



Medicines & Healthcare products
Regulatory Agency

MHRA Central Freedom of
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[MHRA Website](#)

Our Ref: **FOI2025/01032**

17 October 2025

Dear [REDACTED]

Thank you for your Freedom of Information (FOI) request received on 23 September 2025.
You wrote:

*Please can we get Public Assessment Report, clinical and non-clinical review of
Rosemont product PL00427/0222.*

MHRA Response

The marketing authorisation for Broflex Syrup 5mg/5ml (PL 00427/0222) was granted to Rosemont Pharmaceuticals Limited on 07 November 2012 following a Change of Authorisation Holder (CoA). The original marketing authorisation was granted on 27 March 1991 to Bioglan Laboratories Limited (PL 00041/0029) following an abridged simple/informed consent application (HMR Regulation 56).

As the date of grant of the original marketing authorisation predates when MHRA was required to publish Public Assessment Reports (PARs), no PAR is available for this product. Further, as the marketing authorisation was granted following an abridged simple/informed consent application (HMR Regulation 56), no clinical/non-clinical overviews were required and none were provided for the grant of this medicinal product.

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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