



Medicines & Healthcare products
Regulatory Agency

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

Our Ref: **FOI2026/00795**

19 August 2026

Dear [REDACTED]

Thank you for your Freedom of Information (FoI) request received on 22 July. You wrote:

Could you please advise, generic approvals received example Nifedipine 5mg capsules by Relonchem Ltd, I would like to request for FOI on this approval and information submitted in sections 2.4, 2.5, 2.6 and 2.7. I am happy to receive redacted information as per MHRA's standard procedure.

MHRA Response

The Marketing Authorisation for Nifedipine 5 mg capsules (PL 20395/0311) was granted to Relonchem Limited on 01 November 2018 via a Change of Authorisation holder (CoA).

The Marketing Authorisation was originally granted to Strides Pharma Limited on 04 March 1998 (PL 13606/0056). This Marketing Authorisation was granted under Article 4.8a(i) of Directive 65/65/EEC (as amended), equivalent to a current Regulation 56 (informed consent) application. As such, modules 2.4, 2.5, 2.6 and 2.7 are not held for this product as they were not required to be submitted.

Nifedipine 5 mg capsules (PL 13606/0056) cross-refers to Nifedipine 5 mg capsules (PL 04569/0215) which was granted to Generics (UK) Limited on 20 June 1989.

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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