Medicines & Healthcare products
Regulatory Agency

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Ms Kathy Gray

30 August 2022

Dear Ms Gray,

**FOI 21/860 CSC 61174 FOI request**

Thank you for your email dated 28 July 2021 containing an FOI request relating to the COVID-19 vaccines. The MHRA responded on the 26 August 2021 citing Section 22 and explained the information was exempt from disclosure as it was intended for future publication.

As you are aware, we have now confirmed to the ICO that is not clear whether the eventual iDAP publication will include sufficient data to enable a report to be linked to a particular country of the UK and therefore consider that this information cannot be said to be intended for future publication. Following further correspondence with the ICO, they have provided further clarification on the first aspect of your FOI request and therefore we have updated our response as below:

Your original request asked for the following:

*I am writing to request the total number of individuals from Northern Ireland who have died after receiving a COVID-19 vaccine, since December 2020 to present.*

*I am writing to request the total number of individuals from Northern Ireland who have reported adverse reactions after receiving a COVID-19 vaccine, since December to present.*

*In addition, please provide the above information aggregated by month, vaccine administered either Pfizer/BioTech or Oxford/AstraZeneca: Other, and by age groups below:*

*0-19*
*20-39*
*40-59*
*60-79*
*80+*
*Age unknown*

The ICO has since clarified that the first aspect of your request is as follows:
*I am writing to request the total number of reports from Northern Ireland of fatal adverse reactions after receiving a COVID-19 vaccine, since December 2020 to present.*

As explained in our previous response, with regards to point 1, the Northern Ireland Statistics and Research Agency (NISRA) is responsible for the provision of mortality statistics pertaining to Northern Ireland. The Agency can be contacted at info@nisra.gov.uk.

Following receipt of the additional information provided by the ICO as detailed above, we can confirm that up to and including 11 August 2021, the MHRA had received 27 UK spontaneous suspected Adverse Drug Reaction (ADR) reports reporting a fatal outcome following COVID-19 vaccination from a Northern Irish postcode. These data, and the data below have been extracted based on the reporter postal code being in Northern Ireland. If a postal code has been incorrectly provided or if the reporter has only provided their email address, the report will not be included in the output provided.

**Use of Section 41 (information provided in confidence):**
Regarding Section 41, 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. 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.

Where fewer than 5 reports have been received for a specific age breakdown and vaccination, 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 (Northern Ireland). There are fewer than 5 reports for the categories requested with the exception of 5 reports of suspected adverse events with a fatal outcome for the AstraZeneca vaccine in April 2021 in the age group 80+.

It is important to note that a reported suspected adverse event associated with a COVID-19 vaccine with a fatal outcome does not necessarily mean it has been caused by the vaccine. Underlying or concurrent illnesses may be responsible and such events can also be coincidental. Each year, millions of doses of routine vaccines are given in the UK alone, and when any vaccine is administered to very large numbers of people, some recipients will inevitably experience illness following vaccination.

The MHRA takes all suspected ADR reports with a fatal outcome in patients who have received a COVID-19 vaccine very seriously and every report with a fatal outcome is fully evaluated and kept under continual review.

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. Therefore, Yellow Card data cannot be used to determine the incidence of a reaction or to compare the side effect profiles of different medicines or vaccines. Suspected ADR reporting rates are influenced by the seriousness of ADRs, their ease of recognition, and the extent of use of a particular drug or vaccine and may be stimulated by promotion and publicity about a drug. Reporting tends to be highest for newly introduced medicines during the first one to two years on the market and then declines over time.

Regarding point 2, the total number of spontaneous suspected Yellow Card reports from Northern Ireland relating to COVID-19 vaccinations up to and including 11 August 2021 is available in our weekly summary of Yellow Card reporting (Table 4). This was available online at the time of your request but we have attached a copy containing data up to and including 11 August 2021 as the publication has now been updated to include data up to and including 27 July 2022.

Regarding your third point, please see Tables 1 and 2 below which show the above information aggregated by month, vaccine administered and month in which the report was received. Where fewer than 5 reports have been received for a specific age breakdown and vaccination, an asterisk has been used to conceal this number in order to comply with data protection laws and protect patient/reporter confidentiality. Please note that we have been unable to provide a breakdown for vaccines which fall in to the 'Other' category for this reason.

When considering the spontaneous ADR data, it is important to be aware of the caveats outlined above on reported suspected adverse events.

*Table 1: All UK spontaneous suspected Adverse Drug Reaction (ADR) reports associated with COVID-19 Vaccine AstraZeneca reported from Northern Ireland broken down by month and age group*

| | COVID-19 Vaccine AstraZeneca | | | | | | | |
|---|---|---|---|---|---|---|---|---|
| **Patient Age (Years)** | **Jan-21** | **Feb-21** | **Mar-21** | **Apr-21** | **May-21** | **Jun-21** | **Jul-21** | **Aug-21** |
| **0-19** | * | * | 10 | * | * | 5 | * | * |
| **20-39** | 34 | 70 | 185 | 165 | 246 | 106 | 50 | 12 |
| **40-59** | 25 | 92 | 259 | 319 | 154 | 100 | 56 | 18 |
| **60-79** | 8 | 123 | 99 | 77 | 42 | 31 | 13 | * |
| **80+** | 22 | 22 | 10 | 26 | 9 | 9 | * | * |
| **Unknown** | 5 | 36 | 78 | 78 | 51 | 46 | 22 | * |

*Table 2: All UK spontaneous suspected Adverse Drug Reaction (ADR) reports associated with COVID-19 Vaccine Pfizer/BioNTech reported from Northern Ireland broken down by month and age group*

| | COVID-19 Vaccine Pfizer/BioNTech | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|
| **Patient Age (Years)** | **Dec-20** | **Jan-21** | **Feb-21** | **Mar-21** | **Apr-21** | **May-21** | **Jun-21** | **Jul-21** | **Aug-21** |
| **0-19** | * | * | * | * | 8 | * | 8 | * | 6 |
| **20-39** | 23 | 150 | 55 | 112 | 65 | 106 | 125 | 128 | 40 |
| **40-59** | 20 | 160 | 55 | 162 | 105 | 108 | 60 | 55 | 9 |

| | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|
| **60-79** | 5 | 18 | 49 | 36 | 34 | 27 | 16 | 11 | |
| **80+** | * | * | | * | | | | | |
| **Unknown** | 6 | 38 | 18 | 39 | 32 | 41 | 47 | 37 | 10 |

Please note that the database used to capture information from Yellow Cards is dynamic and therefore numbers of reports are subject to change over time. The MHRA sometimes receives multiple reports of the same case from different reporters (for example a family member and a healthcare professional both separately reporting the same event). When these cases of duplicate reporting are picked up by us through our regular monitoring processes, we have a responsibility to merge these cases into one, which can account for fluctuation of numbers in the overall Yellow Card data. Furthermore, numbers may also fluctuate as we receive further information regarding a particular case and it is subsequently updated.

I hope this information is of use to you. Should you have any additional questions, please contact: pharmacovigilanceservice@mhra.gov.uk. 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 this response's date and can be addressed to this email address.

Yours sincerely,

FOI Team,
Safety and Surveillance Group



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, 4-T, 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
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