Medicines & Healthcare products
Regulatory Agency

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[redacted]

5 December 2023

FOI 23/857

Dear [redacted]

Thank you for your email dated 8th November 2023, where you requested:

- *Updated figures for adverse reactions for all brands of COVID-19 vaccines to date received from the Isle of Man, and updated Drug Analysis Print attachments for each vaccine.*

Further to your request I can confirm that up to and including 15/11/2023, the MHRA have received 1,050 suspected spontaneous Adverse Drug Reaction (ADR) reports associated with a COVID-19 vaccine where the reporter postcode was registered within the Isle of Man (IM1 to IM9). Please note that if the postcode is incorrectly provided or if the reporter has only provided their email address, that report will not be included in this output.

Please also find attached Vaccine Analysis Prints (VAPs) for these 1,050 ADR reports received from the Isle of Man. Each VAP contains complete data for all spontaneous suspected adverse drug reactions, or side effects, as well as those which are associated with a fatal outcome. Please refer to the attached information sheet for guidelines on how to interpret the VAP.

When considering the attached spontaneous adverse drug reaction (ADR) data, it is important to be aware of the following points:

- 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.
- 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.
- Many factors have to be considered when assessing whether a vaccine has caused a reported adverse reaction. When monitoring the safety of medicines and vaccines, MHRA staff carry out careful analysis of these factors.

- It is not possible to compare the safety of different vaccines by comparing the numbers presented in the vaccine reports. Reporting rates can be influenced by many factors including the seriousness of the adverse reactions, their ease of recognition and the extent of use of a particular vaccine. Reporting can also be stimulated by promotion and publicity about a product.

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
Wycliffe House
Water Lane
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