Medicines & Healthcare products Regulatory Agency

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Canary Wharf
London
E14 4PU
United Kingdom
www.gov.uk/mhra

[redacted]

12th September 2023

Dear [redacted]

FOI 23/609

Thank you for your Freedom of Information (FOI) request dated 12th August 2023 where you requested the statistics for:

1. **No. of UK males having an ischaemic stroke following the Moderna Vaccine (MV)**
2. **No. of healthy males having such a stroke after MV**
3. **The number of UK males over 70 having such a stroke after the MV**

In relation to question 1 and 3, you may be interested to know that the MHRA publishes the ADR data we receive in the form of interactive Drug Analysis Profiles (iDAPs), which you can find here. Regarding your specific enquiry, you can also find the iDAPs of the COVID-19 Vaccine Moderna monovalent and COVID-19 Vaccine Moderna bivalent.

Each iDAP contains a complete listing of all spontaneous suspected ADRs, or suspected side effects, that have been reported with a particular drug substance by healthcare professionals, members of the public, as well as those received from pharmaceutical companies. There are filters on the left-hand side of the page within each report that will enable you interact with the data so you can understand more about the types of reactions that have been reported, and at a high level about who experienced the side effects. Particularly, in the tab “reaction profile”, you will be able to view a full breakdown on the suspected adverse reaction reported. To view the number of reports we’ve received where an ischaemic stroke was reported, please navigate to the Reactions by System Organ Class table and expand the sections ‘Nervous system disorders', followed by ‘Central nervous system vascular disorders', and finally ‘Central nervous system haemorrhages and cerebrovascular accidents.'

With regards to question 2, unfortunately the MHRA do not hold this information. The Yellow Card scheme is a spontaneous reporting system and as such, does not hold a complete record of all the patients who received a COVID-19 vaccine. Whilst medical history is requested when filling out a Yellow Card form, it is not always provided, and we would not be able to comment on whether an individual was deemed healthy prior to having their vaccine.

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[redacted] It is a key role of the MHRA to provide doctors with advice on the safe use of medicines; however, the final responsibility for the clinical care of the patient remains with the doctor given their clinical expertise and knowledge of your medical history. [redacted] the Patient Advice and Liaison Service (PALS), which offers confidential advice on health-related issues or complaint procedures.

As you will know, 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.

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
Medicines and Healthcare products Regulatory Agency