



Medicines & Healthcare products
Regulatory Agency

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Canary Wharf
London
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United Kingdom
gov.uk/mhra

[REDACTED]

7 October 2024

MHRA reference: **FOI2024/00562**

Dear [REDACTED],

Thank you for your information request, which we received on 17 September 2024.
You asked for:

"I have been monitoring with interest the availability of the new Nuvaxovid vaccine in the US. I am afraid I am struggling to find information regarding this vaccine and it's current submission status and prospects of availability within the UK as I am unfamiliar with the regulatory process involved.

Could you direct me to anything in this topic regarding the MHRA specifically? I would like to know whether their new vaccine has been submitted in the UK for approval, and when. For comparison, I would also like to know when Moderna's Spikevax was submitted for approval, as I understand from this news page that Spikevax JN.1 was approved on 2 September 2024."

We have dealt with your request under the Freedom of Information Act 2000 (FOIA).

We can confirm that the current vaccines authorised by MHRA to Novavax CZ AS are Nuvaxovid dispersion for injection COVID-19 Vaccine (PLGB 54180/0002, authorised on 03/02/2022) and Nuvaxovid XBB.1.5 dispersion for injection (PLGB 54180/0003, authorised on 24/01/2024).

Unfortunately, we cannot provide information on whether there may or may not be an application in progress for any particular product. When we need to refuse a written request for information in this way, we need to do this under the provisions of the Freedom of Information Act 2000 (FOIA) so that we include the relevant exemptions and the reasons why we are applying them. This means that for your enquiry, we need to refuse to confirm or deny whether we hold this information under Section



Medicines & Healthcare products Regulatory Agency

41(2) (S41 – information provided in confidence) and Section 43(3) (S43 – prejudice to commercial interests) of the FOIA.

We will explain these exemptions below.

Section 41 –

(2) The duty to confirm or deny does not arise if, or to the extent that, the confirmation or denial that would have to be given to comply with Section 1(1)(a) would (apart from this Act) constitute an actionable breach of confidence.

Section 43 –

(1) Information is exempt information if it constitutes a trade secret.

(2) Information is exempt information if its disclosure under this Act would, or would be likely to, prejudice the commercial interests of any person (including the public authority holding it).

(3) The duty to confirm or deny does not arise if, or to the extent that, compliance with section 1(1)(a) would, or would be likely to, prejudice the interests mentioned in subsection (2).

Public interest test

Section 17(3) of the Act requires us to conduct a Public Interest Test (PIT) when considering the neither confirm nor deny provision of a qualified exemption. In applying this exemption, we are required to consider whether, in all the circumstances of the case, the public interest in neither confirming nor denying that the information is held outweighs the public interest in confirming or denying whether the MHRA holds the information you have requested. The 'public interest' is not the same as what interests the public. In carrying out a PIT, we consider the greater good or benefit to the community as a whole in saying whether information is held or not. The 'right to know' must be balanced against the need to enable effective procedural governance and to serve the best interests of the public. The FOI Act is 'applicant blind'. This means that we cannot, and do not, ask about the motives of anyone who asks for information. In providing a response to one person, we are expressing a willingness to provide the same response to anyone.

Considerations in favour of confirming whether or not we hold the information

To confirm or deny whether or not an application has been received by MHRA would be of interest to patient groups and healthcare professionals in knowing and understanding whether a relevant treatment could soon be available to patients. It would also be of benefit in general to show transparency in MHRA's day-to-day work for the public to see what applications are currently being considered by MHRA.

Considerations in favour of neither confirming nor denying whether we hold the information

To confirm or deny whether we are currently considering an application for a particular medicine would be of great interest to rival companies who are marketing or looking to market their own products. Knowledge of whether an application is



Medicines & Healthcare products Regulatory Agency

being considered by MHRA can be used as market intelligence in order to gauge when a new product is likely to come onto the market so strategies can be employed to prevent that product getting a foothold in the market. Further, to confirm or deny that we may hold any information on applications that are not yet authorised in the UK can make companies reluctant or unwilling to submit applications for their products to the UK. This would result in fewer medicines being available for patients.

This concludes our response to your request.

If you have a query about this response, please contact us at foi.request@mhra.gov.uk

Please remember to quote the reference number at the top of this letter in any future communications. Details of your appeal rights are below.

Yours sincerely,

Healthcare, Quality and Access Group

Medicines and Healthcare products Regulatory Agency

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: foi.request@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