Medicines & Healthcare products Regulatory Agency

MHRA
Regulating Medicines and Medical Devices

[redacted]

MHRA

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21st February 2023

Dear [redacted]

FOI 23/054 – Covid-19 vaccine AstraZeneca batch PV46676

Thank you for your email dated 24th January 2023, where you asked for information on the following:

- *How many adverse effects have been reported from AstraZeneca batch no PV46676? Can you list them please? Of those reports, how many were spinal strokes?*
- *How many spinal strokes were reported with AstraZeneca being the vaccine? How many spinal strokes were reported across the vaccines?*

Following a search of our database up to and including 8th February 2023, I can confirm that the MHRA have received 2337 spontaneous suspected Adverse Drug Reaction (ADR) reports associated with the batch number PV46676 for the COVID-19 Astra Zeneca vaccine reported in the UK. Regarding your query about how many of these reports were for spinal strokes, we are unable to provide data where the number of reports is less than 5 due to patient and reporter confidentiality, therefore this request has unfortunately not been fulfilled.

Please find attached Table 1, which contains all the reactions associated with batch number PV46676 for the COVID-19 Astra Zeneca vaccine. Please note that where there are less than 5 reports, numbers have been replaced with a ^ in order to prevent patient/reporter identification in line with our duty of confidentiality to patients and reporters. Also, a single ADR report may contain multiple reactions, therefore the sum of reactions in the table will not equal the total number of reports. A list of the recognised adverse effects of the COVID-19 vaccines is provided in the information for healthcare professionals and the recipient information.

Conclusions on the safety and risks of the vaccines cannot be made on the data shown in the report alone. 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. Please be assured that the MHRA reviews Yellow Card 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.

Additionally, in December 2022 the MHRA published COVID-19 Vaccine reports which contain interactive charts and tables displaying data for all COVID-19 vaccines. Here you can view the data for the number of spinal strokes for each of the COVID-19 vaccines. The term 'Spinal stroke' can be found in the following section of the "Reactions Profile" tab: System Organ Class (SOC) 'Nervous system disorders', then 'Central nervous system vascular disorders', then 'Central nervous system haemorrhages and cerebrovascular accidents'.

When viewing the data provided, you should remember that:

- 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.
- 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.

For a vaccine to be considered safe, the expected benefits will be greater than the risk of having harmful reactions. It is important to note that most people receive vaccinations without having any serious side effects. 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. Our analysis of the Yellow Card reports takes into account product batch number.

As you may know the Coronavirus vaccine – summary of Yellow Card reporting, is available here which includes summaries of our assessment so far on particular safety topics surrounding the COVID-19 vaccinations. The MHRA has revised the format of the Summary of Yellow Card reporting to focus on the COVID-19 vaccines administered from the beginning of the Autumn 2022 booster campaign. Any new assessments or safety issues regarding vaccines used in the primary and initial booster campaigns will also be included in this record, however previous and known information on these vaccines will remain available as a record only and can be viewed on the government website (Coronavirus (COVID-19) vaccines adverse reactions - GOV.UK (www.gov.uk)).

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,
Safety and Surveillance

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