Medicines & Healthcare products Regulatory Agency

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

foi.request@mhra.gov.uk.

MHRA Website

[redacted]

Our Ref: **FOI2026/00791**

13 August 2026

Dea[redacted]

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

> *Dear FOI Officers and Information Governance Directorate,*
> *Under the provisions of the Freedom of Information Act 2000, and in explicit reference to my formal communications previously sent to your agency regarding this matter, I hereby issue this notice for immediate administrative disclosure regarding the specific handling, routing, and archive storage of my technical clinical trial alerts.*
>
> *1. Scope of the Request*
> *I require the MHRA to produce and disclose a comprehensive, unedited chronological list of all emails, data packages, and attached technical files received by, sent from, or routed through any MHRA corporate server on, before, or after 30 August 2023, up to and including 18 July 2026, which contain, reference, or are systematically indexed under the file track*[redacted]
>
> *To ensure no historical administrative entry points are omitted, this search boundary explicitly mandates the extraction of all legacy system interactions occurring prior to the formal creation of the case track, alongside all subsequent communications.*
>
> *Crucially, the MHRA Information Governance team is explicitly notified that the Sequenced Evidence Log appended below is a targeted chronological map and is not an exhaustive list of my total historical transmissions. The server database audit must sweep for all matching corporate records, regardless of whether they appear in the illustrative log below.*
>
> *To assist your technical teams with the database query and prevent any claim of administrative over-burden under Section 12 of the Act, the search parameters are strictly defined as follows:*
> • *Primary System Index Key:* [redacted]
> • *Target Inboxes/Repositories/Internal Channels: clintrialhelpline@mhra.gov.uk, the MHRA Internal Fraud Office repository, internal staff-to-staff messaging architectures, and the historic Executive Office archives of the former Chief Executive.*
>
> *2. Specific Metadata Fields Required*

For each matching communication discovered on your live and archived servers (including all internal correspondence), the disclosed chronological list must explicitly display:
1. The exact Server Arrival/Transmission Timestamp (Greenwich Mean Time / British Summer Time).
2. The complete Internet Protocol (IP) Routing Header Data showing internal transfer paths.
3. The specific Internal Folder Classification or archive status (e.g., "Active", "Sidelined", "Forwarded", "Internal Only", or "Deleted").
4. The Recipients' Mailbox Addresses within the MHRA infrastructure who were granted access permissions to these files.

3. Statutory Compliance and Public Interest
This request directly addresses structural regulatory governance, the integrity of active Marketing Authorisation Application (MAA) dossiers, and potential executive-level diversion of public safety alerts. Because this data concerns systemic clinical trial data validation parameters, the public interest in absolute transparency heavily outweighs any commercial or qualified exemptions.

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 it seeks information of a frivolous nature; if it is likely to cause distress or irritation without justification; or if it is aimed at disrupting the work of an authority or is harassing individuals in it; 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 apply Section 14(1).

In this case, the Agency considers that complying with your request would impose a grossly oppressive burden on its resources. The request captures approximately 1,000 emails in scope, each of which would need to be individually reviewed and, where applicable, redacted before the information could be disclosed. This would require a substantial commitment of staff time and resources and would significantly divert staff from their duties and the Agency's wider statutory and operational functions.

Having considered all the circumstances of the request, the Agency considers that the resources required to review and prepare approximately 1,000 emails for disclosure would impose a grossly oppressive burden on its staff and significantly impact on its ability to undertake its core functions.

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

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/