Medicines & Healthcare products Regulatory Agency

MHRA

10 South Colonnade
Canary Wharf
London
E14 4PU
United Kingdom

www.gov.uk/mhra

[redacted]

24th April 2024

Dear [redacted],

FOI 24/303

Thank you for your email dated 26th March 2024, where you asked for how many yellow card reports:

1. Have you received that mention a diagnosis of Lupus following an AstraZeneca Covid 19 vaccine.
2. How many reports of a diagnosis of Lupus have you received following a previous report of thrombosis with low platelets or thrombosis with thrombocytopenia syndrome (VITT) (again this is following the administration of the AstraZeneca Covid 19 vaccine).
3. Has the MHRA concluded an association or causation with a diagnosis of Lupus following an AstraZeneca Covid 19 vaccine.

I can confirm up to and including 19th April 2024, we have received a total of 70 UK suspected spontaneous adverse reaction reports of the COVID-19 Vaccine AstraZeneca associated with Lupus related terms*. None of these 70 reports include patients with a previous history of thrombosis with low platelets or thrombosis with thrombocytopenia syndrome (VITT/TTS). Additionally, none of the 70 reports include VITT/TTS or thrombosis with low platelets reported alongside the lupus reaction as an additional adverse reaction. Please note this is based on the information provided by the reporter at the time the report was submitted to us.

You may be interested to know that the MHRA publish Yellow Card data relating to COVID-19 vaccines. The reports contain all of the UK spontaneous suspected adverse reactions reported in association with each vaccine. For the types of reactions and number of reports received, you should refer to the reaction profile which is available here: COVID-19 Vaccine AstraZeneca | Making medicines and medical devices safer (mhra.gov.uk)

In response to your final request, I can confirm the MHRA has not identified a link between lupus and any of the vaccines used in the UK following close monitoring of safety data for COVID-19 vaccines since December 2020.

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

- 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

*Acute cutaneous lupus erythematosus, Central nervous system lupus, Chronic cutaneous lupus erythematosus, Cutaneous lupus erythematosus, Lupus anticoagulant hypoprothrombinaemia syndrome, Lupus cystitis, Lupus encephalitis, Lupus endocarditis, Lupus enteritis, Lupus hepatitis, Lupus miliaris disseminatus faciei, Lupus myocarditis, Lupus myositis, Lupus nephritis, Lupus pancreatitis, Lupus pleurisy, Lupus pneumonitis, Lupus vasculitis, Lupus vulgaris, Lupus-like syndrome, Neonatal lupus erythematosus, Neuropsychiatric lupus, Pericarditis lupus, Peritonitis lupus, Subacute cutaneous lupus erythematosus, Systemic lupus erythematosus, Systemic lupus erythematosus disease activity index abnormal, Systemic lupus erythematosus disease activity index decreased, Systemic lupus erythematosus disease activity index increased, Systemic lupus erythematosus rash

alone, and when any vaccine is administered to large numbers of people, some recipients will inevitably experience illness following vaccination. The fact that symptoms occur after use of a vaccine or medicine, and are reported via the Yellow Card scheme, does not in itself mean that they are proven to have been caused by it. Underlying or concurrent illnesses may be responsible and such events can also be coincidental.

- 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. ADR reporting rates are influenced by the seriousness of ADRs, their ease of recognition, the extent of use of a particular medicine or vaccine and may be stimulated by promotion and publicity.

As these data do not necessarily refer to proven side effects, you should refer to the product information leaflet (PIL) and the Summary of Product Characteristics (SPC) which can be found here: COVID-19 Vaccine AstraZeneca UK (medicines.org.uk) for details on the known possible side effects of the COVID-19 Vaccine AstraZeneca.

The Medicines and Healthcare products Regulatory Agency (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 individually assessed and cumulative information reviewed at regular intervals. If appropriate, regulatory action would be taken if any serious risks were confirmed.

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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