



Medicines & Healthcare products
Regulatory Agency

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

Our Ref: **FOI2026/00671**

16 July 2026

Dear [REDACTED]

Thank you for your Freedom of Information (FOI) request received on 23 June 2026. You wrote:

The undersigned hereby requests access to the registration documentation for Alkacit 1080 mg modified-release tablets (PL 59076/0001). The request is currently limited to information regarding whether/how the applicant has established a link between the published literature and the applied-for medicinal product (pharmaceutical form, excipients, etc.).

MHRA Response

A marketing authorisation for Alkacit 1080 mg modified-release tablets (PL 59076/0001) was granted following a Reliance Procedure in the UK, using the decentralised procedure DK/H/3439/001/DC as a reference procedure. Further information is available through the Public Assessment Reports (PARs) that have been published by MHRA and by the Reference Member State, Denmark. Links to these are provided below.

<https://mhraproducts4853.blob.core.windows.net/docs/0774fc2ef2e9af3b3c0316ca28f420eb48da9292>

<https://mri-production.cts-mrp.eu/details?productnumber=DK/H/3439/001>

The PAR published by the Reference Member State in particular has an extensive assessment of the data submitted with this well-established use application.

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/>