Medicines & Healthcare products Regulatory Agency

MHRA Central Freedom of Information Team
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MHRA Website

[redacted]

Our Ref: **FOI2026/00599**

23 July 2026

Dea[redacted]

Thank you for your Freedom of Information (FoI) request received on 4 June. You wrote:

> *This is a single, standalone request under the Freedom of Information Act 2000, submitted in narrowed form in accordance with the advice and assistance you gave in your internal review IR2026/00360 dated 30 April 2026.*
> *Purpose and validity of this request*
> *This request supports an active complaint to the Parliamentary and Health Service Ombudsman, referred through [redacted] concerning MHRA's handling of my protected disclosure [redacted] MHRA's Administrative Complaints Officer directed me to the PHSO on 12 March 2026, and the Customer Experience Centre confirmed this route on 26 March 2026. The information sought is necessary documentary evidence for that live complaint.*
> *This request cannot be refused under section 14(1). It is a single request, made in isolation, more than 60 working days after the requests aggregated in IR2026/00360, so no aggregation arises under regulation 5 of the Freedom of Information and Data Protection (Appropriate Limit and Fees) Regulations 2004. In Information Commissioner v Devon County Council and Dransfield [2012] UKUT 440 (AAC), the Upper Tribunal held that the test for vexatiousness turns on whether a request lacks adequate purpose or value and amounts to a manifestly unjustified or improper use of the Act. This request has a clear and serious purpose: it provides evidence for a live statutory complaint, supported by a Member of Parliament, concerning the supply of prescription-only medicines from unlicensed premises to NHS harm reduction contracts. It is the antithesis of a vexatious request.*
> *Request*
> *I request the following recorded information held by MHRA in relation to case [redacted] limited to the period 10 July 2025 to 1 September 2025:*
>
> *1. Any record of a compliance commitment, undertaking or assurance given by [redacted] including its terms and the date given, and any record of steps taken by MHRA to verify or monitor compliance with it.*
> *2. Any record of the decision whether to conduct a for-cause inspection of [redacted] following receipt of the disclosure on 10 July 2025, including any recorded reason for the decision taken.*
> *3. The records documenting the basis for the assessment, referred to in MHRA's FOI response FOI2025/00930, that "the downstream impact to patients due to medicines*

availability was considered to outweigh" the regulatory risk, including any risk assessment underlying the decision of 1 September 2025 to take no further action.
To assist location and retrieval within the cost limit, please confine the search to recorded information held by the GDP Inspectorate and the Compliance team handling [redacted]
Format
Emails, case management records, risk assessments, file notes and internal communications as defined by section 84 FOIA.
Processing
Please comply with sections 1 and 10 FOIA. If you consider the section 12 cost limit is likely to be exceeded, I ask that, consistent with your section 16 duty and the advice you gave in IR2026/00360, you contact me to agree further narrowing before issuing any refusal. Where information is withheld, please specify the exemption relied upon and, for any qualified exemption, provide the public interest test.

MHRA additional ad-hoc response

Following our initial reply to FOI2026/00599 a member of staff, on returning from long-term leave, located further information which we have on balance considered to be within the scope of your request. However, this balance was by no means clear cut, but ultimately a decision was made to release the information:

- in case these emails happen to useful to you and to further your understanding of regulatory decisions
- in the spirit of further / greater disclosure of information.

We provide 5 pages of emails which are too recent to have been disclosed as part of one of your previous requests (FOI 2025/00930).

The emails are considered to loosely fall within the scope of question 2. of your FOI request FOI 2026/00599. However, we wished to highlight that the attached messages relate to inspection decisions which do not fall within the technical meaning of a “for cause inspection”. Nonetheless, as is mentioned above, in the spirit of your request, we believe this information may be of interest to you. The information would better align with the intention for a triggered inspection i.e. if and when the Roman’s building site is registered.

We can confirm that the Agency holds some further information, and we release this with a small number of redactions made under Section 43(2), and Section 40(2).

Basis for redactions made under Section 43(2)
However, the information you have requested is commercially sensitive and is therefore exempt from release under Section 43(2) of the FoI Act.

Section 43(2) exempts information which, if disclosed, would be likely to prejudice the commercial interests of any person including a public authority. It protects not only the commercial interests of third parties but also the commercial interests of the Agency. It is intended to protect the ability of a public authority like MHRA to obtain goods or services on the best possible commercial terms and to protect the legitimate commercial interests of its suppliers. The information you seek falls into this category.

In this instance, in a similar manner to redactions made for FOI 2025/00930, we feel that the release of this information could be used to undermine commercial interests of a third party.

As required by the FoI Act the use of this exemption requires the public interest for and against disclosure to be assessed.

We recognise that there is a public interest in the disclosure of commercial information relating to contractual agreements and quality management. However, these are technical aspects are expected to attract only a very slim / negligible public interest.

However, when considering arguments against disclosure. Competitors would be likely to use this information to gain what is expected to be a small commercial advantage. While we recognise that if the information was to be released to the public domain it would be unlikely to have a major commercial impact, as mentioned about we perceive the public interest in this information to be slim to negligible. Therefore, on balance, the public interest gives way to the real risk of commercial harm.

On balance we are satisfied that, in this instance, the public interest in applying the exemption outweighs the public interest in disclosure.

Basis for redactions made under Section 41(1)
Section 41(1) of the FoI Act has also been engaged, this exemption from disclosure under protects information provided in confidence. The information you have requested relates to information which was obtained by the Agency from another person and the Agency believes that if this information would be released it would breach the confidence of the person(s) the information pertains to, actionable by them or any other person. Therefore, we are not going to be releasing the requested information

If you have any queries about this letter, please contact us quoting the reference number above.

Basis for redactions made under Section 40(2)
We are unable to provide you with some of the information requested as it constitutes personal data of someone other than yourself and as such, it is being withheld in accordance with section 40(2) of the Freedom of Information Act.

Section 40(2) exempts information in response to a request if it is personal data belonging to an individual other than the requester and it satisfies one of the conditions listed in the legislation. In this case the condition contained in section 40(3A)(a) applies - that disclosure would breach one of the data protection principles, specifically that “Personal data shall be processed lawfully, fairly and in a transparent manner...”.

We do not consider that disclosing this information is necessary or justified in order to satisfy your information request and the requirements of the FoI Act. In relation to this request, we consider that there is no strong legitimate interest that would override the prejudice to the rights and freedoms of the data subject.

Personal data are subject to UK General Data Protection Regulation (UK GDPR) and the Data Protection Act 2018

MHRA maintains the following policy on disclosure of personal information:

"All personal information held in MHRA records is regarded as confidential. Information will not normally be disclosed to third parties without the consent of the person concerned. Information may normally be disclosed without consent to meet statutory requirements; to comply with a court order; to prevent duplication of payments from public funds; or where there is a compelling public interest in making the disclosure."

All disclosures made by MHRA, in order to be considered authorised must be able to demonstrate that at least one of the above criteria apply.

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/