Medicines & Healthcare products Regulatory Agency

[redacted]

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

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MHRA Website

Our Ref: **FOI2025/01018**

15 October 2025

Dea[redacted]

Thank you for your Freedom of Information (FoI) request received on 18 September. You wrote:

> *I am writing to make a formal request under the Freedom of Information Act 2000 for access to documentation relating to an MHRA report concerning:*
>
> *Organisation: Cambridge University Hospitals NHS Foundation Trust*
> *Department: Addenbrookes Hospital Radio pharmacy*
> *Inspection Date: 26 - 27th March 2025*
>
> *Background and Context*
>
> *I am a UNISON union rep representing* [redacted] *an employee of Cambridge University Hospitals NHS Foundation Trust who is currently facing serious disciplinary allegations of gross incompetence.*
>
> *These allegations are directly based on findings and outcomes contained within an MHRA report relating to the Radiopharmacy department of the trust.*
>
> *The Trust has provided a copy of what they identify as the relevant MHRA report, however, this has been significantly redacted. Given the severity of the allegations against my member - which could result in immediate dismissal and referral to professional regulatory bodies - it is essential that we have access to the complete evidence upon which these allegations are founded.*
>
> *Specific Information Requested*
>
> *Under the Freedom of Information Act 2000, I formally request:*
>
> * *Copy of the MHRA Post-Inspection Letter relating to Cambridge University Hospitals NHS Foundation Trust concerning Radiopharmacy department Inspection dated approximately 26 - 27th March 2025*
> * *All supporting documentation that formed part of the MHRA's investigation and findings, including:*

1. *Investigation notes and records*
2. *Correspondence with the Trust*
3. *Expert assessments or technical evaluations*
4. *Any follow-up reports or monitoring documents*

* *Explanation of any information that MHRA considers must remain redacted, including:*

Legal basis for such redactions

* *Whether redacted material contains any findings that could be relevant to individual staff performance assessments*

Public Interest Considerations
This request is made in the public interest for the following reasons:

Fair Process: An employee facing career-ending allegations based on an MHRA report has a legitimate right to see the complete findings that form the basis of those allegations.
Transparency: The proper use of MHRA reports in disciplinary processes requires transparency about what the reports actually contain and conclude.
Accountability: Public bodies should be held accountable for how they interpret and apply regulatory findings in employment decisions.
Natural Justice: The principles of natural justice require that individuals have access to evidence being used against them in serious proceedings.

Legitimate Interest
I have a legitimate interest in this information as:

* *The authorised representative of the affected employee*
* *The report is being used as primary evidence in disciplinary proceedings*
* *My member's professional registration and career are at risk*
* *We need to ensure the Trust's interpretation of the report is accurate and complete*

Format and Delivery
I would prefer to receive this information electronically via email. If the information is extensive, please provide it in searchable PDF format or contact me to arrange alternative delivery methods.

Data Protection
I understand that you may need to consider data protection obligations in responding to this request. However, I would highlight that:

* *This information relates directly to disciplinary proceedings involving my member*
* *We have a legitimate interest in accessing evidence being used against our member*
* *Any third-party personal data could be redacted where genuinely necessary*
* *The serious nature of the allegations justifies disclosure in the interests of fairness*

This request is made to ensure that serious disciplinary allegations based on MHRA

findings are founded on complete and accurate information. The public interest in fair employment processes and the proper use of regulatory reports strongly supports full disclosure of this information.

MHRA Response
Under Section 14(1) of the FoI Act, public authorities are not obliged to comply with a request which is deemed vexatious. By way of clarification, it is the request which is treated as vexatious not the person making the request.

A request may be treated as vexatious, if the amount of time required to review and prepare the information for disclosure would impose a grossly oppressive burden on the organisation.

A vexatious request is assessed with reference to all the circumstances of an individual case. There are four broad themes to consider when looking at whether an FoI request(s) is vexatious. These four themes are:

1. the burden (on the public authority and its staff);
2. the motive (of the requester);
3. the value or serious purpose (of the request); and
4. any harassment or distress (of and to staff).

These four broad themes are not a checklist, and they are not exhaustive they simply emphasise that a range of factors need to be considered when applying Section 14(1).

In this case, the Agency is treating your request as vexatious because of the burden that would be placed on MHRA and its staff in fulfilling the request in its entirety.

In order to fulfil the request, staff would be required to locate and prepare the numerous documents listed in your request. These documents, particularly with regard to the investigation notes and records, are not currently held in an easily accessible format. Once located and retrieved, we would then need to go through each of the documents page by page to see if any information in those documents needs to be redacted under sections of the FOIA. We may be required to consult with the inspected site, who may ask for additional information in those documents to be withheld under sections of the FOIA that we would need to consider. This process would require a significant amount of staff time to prepare the documents for release, which would prevent staff in the Standards & Compliance team from carrying out their current inspection-related duties.

On this basis, the Agency has decided that Section 14(1) of the FoI Act applies on this occasion.

Advice and Assistance
We recommend that you reduce the scope of your request to the initial part of your request for a copy of the MHRA Post-Inspection Letter.

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/