



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](https://www.mhra.gov.uk)

Our Ref: **FOI2026/00769**

17 July 2026

Dear [REDACTED]

Thank you for your Freedom of Information (Fol) request received on 15 July. You wrote:

Please provide the following:

- *the number of times statutory powers were exercised to require the disclosure of documents or information in connection with enforcement action or enforcement investigations;*
- *the number of times statutory powers were exercised to compel individuals to attend interviews in connection with enforcement action or enforcement investigations; and*
- *the number of inspections of physical premises undertaken in connection with enforcement action or enforcement investigations.*

MHRA Response

We are unable to deal with your Fol request without clarification of the information you seek. The reason for this is that your request is very broad.

Under Section 16 of the Fol Act we should assist you in helping you focus your request. For example, you could narrow your request to a specific area such as inspections made under Good Distribution Practice or Good Manufacturing Practice regulations, or Criminal Investigations, focusing on a defined period of time.

It may assist you further to explain how the MHRA takes enforcement action. There are two types of enforcement action, regulatory and criminal.

Regulatory enforcement action may be undertaken by MHRA inspectors conducting inspections of businesses that hold MHRA issued licences. Issues relating to compliance may be addressed by inspectors through advice and guidance in inspection reports, conditions or restrictions placed on licences, or revocation of licenses where appropriate.

The MHRA does have statutory powers to require the production of documents and information when carrying out certain inspection functions and investigations, although the precise power depends on the regulatory regime involved (medicines, medical devices, clinical trials, etc.)

The MHRA also has a Criminal Enforcement Unit that deals mostly with medicine related crime. Criminal Investigators have the same powers of entry, inspection and seizure as regulatory inspectors. Legal powers are set out in relevant legislation. The MHRA's regulatory and criminal investigators cannot compel individuals to attend interviews.

It will greatly assist us to answer your final point if you can focus on the number of inspections (within a defined period of time) of physical premises undertaken in relation to either regulatory or criminal enforcement activity. Please also indicate the regime you are most interested in; medicines, medical devices, clinical trials, etc.

We will consider any revised request however we cannot guarantee that any revised request will fall within the cost limit.

We recommend that you familiarise yourself with the Information Commissioners Office guidance on how to submit an FOI to a public authority. We have provided these links below to aid in future requests:

<https://ico.org.uk/for-the-public/official-information/preparing-and-submitting-your-information-request/>

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](https://ico.org.uk/for-the-public/official-information/preparing-and-submitting-your-information-request/) or telephone 0303 123 1113.

Re-use of our information

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<https://www.nationalarchives.gov.uk/doc/open-government-licence/version/3/>