FOI 24/195 - URGENT - SaNOtize NASAL SPRAY

MHRA Customer Services <MHRACustomerServices@mhra.gov.uk>

Wed 13/03/2024 12:46

To [redacted]

FOI 24/195

Dear [redacted]

Regarding your below request concerning SaNOtize Nasal Spray:

“Please can you advise how much longer we have to wait for this to be Approved in the UK?”

Currently, no marketing authorisation has been granted for “SaNOtize Nasal Spray.”

Unfortunately, we cannot provide information on whether there may or may not be an application in progress for any particular product. Whether an application for a medicinal product called “SaNOtize Nasal Spray” has been received by MHRA, we neither confirm nor deny we hold information relevant to your request. Section 41(2) and Section 43(3) of the Freedom of Information Act (FOIA) absolves us from the requirement to say whether or not we hold information:

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.

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 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 create a chilling effect, with companies reluctant or unwilling to submit applications for their products to the UK. This would result in fewer medicines being available for patients.

We suggest that you contact the company that is conducting research into the use of "SaNOtize Nasal Spray" directly to ask them for an update on their plans to market the product in the UK.

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:

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

From: [redacted]
Sent: Monday, February 26, 2024 7:04 PM
To: Clinical Trial Helpline <ctdhelpline@mhra.gov.uk>
Cc: MHRA Customer Services <MHRACustomerServices@mhra.gov.uk>
Subject: FOI 24/195 URGENT - SaNOtize NASAL SPRAY
Importance: High

Dear Sir/Madam,

The first UK clinical trials of **SaNOtize Nasal Spray**, **proven to kill 99.9% of the coronavirus that causes Covid-19**, began on **January 11th 2021**, at Ashford and St Peter's Hospitals NHS Foundation Trust, in Surrey.

As it is now **3 years later**, and the results of this and other trials have been so successful, showing marked reduction of the Covid virus in those tested, Including those individuals at higher risk of severe illness and death, can you tell me **WHEN** this product is likely to be Approved for use in the United Kingdom?