Medicines & Healthcare products Regulatory Agency

MHRA Central Freedom of Information Team
10 South Colonnade
Canary Wharf
London
E14 4PU

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MHRA Website

[redacted]

Our Ref: **FOI2026/00476**

29 June 2026

Dea[redacted]

Thank you for your Freedom of Information (FoI) request received on 30 April. You wrote:

> *I would like to submit a FOIA request for information relating to three clinical trials performed in the UK.*
>
> *I am specifically interested in the investigative medicinal product dossiers (IMPD) submitted in support of trials EudraCT 2019-002352-17, NCT 03652363 and EudraCT 2013-001881-40. I am also interested in any supportive preclinical data.*

MHRA Response

The Agency has completed its search for the information you have requested and we are able to confirm that do hold the information you have requested.

A redacted copy of the Investigators Brochure (IB) for EudraCT 2019-002352-17 is attached as an annex.

However, some of the information you requested is being withheld as it falls under the exemption in Section 43(2) of the FoI Act:

- EudraCT 2019-002352-17 product dossier (IMPD) and Investigators Brochure (IB)
- NCT 03652363 product dossier (IMPD) and Investigators Brochure (IB)
- EudraCT 2019-002352-17 product dossier (IMPD)

Section 43(2) exempts information which, if disclosed, would be likely to prejudice the commercial interests of any person including a public authority. It protects not only the commercial interests of third parties but also the commercial interests of the Agency. It is intended to protect the ability of a public authority like MHRA to obtain goods or services on the best possible commercial terms and to protect the legitimate commercial interests of its suppliers. The information you seek falls into this category.

In this instance we feel that the release of this information could put commercial interest at risk.

As required by the FoI Act the use of this exemption requires the public interest for and against disclosure to be assessed.

We recognise that there is a public interest in the disclosure of commercial information relating to clinical trials of Parkinsons Disease. However, when considering arguments against disclosure, including the potential commercial harm by releasing these documents which are still under external legal agreements. We have sought third party representations and received strong objections to the release of the information.

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.

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Yours sincerely,

MHRA Central Freedom of Information Team
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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