Medicines & Healthcare products Regulatory Agency

MHRA
Regulating Medicines and Medical Devices

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**MHRA**
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**22nd May 2024**

Dear [redacted],

**RE: FOI 2024/00051**

Thank you for your email dated 23rd April 2024 where you asked for the following information further to FOI 23/146:

- *Provide updated figures for adverse events for Isle of Man postcodes for ALL brand Covid-19 vaccines to date.*
- *Please state number of reports classed as serious, and state criteria used for this classification.*
- *How many deaths have been reported?*
- *Provide the top 3 most reported batch numbers for the Isle of Man.*

Further to your request I can confirm that up to and including 16 May 2024, the MHRA have received 1054 UK suspected spontaneous Adverse Drug Reaction (ADR) reports for COVID-19 vaccines, containing 3516 reactions where the reporter postcode was registered within the Isle of Man (IM1 to IM9). Individual reports can contain more than one adverse reaction. As we mentioned in our previous responses, addresses and post codes are not mandatory fields for completing an ADR report therefore, this information may not be a complete representation of all reports from this area as reports where the postcode is incorrectly provided or where the reporter has only provided their email address will not be included in this output.

You also asked for the numbers of these reports that were classified as serious. 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, a Yellow Card can be considered serious by the original reporter, whereby they can select based on 6 criteria[1]. Following restriction of the data by these two methods, 673 of the reports were considered serious (including fatal reports).

[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.

Of the 1054 spontaneous suspected ADR reports received for COVID-19 vaccines from the Isle of Man, 5 reports include a fatal outcome. Please note that these reports are included in the number of reports considered serious provided above.

It is important to note that conclusions on the safety and risks of the vaccines cannot be made on this data alone. 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. As is the case with fatalities, 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 and many suspected ADRs reported on a Yellow Card do not have any relation to the vaccine or medicine and it is often coincidental that symptoms occurred around the same time as administration. 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. Underlying or concurrent illnesses may be responsible and such events can also be coincidental.

Please be assured that all reports are continually reviewed to detect possible new side effects that may require regulatory action, and to differentiate these from things that would have happened regardless of the vaccine or medicine being administered, for instance due to underlying or undiagnosed illness. Details of our proactive vigilance strategy for COVID-19 vaccines can be found here.

With regards to the last point in your request, the 3 batch numbers most frequently reported within the 1054 reports from the Isle of Man for COVID-19 vaccines is provided below in table 1. It is important to note that it is not mandatory to provide batch numbers when submitting a Yellow Card report.

Furthermore, different batches would have been used at different stages of the vaccination campaign, and in different patient groups, which could also impact reporting rates. For example, reporting rates were typically higher at the beginning of the vaccination campaign as individuals received their first dose and the likelihood of experiencing a reaction, as well as the propensity to report it, differs across patients of different ages.

**Table 1: 3 most frequently reported batch numbers for COVID-19 vaccines received from the Isle of Man up to and including 16 May 2024.**

| COVID-19 Vaccine | Batch Number |
|---|---|
| COVID-19 Vaccine AstraZeneca | 41202002 |
| COVID-19 Vaccine AstraZeneca | PV46671 |
| COVID-19 Vaccine AstraZeneca | PW40010 |

Please note that reporters have the option to include batch number within a free text field, however this is not mandatory. As this information is collected in a free text field, entries within that field may vary between reports depending on how the reporter details the batch number. For the purpose of this FOI request, we have searched the batch number field for batch numbers as they are listed in table 1 and have also accounted for variations including the following:

- A space between letters and numbers

- A dash or forward slash between letters and numbers
- Variations between the number 0 and the letter O
- Variations between the number 2 and the letter Z
- Variations between the letters V U and Y
- Variations between the letters P and B

I would like to assure you that the MHRA continuously monitors the safety of vaccines through a variety of pharmacovigilance approaches including the Yellow Card scheme. As part of our signal detection processes all adverse reaction reports received by the Yellow Card scheme are assessed and cumulative information reviewed at regular intervals. Please note that our analysis of the reports relating to all vaccines takes into account product batch number and did not result in any safety concerns. Please be assured that the MHRA reviews this data regularly and we would communicate any concerns raised with the public and healthcare professionals.

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



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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