



Government Legal Department

By email only:

Litigation Group
102 Petty France
Westminster
London
SW1H 9GL

T 020 7210 3000

DX 123243, Westminster 12 www.gov.uk/gld

Your ref:
Our ref: Z2606488/JOO/HOI7

15 September 2026

Dear [REDACTED]

FOI Request number FOI 2026/00959; FOI Request number FOI 2026/01013

1. We write on behalf of the Medicines and Healthcare products Regulatory Agency ("**MHRA**") further to:
 - a. An FOI request received from Morgan, Lewis & Bockius LLP on behalf of AstraZeneca UK Limited for particular communications between the MHRA and the marketing authorisation holder, and particular extracts from the MHRA's reports, in respect of the marketing authorisation for Aumseqa, with number FOI 2026/00959 (the "**AstraZeneca FOI**"). We confirm that this AstraZeneca FOI follows from earlier FOIs from AstraZeneca. We have attached these along with the MHRA responses.¹
 - b. The email received from [REDACTED] (SFL Pharmaceuticals Deutschland GmbH) on 7 September 2026, expressing concern that the AstraZeneca FOI may have been submitted in breach of the obligations under rule 31.22 of the Civil Procedure Rules ("**CPR**"). This followed the MHRA notifying SFL that it would be seeking representations from SFL on the documentation in the AstraZeneca FOI.
 - c. A subsequent FOI request received from Pinsent Masons LLP, on behalf of SFL on 8 September 2026 for details of FOI requests submitted in respect of Aumseqa with number FOI 2026/01013 (the "**SFL FOI**").
2. Please treat this letter as a response to both the AstraZeneca FOI and SFL FOI.
3. These letters and requests have arisen in the context of AstraZeneca having brought a judicial review in respect of the Aumseqa marketing authorisation which is held by SFL. Documents have been disclosed in that litigation pursuant to the MHRA's duty of candour, which is continuing.
4. The MHRA is also aware that not only has AstraZeneca brought proceedings in the EU courts in respect of the marketing authorisation for Aumseqa, but also that there is ongoing private litigation between AstraZeneca and SFL relating to Aumseqa (to which the MHRA is not a party).

¹ Please note, duplicate responses were issued simply to correct the date on which each of the responses was sent. Names of individuals have been redacted.



5. We note the concern of SFL that "[t]he specificity of the request made of MHRA suggests that these documents may have been used to direct the FOI request and this, in our view, would amount to a breach of the CPR." We are conscious that SFL has requested that AstraZeneca confirm that there has not been a breach of CPR 31.22 and will consider this in due course. More broadly, however, the context and background of litigation in respect of Aumseqa is of concern to the MHRA, which has been seeking to respond to requests for information received in accordance with its obligations. The FOI process is not intended to place public authorities in the middle of commercial disputes between private parties, particularly in relation to litigation where there are disclosure obligations in any event.
6. Under section 31(1)(c) of the Freedom of Information Act, information is exempt where its disclosure would, or would be likely to, prejudice the administration of justice. The ICO guidance makes clear that the administration of justice is a "*broad term*", which applies to the justice system as a whole. As well as protecting information whose disclosure could undermine particular proceedings, it also protects "*a wide range of judicial bodies, such as courts.... From disclosures that could interfere with their efficiency, effectiveness or their ability to conduct proceedings fairly*".
7. The MHRA is concerned that the disclosure of information would undermine both the judicial review and patent proceedings and more broadly the disclosure process which is part of the administration of justice: FOIA is not intended to be a route to sidestep disclosure requirements in litigation.
8. In the circumstances, disclosing the information sought would, or would be likely to, prejudice the administration of justice, as the release of information into the public domain is irreversible and cannot be subsequently remedied. We consider that the public interest in maintaining the exemption outweighs the public interest in disclosure.
9. Further, in respect of the information sought which is the same as that disclosed in the judicial review proceedings, we consider that information is exempted by section 21, as it is reasonably accessible to AstraZeneca by other means.
10. Accordingly:
 - a. As to the AstraZeneca FOI, we confirm that the information requested is held.² We refuse the AstraZeneca FOI for the reasons set out above.
 - b. the enclosed materials provide a full response to the SFL FOI.
11. We would be grateful if future correspondence and any FOI requests in relation to the Aumseqa marketing authorisation are directed to [REDACTED]

Yours sincerely,

[REDACTED]
For the Treasury Solicitor

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E [REDACTED]

² Save as to your request concerning scientific advice, as to which we cannot provide information on whether there may or may not have been a scientific advice meeting for any particular product under section 41(2) and 43(3) of FOIA. We consider that the public interest in neither confirming nor denying whether the information is held outweighs the public interest in confirming or denying whether the MHRA holds the information you have requested.

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.