



Medicines & Healthcare products
Regulatory Agency

MHRA Central Freedom of
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E14 4PU

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[MHRA Website](#)

Our Ref: **FOI2026/00495**

2 June 2026

Dear [REDACTED]

Thank you for your Freedom of Information (FOI) request received on 7 May 2026. You wrote:

We would like to Request Public Assessment Report for Prednisolone 5mg Suppository PL 36301/0055.

We would like to seek confirmation of the legal basis under which product PL36301/0055 has been approved.

MHRA Response

A marketing authorisation for Prednisolone 5mg Suppositories (PL 36301/0055) was granted to RPH Pharmaceuticals AB on 22 May 2017 following a Change of Authorisation holder (CoA) application. The original marketing authorisation for this medicinal product was granted to UCB Pharma Limited on 23 February 1993 following an abridged simple procedure in the UK (PL 00039/0395). The legal basis for this application was Article 4.8(a)i of Directive 65/65/EEC, as amended (equivalent to Article 10c of Directive 2001/83/EC, as amended).

As the grant of the original marketing authorisation for this medicinal product predates when the requirement for regulatory agencies to publish Public Assessment Reports (PARs) came into effect, no PAR is available for this medicinal product.

Please note that the purpose of an FOI request is to confirm whether we hold information and consider that information for release, on request. We cannot advise on suitable reference products or requirements for applications through an FOI request. Please contact the Regulatory Information Service (RIS): RIS.NA@mhra.gov.uk, for information on suitable reference products and requirements for applications in the UK. Alternatively, you may wish to request a scientific advice meeting if you think this would be helpful. Further information on how to do this is available on our website:

<https://www.gov.uk/guidance/medicines-get-scientific-advice-from-mhra>

If you have any queries about this letter, please contact us quoting the reference number above.

Yours sincerely,

MHRA Central Freedom of Information Team

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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