



Medicines & Healthcare products Regulatory Agency

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

Our Ref: **FOI2026/00629**

14 July 2026

Dear [REDACTED]

Thank you for your Freedom of Information (FOI) request received on 12 June 2026. You wrote:

Under the Freedom of Information Act, I respectfully request the following information regarding MHRA review timelines for oncology Marketing Authorisation Applications:

- 1. The average duration, in calendar days, of MHRA reviews for oncology Marketing Authorisation Applications that received a final determination between January 1, 2020 and the present.*
- 2. The median duration, in calendar days, of MHRA reviews for oncology Marketing Authorisation Applications that received a final determination between January 1, 2020 and the present.*
- 3. The longest review duration, in calendar days, for any oncology Marketing Authorisation Application that received a final determination during that period.*
- 4. The number of oncology Marketing Authorisation Applications currently under review that have remained under assessment for:*

- More than 12 months*
- More than 24 months*
- More than 36 months*

5. Any publicly releasable policies, guidance documents, performance targets, service standards, or internal metrics relating to expected review timelines for Marketing Authorisation Applications.

I am not requesting confidential information relating to any specific applicant, product, or active application. I am seeking statistical and process-related information regarding MHRA review timelines and regulatory performance.

MHRA Response

We can confirm we hold information requested, but it is exempt from disclosure under Section 12(1) of the FOI Act.

This is because we estimate the cost of searching for and identifying the requested information would exceed the cost limit of £600 specified in the Freedom of Information and Data Protection (Appropriate Limit and Fees) Regulations 2004. This represents the

estimated cost of at least one person spending 3½ working days (equivalent to 24 staff-hours) in determining whether the Agency holds the information, and locating, retrieving and extracting it.

Under Section 12(1) of the FOI Act, the Agency is not therefore obliged to comply with your request, and we will not be processing it further. The reason being that to provide the information requested in questions 1, 2 and 3 alone would require us to open every marketing authorisation that has been granted or refused between 01 January 2020 and the present to see if it concerns an oncology product and then (if it does) work out the timelines. Bearing in mind that MHRA has granted over 5,000 marketing authorisations since 01 January 2020 and to open each one to ascertain if it is an oncology medicine and (if it is) to ascertain the timelines to from submission to granting would take 5-10 minutes per marketing authorisation, to provide the information you have requested would take longer than 24 working hours.

Under Section 16 of the FOI Act we should help you narrow your request so that it may fall beneath the cost limit. We would ask that you restrict your request to a specific Product Licence (PL) number or a set of specific PL numbers that you would like this information for.

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.

Re-use of our information

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