Medicines & Healthcare products
Regulatory Agency

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Ms [redacted]

12 January 2023

FOI 23/980

Dear [redacted],

Thank you for your information request dated 14 December 2023, where you asked:

“Please can I have all reported issues that patients have reported regarding batch 4120z003 covid 19 vaccine.

Particularly any bilateral muscle pain and protruding veins particularly in the uterus. Origin of the batch and production information. Labelling, ingredients, and names this batch has been referred as. Any issues reported on the same vaccine type under different names”.

Firstly, I would like to explain that the MHRA continuously monitors the safety of vaccines through a variety of pharmacovigilance processes 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. The MHRA takes all reports of side effects with the utmost seriousness, including those that sadly report a fatal outcome.

Please note that our analysis of the reports relating to this vaccine, which takes into account product batch number, 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. If you would like further information on batch usage, please contact the UK Health Security Agency (UKHSA) who hold this information.

Not all batches of the COVID-19 vaccines are the same size, and some batches may have had more wastage than other batches or be distributed more widely outside of the UK. Therefore, we would not expect the number of ADR reports for all batches to

be the same as they have been administered to different numbers of patients. 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.

I can confirm that the MHRA has received a total number of 4,496 UK spontaneous suspected ADR reports relating to the COVID-19 AstraZeneca vaccine with batch number 4120Z003 up to and including 7 January 2024.

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 Annex 1 and have also accounted for the following variations:

- 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

As per your request, please find attached a file containing the Vaccine Analysis Print (VAP) for the COVID-19 Vaccine AstraZeneca with the batch number 4120Z003 up to and including 7 January 2024. The attached guidance sheet provides you with further information on how to interpret the print.

When reviewing the data within a VAP it is important to recognise that 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 website. 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 VAP. 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.

- 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.

With regards to your request for information the about the origin of the batch and production information as well as the labelling, ingredients, and other names this batch has been referred as, batch 4120Z003 was manufactured by the Serum Institute India Pvt. Ltd (SIIPL) and was treated as COVID-19 Vaccine AstraZeneca. The ingredients, names and labelling were as for COVID-19 Vaccine AstraZeneca. The ingredients are listed in the Product Information Leaflet (PIL). The Summary of Product Characteristics and Public Assessment Report (PAR) for the COVID-19 Vaccine AstraZeneca (PLGB 17901/0355) are available on our products website: MHRA Products | Home

With regards to your question about any other issues reported on the same vaccine type under different names, the Interactive Drug Analysis Profile (IDAP) for the COVID-19 vaccine AstraZeneca displays an overview of all UK spontaneous suspected adverse reactions related to this vaccine reported through the Yellow Card scheme.

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

If you have a query about the information provided, please reply to this email

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