Medicines & Healthcare products Regulatory Agency



MHRA

10 South Colonnade Canary Wharf London E14 4PU United Kingdom

www.gov.uk/mhra

25 August 2023

FOI 23/575

Dear

Thank you for your email dated 7th August 2023 where you requested:

"Overall how many Stevens-Johnson Syndrome cases there have been in the UK since 1st January 2021 to the present day, and how many have been attributed to the Covid-19 Vaccines. Also how many deaths from Stevens-Johnson Syndrome there have been in that period and again how many were attributed to Stevens-Johnson Syndrome."

I can confirm that the MHRA does not hold the information you have requested. The MHRA does not hold information relating to the total numbers of any specific clinical diagnoses occurring across the UK, the outcome of that clinical diagnosis or whether it has been attributed to a COVID-19 vaccine. We suggest directing your request to NHS-E who may be able to assist you further.

Suspected adverse drug reactions reported to the MHRA via the Yellow Card Scheme cannot be considered as attributed to the reported medicine or vaccine as the MHRA encourages reporting of *suspected* ADRs i.e. the reporter does not have to be sure of a causal association between the drug and the reactions – a mere suspicion will suffice.

As mentioned in our previous correspondence, the MHRA publishes information received via the Yellow Card Scheme, including for COVID-19 vaccines in the form of interactive Drug Analysis Profiles (iDAPs), which can be accessed here: <u>https://yellowcard.mhra.gov.uk/idaps</u>. The information published includes a count of reports received for each suspected adverse reaction, which includes Stevens-Johnson Syndrome, along with the numbers of reports associated with a fatal outcome (provided there are more than 5 reports).

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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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 Wilmslow Cheshire SK9 5AF

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