FOI 24/044

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

Fri 09/02/2024 16:18

To [redacted]

1 attachments (2 MB)

Inspection report - Parexel International Limited- 30th Nov 2021.pdf;

FOI 24/044

Dear [redacted]

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

> "Please could you supply copies of any Inspection Reports arising from MHRA GMDP Inspections conducted within the last 5 years at the following site?
>
> PAREXEL INTERNATIONAL LIMITED, CLINICAL PHARMACOLOGY RESEARCH UNIT, LEVEL 7, NORTHWICK PARK HOSPITAL,
> WATFORD ROAD, HARROW, HA1 3UJ, UNITED KINGDOM
> UK MIAIMP 12689"

Our response

We have located one GMP inspection report prepared in response to inspections conducted in the last 5 years for the site listed in your request.

Please find this documents attached. Redactions have been made to this document 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 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 6:57 PM
To: MHRA Customer Services <MHRACustomerServices@mhra.gov.uk>
Subject: FOI 24/044 - FOI Request: MHRA GMP Inspection Report for

Please could you supply copies of any Inspection Reports arising from MHRA GMDP Inspections conducted within the last 5 years at the following site?

PAREXEL INTERNATIONAL LIMITED, CLINICAL PHARMACOLOGY RESEARCH UNIT, LEVEL 7, NORTHWICK PARK HOSPITAL,
WATFORD ROAD, HARROW, HA1 3UJ, UNITED KINGDOM
UK MIAIMP 12689

Thank you,

[redacted]