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: **FOI2026/00921**

01 September 2026

Dear [redacted]

Thank you for your Freedom of Information (FoI) request received on 31 July. You wrote:

> *I am writing with a general enquiry about MHRA policy and procedure. This is not a request under the Freedom of Information Act and is not case-specific.*
>
> *I would be grateful if you could tell me, or point me to where the following is published:*
>
> *1. How MHRA assesses an allegation that a person has concealed information or products from, or otherwise deliberately misled, an MHRA inspector.*
>
> *2. Whether there is a procedure or threshold governing referral of such allegations from the inspectorate to the Criminal Enforcement Unit.*
>
> *3. The definition of "for cause inspection" applied by the Agency, and the circumstances in which a for-cause inspection is conducted following receipt of intelligence alleging unlicensed activity.*
>
> *4. The criteria applied in deciding whether alleged breaches of the Human Medicines Regulations 2012 are addressed through compliance measures rather than enforcement action.*

**MHRA Response**
We have answered each of your questions below:

*1. How MHRA assesses an allegation that a person has concealed information or products from, or otherwise deliberately misled, an MHRA inspector.*

We do not hold a written procedure on this and this information is not published. The MHRA assessment of such allegations would be considered on case-by-case basis.

*2. Whether there is a procedure or threshold governing referral of such allegations from the inspectorate to the Criminal Enforcement Unit.*

We do not hold a written procedure on this and this information is not published.

*3. The definition of "for cause inspection" applied by the Agency, and the circumstances in which a for-cause inspection is conducted following receipt of intelligence alleging unlicensed activity.*

A 'for cause' inspection occurs a result of a specific signal being brought to the attention of the agency. They are not restricted to an unlicensed activity and usually take place as a result of actual or alleged non-compliance issues at licensed premises.

*4. The criteria applied in deciding whether alleged breaches of the Human Medicines Regulations 2012 are addressed through compliance measures rather than enforcement action.*

There are no set criteria for determining this. In general, compliance measures are conditions that are implemented where significant and major concerns are raised through inspection. The MHRA Criminal Enforcement Unit may become involved when there is evidence that illegal activity has occurred.

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

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**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.

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