FOI 24/152 - FOI REQUEST

MHRA Customer Services <MHRACustomerServices@mhra.gov.uk>
Tue 12/03/2024 12:06
To [redacted]>

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Dear [redacted]

Regarding your request for further information on the Moderna Spikevax vaccine, please see responses to your questions below:

1. *Clinical Trial data from Moderna Spikevax vaccine 2021-22 including total number and over what period of time this was conducted?*
2. *A breakdown of the number of participants involved by race and gender and age*
3. *A breakdown of any existing or pre-disposed morbidities or illnesses on those who participated in trials by race, gender, age*

The clinical trial data for the authorisation of the Moderna vaccine (Spikevax) have been published by the European Medicines Agency (EMA), including demographic data of the subjects included in each study. A link to the EMA's clinical data repository is provided below:

https://clinicaldata.ema.europa.eu/web/cdp/home

> Clinical trial data can also be viewed on public registries including ClinicalTrials.Gov. Please see links provided below for trials including the Moderna Spikevax vaccine between 2021-2022:

- A Study to Evaluate the Immunogenicity and Safety of Omicron Variant Vaccines in Comparison With mRNA-1273 Booster Vaccine for COVID-19 - Full Text View - ClinicalTrials.gov
- ISRCTN - ISRCTN53507177: Clinical trial studying antibody treatment combined with COVID-19 vaccination in immunocompromised individuals

4. *What were the requirements by the MHRA to fully approve the Spikevax vaccine between 2021 and 2022 ?*
5. *What parameters and standards were used to determine safety, effectiveness and quality ?*

All medicines authorised by MHRA are assessed to ensure that they have a positive benefit/risk. Further details on the specific requirements for approval of each Spikevax vaccine product can be found in the Public Assessment Reports (PARs) that are published by MHRA and the EMA. Links to these are provided below:

https://products.mhra.gov.uk/search/?search=spikevax&page=1&doc=Par&rerouteType=0

https://www.gov.uk/government/publications/regulatory-approval-of-covid-19-vaccine-moderna

https://www.ema.europa.eu/en/medicines/human/EPAR/spikevax-previously-covid-19-vaccine-moderna

6. *How many Yellow Card reports have been received about Moderna Spikevax between 2021 and 2022?*
7. *A listing of any side effects to Spikevax by age, sex, race*

We can confirm that we do hold this information however it is exempt from release under Section 21 of the FOIA (Information accessible by other means), as this is already publicly available and can be found on our website.

The COVID-19 vaccine reports contain a complete listing of all suspected adverse reactions that have been reported to the MHRA via the Yellow Card scheme for all COVID-19 vaccines including Spikevax. The reports enable users to view the data by categories of their choice such as age, sex and seriousness of reports. With regards to ethnicity, please see Table 1 below which provides the number of UK spontaneous suspected ADR reports for all Spikevax Covid-19 vaccines for each reportable ethnicity.

Table 1: UK spontaneous suspected ADR reports for all Spikevax Covid-19 vaccines per ethnicity since start of the Yellow Card Scheme until 18/02/2024

Patient ethnicity	Number of UK spontaneous ADR reports
African	145
Any other Asian background	242
Any other black background	34
Any other ethnic group	186

Any other mixed background	257
Any other white background	2,740
Bangladeshi	62
British	30,704
Caribbean	80
Chinese	265
Indian	413
Irish	497
Pakistani	157
White & Asian	237
White & Black African	65
White & Black Caribbean	120
Unknown	13,136

When considering the spontaneous adverse reaction data detailed above, 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 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.

- Yellow Card data cannot be used to determine the incidence of a reaction or to compare the side effect profiles of different vaccines in different patient sub-groups. ADR reporting rates are influenced by the seriousness of ADRs, their ease of recognition, the extent of use of a particular drug or vaccine and may be stimulated by promotion and publicity about a drug. Reporting tends to be highest for newly introduced medicines or vaccines during the first one to two years on the market and then falls over time.

- Patient ethnicity is not a mandatory field when reporting a Yellow Card and therefore is not always known.

8. *The total duration of the trials?*

Information on the duration of the clinical trial data submitted to MHRA is provided in the clinical data that has been published by the EMA, a link to this is provided above.

9. *In approving the vaccine what further information or further requests for evidence was provided and if any please provide.*

Details on any conditions of authorisation and any post authorisation clinical data submitted to MHRA are available through the PARs published by MHRA and the EMA, and through the EMA clinical data repository. Links to these have been provided in response to the questions above.

If you have a query about the information provided, please reply to this email

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 you receive this response and addressed to: info@mhra.gov.uk

Please remember to quote the reference number above in any future communications.

If you were to remain dissatisfied with the outcome of the internal review, you would have the right to apply directly to the Information Commissioner for a decision. Please bear in mind that the Information Commissioner will not normally review our handling of your request unless you have first contacted us to conduct an internal review. The Information Commissioner can be contacted at: