FOI 23/036

26th March 2023

Dear

Thank you for your email.

Spikevax bivalent Original/Omicron BA.1 (50 micrograms/50 micrograms)/mL dispersion for injection (PLGB 53720/0004) was authorised as a booster dose for active immunisation to prevent COVID-19 caused by SARS-CoV-2 in individuals 6 years of age and older, who have previously received at least a primary vaccination course against COVID 19 on 12 August 2022.

Spikevax bivalent Original/Omicron BA.4-5 (50 micrograms/50 micrograms)/mL dispersion for injection (PLGB 53720/0006) and Spikevax bivalent Original/Omicron BA.4-5 25 micrograms/25 micrograms dispersion for injection (PLGB 53720/0007) were authorised as booster doses for active immunisation to prevent COVID-19 caused by SARS-CoV-2 in individuals 12 years of age and older who have previously received at least a primary vaccination course against COVID 19 on 21 February 2023.

The link to the Public Assessment Report (PAR) for Spikevax bivalent Original/Omicron BA.1 (50 micrograms/50 micrograms)/mL dispersion for injection (PLGB 53720/0004) published by MHRA is provided below:
https://mhraproducts4853.blob.core.windows.net/docs/ce60c3eba417c19726286be297e61f624ac6e911

The PAR for Spikevax bivalent Original/Omicron BA.4-5 (50 micrograms/50 micrograms)/mL dispersion for injection (PLGB 53720/0006) and Spikevax bivalent Original/Omicron BA.4-5 25 micrograms/25 micrograms dispersion for injection (PLGB 53720/0007) is currently being prepared for publishing and should be published in the next 60 days.

The PARs should provide details of the studies that were assessed for authorisation of the above products.

In addition to the above, PARs published by the European Medicines Agency (EMA) are available via the below link:
https://www.ema.europa.eu/en/medicines/human/EPAR/spikevax

Further, the clinical data used for the authorisation of the Spikevax bivalent vaccines is published by the EMA and should be available via the below link:
https://clinicaldata.ema.europa.eu/web/cdp/home

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

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