



Medicines & Healthcare products Regulatory Agency

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

Our Ref: **FOI2026/00971**

21 September 2026

Dear [REDACTED]

Thank you for your Freedom of Information (FoI) request received on 28 August. You wrote:

I am requesting from the MHRA's viewpoint and records information to answer the following two questions, please:

- 1. I would like please to receive records of the policy decision making that went in to the MHRA's guidance issued online on 29th July 2026, concerning both public safety and government fiscal policy.*
- 2. I would like in particular to understand how the UK Government funded research initiatives such as CERSI-AI and the outputs of the National Commission into the Regulation of AI in Healthcare have been considered and integrated in to the guidance, and any rationale of dismissing any findings for example in the CERSI-AI report on LLMs (which the MHRA sent contributing staff members) and the CERSI-AI and any MHRA internal initiative on borderline manual(s) regarding AI qualification and classification as a medical device.*

MHRA Response

We are unable to deal with your FOI request without clarification of the information you seek. This is because officials are unclear on what is specifically meant by the term 'policy decision making'. It would also be helpful if you can clarify the specific MHRA guidance which this FOI request relates to.

If further clarification on these points can be provided, the MHRA will consider this updated FOI request and, if appropriate, issue a response from there.

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](#) or telephone 0303 123 1113.

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