Medicines & Healthcare products Regulatory Agency

10 South Colonnade
Canary Wharf
London
E14 4PU
United Kingdom
gov.uk/mhra

28 March 2024

Dear [redacted]

FOI 24/211

Thank you for your request dated 29 February 2024 which asked:

> *"Freedom of Information Request*
>
> *I have been informed in writing that covid 19 vaccination for private administration / purchase (Novavax / Nuvaxoid) are ready in Holland for shipment. However it is stated that same is "waiting for approval from the relevant authorities to ship the vaccination in to the UK to offer private individuals...."*
> *Vaccination appointments have been cancelled with no date available for re booking.*
>
> *Information Requested*
>
> *Any records, documents,, emails, file notes or other correspondence (internal or external relating to:*
>
> *1. The authorisation by any means for the import to the UK of the stated vaccine for private bookings*
> *2. The date expected or confirmed for the authorisation of the shipping to the UK of the stated vaccine for private bookings*
> *3. Any information indicating or stating the reason for the delay of the import of the vaccine."*

We have dealt with your request under the Freedom of Information Act. We will respond to each of your questions in turn.

1. *The authorisation by any means for the import to the UK of the stated vaccine for private bookings*

Our response:
Because you have asked about the 'authorisation', we confirm we hold records that Novavax have made and had an application for a Wholesale Dealer's Authorisation approved. There is a public record of the Wholesale Dealer's Authorisation available here: WDA | MHRA. In terms of the company's application, because this does *not* represent the 'authorisation' per se, we have considered the information within the application to be out of scope of your request. Please also note, if a request was made for the application, it would be likely that this information would be exempt from release under Section 41 of the FOIA, because the information was obtained in confidence.

In terms of the WDA approval there does not appear to have been a delay, according to our records the WDA was granted in 85 days, which is ahead of the statutory period.

"The licensing authority must grant or refuse an application for a licence within the period of 90 days beginning immediately after the day on which it receives the application."

Please also, note that a WDA application does not provide details regarding the 'private bookings' of this vaccine, I have only identified a single line which mentions that the vaccine will also be sold for the private sector.

"A wholesale dealer's licence does not authorise the distribution of a medicinal product by way of wholesale dealing, or possession for the purpose of such distribution, unless a marketing authorisation, Article 126a authorisation, certificate of registration or traditional herbal registration is in force in respect of the product (but this is subject to the exceptions in regulation 43(6))."

2. *The date expected or confirmed for the authorisation of the shipping to the UK of the stated vaccine for private bookings*

Our response: We do not hold any information in relation to the above question.

3. *Any information indicating or stating the reason for the delay of the import of the vaccine.*

Our response: We do not hold any information in relation to the above question. We have checked our records and we have not yet been made aware of the date that the Company intend to market the product.

Advice and assistance
We suggest contacting the MAH, Novavax, to ask about their intentions for the private market, and timelines for, if, and when, the vaccine will become available. However, please note, we cannot guarantee that the MAH would be willing to share this information.

Contact details for Novavax:
Contact us | Novavax

Please also note the below:
"Novavax XBB COVID-19 vaccine (Nuvaxovid®XBB.1.5) This updated version of Novavax's COVID-19 vaccine has been re-formulated to target the Omicron XBB.1.5 subvariant and was approved by the MHRA in December 2023. It is a protein-based vaccine containing

updated recombinant protein nanoparticles adjuvanted with Matrix-M™. This vaccine has not been used in the routine UK programme, but is expected to enter the private UK market in 2024."

Source: COVID-19 Greenbook chapter 14a (publishing.service.gov.uk)

This completes our response to your request.

Yours sincerely

HQA FOI Team
Medicines and Healthcare products Regulatory Agency
10 South Colonnade, Canary Wharf, London E14 4PU

Appeal rights
If you are dissatisfied with the handling of your request, you can ask us to conduct 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

If you remain dissatisfied with the outcome of the internal review, you 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 a request unless the requester has first asked us to conduct an internal review.

The Information Commissioner can be contacted through their online webform at: https://ico.org.uk/make-a-complaint/foi-and-eir-complaints/foi-and-eir-complaints/

Or in writing to: Information Commissioner's Office, Wycliffe House, Water Lane, Wilmslow, Cheshire, SK9 5AF