Medicines & Healthcare products Regulatory Agency

MHRA Central Freedom of Information Team
10 South Colonnade
Canary Wharf
London
E14 4PU

foi.request@mhra.gov.uk.

MHRA Website

[redacted]

Our Ref: **FOI2026/00483**

22 May 2026

Dea[redacted]

Thank you for your Freedom of Information (FOI) request received on 4 May 2026. You wrote:

> *We request agency to provide Public Assessment Report for below product.*
> *Product Name: Acetylcysteine 200mg/ml Injection.*
> *MAH: Aurum Pharmaceuticals Ltd*
> *MA No: PL 12064/0026*

MHRA Response
The marketing authorisation for Acetylcysteine 200mg/ml Injection (PL 12064/0026) was authorised on 02 November 2004, following a national procedure under Article 4.8a(iii) of Directive 65/65/EEC.

As this marketing authorisation was authorised before it was a requirement for MHRA to publish Public Assessment Reports (PARs) for granted marketing authorisations, no PAR has been produced by MHRA.

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
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/