



Medicines & Healthcare products
Regulatory Agency

MHRA Central Freedom of
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[MHRA Website](https://www.mhra.gov.uk)

Our Ref: **FOI2026/00849**

01 September 2026

Dear [REDACTED]

Thank you for your Freedom of Information (FOI) request received on 1 August 2026. You wrote:

Dear FOI Team,

Under the Freedom of Information Act 2000, I am requesting a copy of the following information held by the Medicines and Healthcare products Regulatory Agency (MHRA):

The report "Regulating Large Language Models in Healthcare: Expert and Multi-Stakeholder Perspectives," authored by the CERSI-AI team and workshop attendees (including Dr Joe Alderman and Professor Alastair Denniston), submitted to MHRA and/or the National Commission into the Regulation of AI in Healthcare. A draft version dated January 2026 (Version 2026-01-15) is known to exist; please provide this version and/or any later or final version, whichever you hold.

If any part of this information is withheld under an exemption, please specify which exemption(s) are relied upon, and where the exemption is qualified, provide your public interest balancing reasoning, as required under the Act.

MHRA's guidance on the regulatory status of AVT products, published 29 July 2026, represents a regulatory decision that has already been made and published. Any research, findings or analysis that related specifically to that decision are not, in my view, protected by an ongoing-deliberation rationale, since that particular deliberation has concluded.

I look forward to your response within the statutory 20 working days.

Yours faithfully

MHRA Response

We can confirm that the Agency holds the information you are seeking.

However, we are engaging an exemption from disclosure under Section 22(1) of FOI Act as the information is intended for publication in an academic journal at a future date.

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

We have considered factors in favour of disclosure, such as if there are any serious regulatory issues or anomalies that would necessitate publication ahead of the planned publication by CERSI-AI and have identified no such issues.

We also recognise that there is a general public interest in the information regarding regulation of large language models used in healthcare applications.

However, when considering factors against disclosure, there is a strong public interest in maintaining the planned publication when the report is in its final form, in order to provide the most accurate information to a wider audience.

On balance MHRA is satisfied that in this instance the public interest in maintaining the exemption outweighs the public interest in disclosure. Therefore, the information you seek will not be released at this time.

We are also engaging an exemption from disclosure under Section 41(1) of the FOI Act, which protects information provided in confidence.

The information you have requested relates to a report which was obtained by the Agency from CERSI-AI and the Agency believes that if this information would be released it would breach the confidence of the organisation, actionable by them or any other person. Therefore, we are not going to be releasing the requested information.

Section 41(1) is an absolute exemption and no consideration of the public interest is required.

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](#) or telephone 0303 123 1113.

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