Medicines & Healthcare products Regulatory Agency

MHRA Central Freedom of Information Team
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London
E14 4PU

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MHRA Website

[redacted]

Our Ref: **FOI2026/00716**

4 August 2026

Dear [redacted]

Thank you for your Freedom of Information (FoI) request received on 3 July. You wrote:

> *I am writing to request information under the Freedom of Information Act 2000.*
>
> *Previously, I requested information via FOI2026/00625, but was told my request was not specific enough and would not fall within the costs limit.*
>
> *I would like to make a revised request relating to CTA 56887/0001/001.*
>
> ** All formal submissions to the MHRA relating to safety and any MHRA response for the clinical trial CTA 56887/0001/001.*
> ** Final copies of the clinical trial documents (e.g. protocol, Investigator's Brochure) for the clinical trial CTA 56887/0001/001.*
>
> *I appreciate the cost limit is in place, but if both these aspects exceed the limit, could I please have as much relevant documentation as would be possible within the £600 limit.*

MHRA Response

All formal submissions to the MHRA relating to safety and any MHRA response
We can confirm that the Agency holds the information you are seeking. However, we are engaging an exemption from disclosure under Section 30 of the FoI Act, which protects information as part of ongoing Investigations and Proceedings Conducted by Public Authorities.

We recognise that the there is a public interest in releasing this information particularly given that a participant died during the course of the study. Disclosure promotes transparency and accountability in the regulation and conduct of clinical trials and may increase public confidence in the regulatory system.

However, on this occasion we feel that these factors when balancing the public interest test are outweighed due to the integrity of the investigation and risk of reduced compliance from individuals/organisations by releasing information before an investigation is concluded.

Final Copies of the clinical trial documents

We are unable to provide you with some of the information requested as it constitutes personal data of someone other than yourself and as such, it is being withheld in accordance with section 40(2) of the Freedom of Information Act.

Section 40(2) exempts information in response to a request if it is personal data belonging to an individual other than the requester and it satisfies one of the conditions listed in the legislation. In this case the condition contained in section 40(3A)(a) applies - that disclosure would breach one of the data protection principles, specifically that "Personal data shall be processed lawfully, fairly and in a transparent manner...".

We do not consider that disclosing this information is necessary or justified in order to satisfy your information request and the requirements of the FoI Act. In relation to this request, we consider that there is no strong legitimate interest that would override the prejudice to the rights and freedoms of the data subject.

Please note that this exemption has only been applied to personally identifiable information (PII) within the documents provided (e.g. names and contact details) and has not been used to redact whole documents.

In addition to the section 40(2) exemption detailed above (only PII), some of the information you have requested is commercially sensitive and is therefore exempt from release under Section 43(2) of the FoI Act.

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. Some of the information you seek falls into this category.

We feel that the release of this information could prejudice further commercial work on this compound by new owners. We have considered the position that the company is no longer trading and applied redactions that we feel appropriate in this circumstance.

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 information relating to this trial, particularly given that a participant died during the course of the study. Disclosure promotes transparency and accountability in the regulation and conduct of clinical trials and may increase public confidence in the regulatory system.

However, we consider that the public interest in disclosure is largely met through the release of the remaining documentation associated with the trial. The withheld documents, the Investigational Medicinal Product Dossier (IMPD) & Investigational Brochure (IB), contain detailed information relating to the development, manufacture, formulation and control of the investigational medicinal product. Whilst the original sponsor is no longer trading, disclosure under the Freedom of Information Act is effectively disclosure to the world at large and could prejudice any ongoing or future commercial development of the compound or related intellectual property by current or future rights holders.

We have carefully considered whether disclosure of the IMPD and IB would contribute to a better understanding of the participant fatality or the decisions taken by the MHRA in relation to the trial. We do not consider that it would provide any material additional insight into the

circumstances of the fatality beyond that available from the information being disclosed. In these circumstances, we conclude that the public interest in maintaining the exemption outweighs the public interest in disclosure, and therefore Section 43(2) applies to the withheld information.

On balance we are satisfied that, in this instance, the public interest in applying the exemption outweighs the public interest in disclosure for the IMDP and IB document.

Please see the table below for details of the documents that were in scope of your request for clinical trial documentation:

Document	**Exemption Details**
Bottle Label	Only PII Removed – Section 40(2)
GMP Certificate	Released in Full
GMP Statements	Only PII Removed – Section 40(2)
IB Version 7.0	Withheld in full – Section 43(2) Exemption
IMDP Dexpramipexole Version 7.0	Withheld in full – Section 43(2) Exemption
Protocol Global Amendment 3	PII & Commercially Sensitive Removed – Sections 40(2) & 43(2)
QP Declaration	Only PII Removed – Section 40(2)

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
The MHRA information supplied in response to your request is subject to Crown copyright. Information created by the MHRA which is disclosed under the Freedom of Information Act is made available for re-use under the Open Government Licence (OGL) v3.0, except where this is otherwise stated. There are some restrictions on re-use under the OGL and these can be viewed here:

https://www.nationalarchives.gov.uk/doc/open-government-licence/version/3/