

Medicines & Healthcare products Regulatory Agency

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gov.uk/mhra



10th October 2023

Dear

FOI 23/670

Thank you for your information request dated 12 September 2023, where you asked:

"I would like to see the weekly Covid-19 AstraZeneca Vaccine Analysis Prints for January to May 2021".

As requested, please find attached a file containing the Vaccine Analysis Prints (VAPs) for the COVID-19 Vaccine AstraZeneca dated between January and May 2021. Please note that the earliest VAP published covers all UK spontaneous reports received between 4 January 2021 and 24 January 2021.

When reviewing the data within a VAP it is important to recognise that whilst these are useful in helping identify possible vaccine safety issues, the information does not present a complete overview of the potential side effects associated with specific vaccines. A list of the recognised adverse effects to the COVID-19 Vaccine AstraZeneca is found in the product information which can be found via our <u>website</u>. Conclusions on the safety and risks of vaccines cannot be made on the data shown in the VAP.

When using a VAP, you should remember that:

- The likelihood of experiencing an adverse reaction when taking a vaccine cannot be estimated from the information in VAPs. This is because we have limited information about how many people have taken the vaccine without experiencing a reaction.
- 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 on a VAP does not necessarily mean that the vaccine has caused the reaction.



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- 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 a vaccine.
- Many factors must 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 however please do not hesitate to contact me if I can be of further assistance.

Yours sincerely,

FOI Team, Safety and Surveillance

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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 you receive this response and addressed to: info@mhra.gov.uk

Please remember to quote the reference number above in any future communications.

If you were to remain dissatisfied with the outcome of the internal review, you would have the right to apply directly to the Information Commissioner for a decision. Please bear in mind that the Information Commissioner will not normally review our handling of your request unless you have first contacted us to conduct an internal review. The Information Commissioner can be contacted at:

Information Commissioner's Office Wycliffe House Water Lane Wilmslow Cheshire SK9 5AF