

FOI 23/342

RE: MHRA 9 May 2023 press release confirming "Spikevax" the Covid 19 vaccine from Moderna has been authorised for use in infants and children aged 6 months to 5 years and ongoing clinical trial

MHRA RESPONSE

13 June 2023

Dear

Thank you for your email.

Regarding the below questions:

- 1. Start and end date of the ongoing trial referred to, and**
- 2. A copy of the trial findings used to inform MHRA decision to authorise use of "Spikevax" in infants and children aged 6 months to 5 years.**

Further information on the authorisation of Moderna's Spikevax vaccine in infants/children 6 months to 5 years is available through the EMA, a link is provided below:

<https://www.ema.europa.eu/en/medicines/human/EPAR/spikevax>

Further to this, the data submitted for this authorisation has been published by the EMA and should be available in the EMA's clinical repository, link provided below:

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

Trial conducted in US and Canada

Start date: March 2021 – end planned November 2023 – see below

<https://clinicaltrials.gov/ct2/show/NCT04796896>

Regarding the trial findings, the reference to EMA is appropriate but should be more precise for customers to find the relevant EPAR.

https://www.ema.europa.eu/en/documents/variation-report/spikevax-previously-covid-19-vaccine-moderna-h-c-005791-ii-0067-epar-assessment-report-variation_en.pdf

Finally, uncommon side effects are mentioned in the SmPC.

https://assets.publishing.service.gov.uk/government/uploads/system/uploads/attachment_data/file/1155199/Spikevax_0.1-mL_SmPC_09-05-2023.pdf.pdf

If you disagree with how we have interpreted the Freedom of Information Act 2000 in answering your request, you can ask for an internal review. Please reply to this email, within two months of this reply, specifying that you would like an Internal Review to be carried out.

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:

Information Commissioner's Office
Wycliffe House
Water Lane
Wilmslow
Cheshire
SK9 5AF

Yours sincerely

MHRA Customer Experience Centre
Communications and engagement team
Medicines and Healthcare products Regulatory Agency
10 South Colonnade, Canary Wharf, London E14 4PU
Telephone 020 3080 6000