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: **FOI2026/00661**

07 July 2026

Dear [redacted]

Thank you for your Freedom of Information (FoI) request received on 22 June. You wrote:

> *I would be grateful if you could provide copies of all finalised Pharmacovigilance inspection reports from PV inspections conducted by the MHRA between 01-Jan-2025 to 01-Jun-2026. PDF PV inspection reports can be redacted for company proprietary information i.e. EU QPPV details and finding responses/CAPA plans.*

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 apply Section 14(1).

In this case, the Agency is treating your request as vexatious for the following reasons:

We have identified 33 completed inspections related to the period cited in your request (01 January 2025 to 01 June 2026).

Based on our knowledge of pharmacovigilance inspection reports we estimate the average length of these reports to be ~50 – 60 pages. However, some reports can be much greater in

length. Of the reports identified, 25 of the 33 have not previously been released into the public domain.

Before we release inspection reports, we have to consider redactions which are made to discrete pieces of information within the reports; this is a manual process and a rapid/ automated method to complete this process does not exist. Due to the risk of human error, a QA check also takes place on the draft redactions which, while necessary, nonetheless places an additional burden on our resources.

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

Advice and assistance
If you wish to make a new request, please narrow the scope, for example by limiting the request to a maximum of 5 GPvP reports from the attached list.

Please note, there were 12 additional inspections conducted within the specified timeframe, but their details are not provided in the attached list as the inspections are not yet closed out. Inspection reports for these inspections are exempt from release according to Section 43(2) (Commercial interests) of the FoI act. Section 43(2) is engaged to withhold inspection reports when the inspection findings are currently subject to an on-going regulatory procedure. The reports may include omissions or inaccuracies that would be likely to cause commercial harm. We perceive the public interest to be best served by with-holding the reports until the regulatory procedure is finalised. The reports will then be available to request through FOI.

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