



Medicines & Healthcare products
Regulatory Agency

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

Our Ref: **FOI2026/00984**

22 September 2026

Dear [REDACTED]

Thank you for your Freedom of Information (FOI) request received on 2 September 2026.
You wrote:

Please can you provide the Public Assessment Report, or any equivalent assessment documentation held by the MHRA for PL 46302/0163 – Elidel 10 mg/g Cream, held by Viatris Products Limited, Station Close, Potters Bar, EN6 1TL, United Kingdom.

Our aim is to obtain any documentation that may confirm the historical regulatory relationship between the UK and EU reference products, including details relating to the original MRP approval and the subsequent maintenance of the license following Brexit.

MHRA Response

The marketing authorisation for Elidel 10 mg/g cream (PL 46302/0163) was granted on 19 March 2019 following a Change of Authorisation holder (CoA). The original marketing authorisation was granted to Novartis Pharmaceuticals UK Limited on 03 October 2002 (PL 00101/0659) following an incoming mutual recognition procedure (DK/H/0339/001/MR) with Denmark as the Reference Member State (RMS). Because the UK was not the RMS for this procedure, we have not prepared any Public Assessment Report (PAR) for this product. Further the release of any assessment reports prepared by the RMS country would be exempt from release under Section 27 (international relations) of the FOI Act. We believe that to release any assessment reports authored by another member state would harm relations between the UK and that member state.

We advise that you approach the RMS country for the PAR or an assessment report, for them to consider under their FOI legislation.

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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