Medicines & Healthcare products Regulatory Agency

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[redacted]

Our Ref: **FOI2025/00105**

26 February 2025

Dear [redacted]

Thank you for your Freedom of Information (FOI) request received on 1 February 2025. You wrote:

> *I refer to the above subject and attach article published by BBC News 30 January 2025. I note there are 2,500 UK participants in the global trial.*
>
> *I would be grateful if you could arrange to provide me with further information regarding the messenger ribonucleic acid [mRNA] Norovirus vaccine currently under trial by Moderna.*

MHRA Response
There is information already in the public domain concerning this trial, please see the links below:

UK's first norovirus mRNA vaccine tri al launched | NIHR

Study Details | A Study to Investigate the Safety and Efficacy of mRNA-1403 in Participants ≥18 Years of Age for the Prevention of Acute Gastroenteritis | ClinicalTrials.gov

For any further information specifically about "the messenger ribonucleic acid [mRNA] Norovirus vaccine currently under trial by Moderna", this information is exempt from release under Section 41 (information provided in confidence) and S43 (commercial interests) of the FOI Act.

Section 41:
(1) Information is exempt information if — (a) it was obtained by the public authority from any other person (including another public authority), and, (b) the disclosure of the information to the public (otherwise than under this Act) by the public authority holding it would constitute a breach of confidence actionable by that or any other person.

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).

Regarding the use of Section 41, information specifically on "the messenger ribonucleic acid [mRNA] Norovirus vaccine currently under trial by Moderna", was given to MHRA on the

expectation that it would not be released. As such, the Agency believes that if this information were released it would be an actionable breach of confidence. Therefore, we are not going to be releasing the requested information.

Regarding the use of Section 43, this exempts information which if disclosed would be likely to prejudice the commercial interests of any person, including a public authority. This information falls into this category. In order to apply Section 43 properly, a consideration of the public interest (public interest test) is required.

Public interest test
Section 17(3) of the Act requires us to conduct a Public Interest Test (PIT) when applying 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 withholding the information outweighs the public interest in releasing the information held. 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 withholding. 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 releasing the information
To release this information would benefit in general by showing transparency in MHRA's day-to-day work to the public and for the public to see all information about the vaccine used in this trial.

Considerations in favour withholding the information
Information on this vaccine is commercially sensitive and would be considered trade secrets that would cause commercial harm if they were released. To publish this information would provide competitors with information that could be used to develop their own clinical trials or pharmaceutical development of a rival product at the expense of the sponsor of this clinical trial. Further, to release this information could make companies reluctant or unwilling to submit applications for their clinical trials to the UK. This would result in fewer clinical trials being performed in the UK.

On balance we are satisfied that, in this instance, the public interest in applying the exemption outweighs the public interest in disclosure.

If you have any queries about this letter, please contact us quoting the reference number above.

Yours sincerely,

MHRA Central Freedom of Information Team
Medicines & Healthcare products Regulatory Agency

Your right to complain under the Freedom of Information Act

If you are not happy with this response you may request an internal review by e-mailing foi.request@mhra.gov.uk or by writing to: MHRA Central Freedom of Information Team, 10 South, Colonnade, Canary Wharf, London, E14 4PU

Any request for an internal review must be received by us within 40 working days of the date of this letter. Please note we are not obliged to provide a review if it is requested after more than 40 working days.

If you are not content with the outcome of the internal review, you may apply directly to the Information Commissioner's Office for a decision. Generally, the Commissioner cannot make a decision unless you have exhausted our own complaints procedure. The Information Commissioner can be contacted at: The Information Commissioner's Office, Wycliffe House, Water Lane, Wilmslow, Cheshire SK9 5AF.
Website: ICO FOI and EIR complaints or telephone 0303 123 1113.

Re-use of our information
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