

FOI 24/039 - RE: FOI request

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

Fri 09/02/2024 16:12

To [Redacted]

2 attachments (4 MB)

GREAT ORMOND STREET HOSPITAL Zayed GMPReport Insp IMP 1732823930512-005 redacted.pdf; GMPReport_Cellular Therapies 17328-2091287-0004 redacted and issued on 20 Dec 2022.pdf;

FOI 24/039

Dear [Redacted]

Thank you for your request for information date Friday, January 12, 2024, where you asked:

“Please can you send the last two GMP inspection reports for

UK MIA(IMP) 17328	GREAT ORMOND STREET HOSPITAL FOR CHILDREN NHS FOUNDATION TRUST	<ul style="list-style-type: none"> • ZAYED CENTRE FOR RESEARCH INTO RARE DISEASE IN CHILDREN, 20 GUILFORD STREET, LONDON, WC1N 1DZ, UNITED KINGDOM • GREAT ORMOND STREET HOSPITAL FOR CHILDREN NHS FOUNDATION TRUST, GENE AND STREET CELL THERAPY, GREAT ORMOND STREET, LONDON, WC1N 3JH, UNITED KINGDOM 	Investigational	16/10/2023
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Our response

We have located the two most recent GMP inspection reports for each site detailed in your request.

Please find these documents attached. Redactions have been made to these documents under the below Sections of the FOIA.

• Section 40 – This information contains elements of personal data, the disclosure of which would be unfair in that it would breach the first principle of the Data Protection Act which says that information must be processed fairly and lawfully.

• Section 43(2) – Release of all, or part of, the information would, or would be likely to, cause harm to the third party's commercial interests.

We have considered the balance of the public interest when applying this exemption. The exemption is to safeguard the commercially sensitive information / industrial secrets of a third party / commercial enterprise (which can include a Government Department). This exemption is conditional on the public interest in releasing it not outweighing the company's/commercial enterprise's right to confidentiality and the probable damage that the company/commercial enterprise could suffer as a result of the information being released. In this case we have not identified any issues which would benefit the public as a whole by being brought to their attention (examples of issues would be a major public health risk or a major procedural failure or irregularity) .

Please note the GMP report for Cellular Therapies at GOSH has previously been released through FOI. However, for ease we attached the report to this email.

We trust that you will find these reports useful. Nonetheless, if you disagree with how we have interpreted the Freedom of Information Act 2000 in answering your request, you can ask us to review our actions and decisions by writing to: info@mhra.gov.uk, and requesting an internal review.

Please note that your internal review request must be in a recordable format (email, letter, audio tape etc.), and that you have 40 working days upon receipt of this letter to ask for a review. We aim to provide a full response to your review request within 20 working days of its receipt. Please quote the reference number above in any future communications.

If you are not content 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 online via an electronic form: <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

Yours sincerely,

MHRA Customer Experience Centre
Communications and engagement team
Medicines and Healthcare products Regulatory Agency
10 South Colonnade, Canary Wharf,
London E14 4PU
Telephone 020 3080 6000

From: [REDACTED]
Sent: Friday, January 12, 2024 11:01 AM
To: FOILicensing <FOILicensing@mhra.gov.uk>
Subject: FOI request

Dear MHRA

Please can you send the last two GMP inspection reports for

		<ul style="list-style-type: none">• ZAYED CENTRE FOR RESEARCH INTO RARE DISEASE IN CHILDREN, 20 GUILFORD STREET, LONDON, WC1N 1DZ, UNITED KINGDOM• GREAT ORMOND STREET HOSPITAL FOR CHILDREN NHS FOUNDATION TRUST, GENE AND		
UK.MIA(MP).17328	GREAT ORMOND STREET CELL THERAPY, GREAT ORMOND STREET, HOSPITAL FOR CHILDREN NHS FOUNDATION TRUST	LONDON, WC1N 3JH, UNITED KINGDOM	Investigational	16/10/2023

Thanks [REDACTED]

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