Medicines & Healthcare products Regulatory Agency

MHRA Central Freedom of Information Team
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E14 4PU

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MHRA Website

[redacted]

Our Ref: **FOI2026/01079**

13 October 2026

Dea[redacted]

Thank you for your Freedom of Information (FOI) request received on 17 September 2026. You wrote:

> *Could you please advise regulatory pathway, RLD used, and available Mod 4/5 data for Nifedipine 10 mg capsules as shared 5mg is lower strength.*

MHRA Response
A marketing authorisation for Nifedipine 10 mg capsules (PL 13606/0057) was granted to Strides Pharma UK Limited following an abridged simple application (Article 10c) on 04 March 1998. This abridged simple application cross-refers to Nifedipine 10 mg capsules (PL 04569/0067), which was granted a marketing authorisation to Generics (UK) Limited on 16 July 1985.

As this marketing authorisation was granted through an abridged simple application, no Module 4 or Module 5 data were submitted with the 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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