Medicines & Healthcare products Regulatory Agency

10 South Colonnade
Canary Wharf
London
E14 4PU
United Kingdom
gov.uk/mhra

[redacted]

28 June 2023

Dear [redacted]

FOI 23/385

Thank you for your email, dated 31 May 2023, in which you requested:

- Any studies contained in the initial or later/subsequent submission for marketing approval for use in chronic angina pectoris patients by the MHRA (or its predecessor agency/UK governmental institutions at the time with the same drug safety, efficacy and approval for human use oversight) related to testing nicorandil for potential drug-to-drug interactions.

MHRA response:

The Marketing Authorisations for the innovator products, Ikorel/Nicorandil 10 mg and 20 mg Tablets (PL 04425/0327-0328), were granted in the UK to Aventis Pharma Limited on 24 September 2009, following a change of authorisation holder (CoA). The original Marketing Authorisations, Ikorel/Nicorandil 10 mg and 20 mg Tablets (PL 00012/0229-0230), were authorised to May and Baker Limited on 06 June 1994.

We have searched our records and have not found the requested information. Therefore, having exhausted all the usual avenues in our search for this information, we have concluded that it is no longer on our systems in a retrievable form.

We now consider this FOI request closed. If you have a query about this letter, please contact the MHRA FOI Licensing mailbox using the email address listed below.

If you are dissatisfied with the handling of your request, you have the right to ask for an internal review. Internal review requests should be submitted within 2 months of the date you receive this response and addressed to: info@mhra.gov.uk, quoting reference FOI 23/385.

If you are not content with the outcome of the internal review, you have the right to apply directly to the Information Commissioner for a decision. The Information Commissioner can be contacted at: Information Commissioner's Office, Wycliffe House, Water Lane, Wilmslow, and Cheshire, SK9 5AF.

Yours sincerely,

The FOI Team
Healthcare, Quality and Access.

Email: FOILicensing@mhra.gov.uk