the Yellow Card Scheme. As per FOI 24/220, this number stands at 58. Please provide the exact ages without putting them into age brackets.

I can confirm that we hold the information requested, however provision of provision of individual patient age is exempt from release under Section 40 (personal information) and Section 41 (information provided in confidence) of the FOI Act. Supplying you with this information could lead to patient or reporter identification. Further to the use of Section 40 and 41, as outlined in our Privacy Policy, 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.

However, in accordance with Section 16 of the FOIA, concerning the provision of advice and assistance to those requesting information under FOI we have provided Table 7 in the attached Excel spreadsheet which displays the spontaneous suspected ADR reports with a fatal outcome by ten-year age bands for each COVID-19 vaccine.

4) Furthermore, please clarify your response to FOI 24/220, by explaining what qualifies as "correct interpretation" of data provided? Also, please clarify your request for the "confidentiality" of data the MHRA provided through their response.

Correct interpretation of the data provided relies on the reader taking into account the bullet points included in response to question 1 above which are the same as that provided to you in FOI 24/220.

Regarding confidentiality, this was included in error. The data provided abides by our privacy policy and keeps patients and reporter identities confidential. Apologies for any confusion this has caused.

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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