Medicines & Healthcare products Regulatory Agency

[redacted]

MHRA Central Freedom of Information Team
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MHRA Website

Our Ref: **FOI2026/00466**

19 May 2026

Dear [redacted]

Thank you for your Freedom of Information (FOI) request received on 20 April 2026. You wrote:

> *We are continuing to take our client's instructions on the substantive issues raised in your letter of 2 April and in the MHRA's earlier correspondence and will respond on those matters as soon as we are in a position to do so.*
>
> *In the meantime, we would be grateful if you could provide copies of documents and information held by the MHRA relating to the complaint(s) made against* [redacted] *which led to the issue of the Notice under Regulation 165 of the Human Medicines Regulations 2012.*
>
> *In particular, this request extends to:*
> *• the complaint(s) themselves;*
> *• any supporting material provided by the complainant(s); and*
> *• internal MHRA assessments, memoranda, or records relating specifically to the receipt and consideration of those complaint(s), insofar as they relate to our client*

MHRA Response

We can confirm that the Agency holds the information you are seeking. However, the requested information is exempt from disclosure under Section 30(1) and Section 40(1) of the Freedom of Information Act (FOIA), these exemption apply to all information sought. For ease we will address each exemption separately.

Section 30(1)

Information obtained by the MHRA during the course of an investigation is withheld as it is exempt from disclosure under Section 30(1) of the FOI Act, which protects information as part of Investigations and Proceedings Conducted by Public Authorities.

Section 30(1) is a class-based exemption, this means that the type of information rather than the specific information you seek is exempt from disclosure. We understand there is public interest in releasing this information to demonstrate how we conduct investigations and to promote transparency. Releasing this information could prejudice future investigations by revealing methods and/or tactics used by the MHRA when conducting

investigations that could be used to subvert future investigations which would have a negative impact on public and patient safety. We also believe disclosure of complaint material and associated assessments would discourage the provision of information to the authority and reduce the effectiveness of its regulatory and enforcement activities.

When considering the public interest test for and against disclosure we believe that the factors against outweigh the factors in favour. For this reason, we are withholding the information you have requested.

Section 41(1)

The information requested, namely the complaints received by MHRA, any supporting material provided by complainants, and internal MHRA assessments relating to the receipt and consideration of those complaints insofar as they relate to the client, is exempt from disclosure under section 41(1) of the Act (information provided in confidence). This is because the information was obtained in circumstances importing an obligation of confidence, and disclosure would constitute an actionable breach of confidence.

The material in scope consists of complaint submissions and associated evidence provided to MHRA as part of its statutory regulatory functions under the Human Medicines Regulations 2012, including consideration of potential enforcement action (such as under Regulation 165). This information is not publicly available and retains the necessary quality of confidence. It includes untested allegations, supporting documentation, and associated analysis relating to regulatory compliance, all of which are inherently sensitive.

The circumstances in which the information was obtained give rise to a clear and objectively reasonable obligation of confidence. The information was provided, or gathered, within a regulatory and investigatory context, where it is well understood that material will be used solely for the purpose of assessing compliance with medicines legislation and not disclosed more broadly. This expectation is reinforced by the statutory framework itself, in particular Regulation 327 of the Human Medicines Regulations 2012, which restricts the onward disclosure of information obtained under the Regulations and establishes a controlled regime for information sharing. While this does not create an absolute statutory prohibition on disclosure, it strongly supports the existence of an implied obligation of confidence by limiting disclosure to specified circumstances and signalling that such information is to be handled within a closed regulatory system.

In addition, complainants who provide information to MHRA do so in circumstances where there is a reasonable expectation that their communications, and any supporting material, will not be disclosed publicly. Disclosure could expose complainants to potential reputational, professional, or commercial risks, and would undermine trust in the regulator. Similarly, internal MHRA assessments are derived directly from that confidential material and form part of the same confidential regulatory process; their disclosure would reveal the substance of confidential inputs and the authority's evaluative approach to those inputs.

Disclosure would therefore give rise to an actionable breach of confidence. It would undermine the trust placed in MHRA by complainants and other information providers, and would be likely to deter individuals and organisations from coming forward with information in the future or reduce the candour of such information. This would cause

real detriment to the effectiveness of the regulatory regime by impairing MHRA's ability to gather intelligence and assess potential non-compliance.

Although section 41 is an absolute exemption and does not require a Public Interest Test under FOIA, consideration has been given to whether a public interest defence under the common law of confidence would apply. In this case, there is no overriding public interest sufficient to justify disclosure. The material consists largely of unverified allegations and investigatory content, and disclosure would risk misleading the public, unfairly prejudicing the parties concerned, and undermining the integrity of regulatory processes. The public interest is better served by maintaining the confidentiality of information provided to regulators so that they can carry out their statutory functions effectively.

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

Yours sincerely,

MHRA Central Freedom of Information Team
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Your right to complain under the Freedom of Information Act

Please note that there is no right to complain under the FoI Act where the FoI is deemed to be invalid under Section 8.

Therefore, MHRA will not process any complaints where the FoI is deemed to be invalid under Section 8 of the FoI Act.

The ICO also states that "An individual submitting an invalid request under Section 8 does not have any further rights of complaint to the Information Commissioner". This statement can be viewed on the ICO website: Recognising a request made under the Freedom of Information Act (section 8) | ICO

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/