Medicines & Healthcare products Regulatory Agency

MHRA

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www.gov.uk/mhra

[redacted]

20th February 2024

Dear [redacted]

FOI 24/131

Thank you for your email dated 23 January 2024, where you requested the number of Yellow Card reports relating to COVID-19 vaccine AstraZeneca and new onset MS, for which an initial response was provided directing you to available published information. Subsequently you have followed up on this initial response with the below and as such this will be handled under the Freedom of Information act;

> *It is unclear how many reports related to new onset MS. As the vaccine is no longer in use, it may not trigger the drug-event algorithm software. Has there been any consideration of the significance of the number of reports of new onset MS following this vaccine?*

I can confirm we hold the information you have requested and would also like to apologise if our initial response to your request did not provide all the information you had hoped to receive. The below response provides information pertaining to your initial request and your follow up request.

Further to your request I can confirm up to and including 19th February 2024 the MHRA has received 78 UK spontaneous adverse reaction reports where multiple sclerosis was reported as a suspected ADR with the AstraZeneca COVID-19 vaccine. As your request was to specifically look at new onset multiple sclerosis it's important to note that it's not always possible to tell from the information provided on adverse reaction report as to whether the event was new-onset or an exacerbation of pre-existing illness. On further review of the narrative included in the 78 reports received, 61 reports were associated with MS aggravation or exacerbation, the remaining 17 reports did not indicate that the events were associated with pre-existing MS and therefore may have represented a new-onset.

Reporters to the scheme can submit Yellow Cards at any time after their vaccination and all reports, regardless of when they were received are considered as part of our routine signal detection processes. Spontaneous adverse reaction reports of Multiple Sclerosis have been considered as part of a wider review on COVID-19 vaccines and neurological disorders but a link has not been established and therefore it is currently not listed in the product information for the AstraZeneca COVID-19 vaccine as a side effect.

When considering the above spontaneous data, it is important to be aware of the following points:

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- A reported reaction does not necessarily mean it has been caused by the vaccine, only that the reporter had a suspicion it may have. 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.
- Additionally, the number of reports received via the Yellow Card scheme does not directly equate to the number of people who suffer adverse reactions and therefore cannot be used to determine the incidence of a reaction or compare the safety profile of different vaccines.

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