



Medicines & Healthcare products
Regulatory Agency

MHRA Central Freedom of
Information Team
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E14 4PU

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[MHRA Website](#)

Our Ref: **FOI2026/00417**

13 May 2026

Dear [REDACTED]

Thank you for your Freedom of Information (FOI) request received on 17 April 2026. You wrote:

We would like to request information regarding the product Nevanac. From what our research has shown, Nevanac was originally approved on 11th December 2007, and the initial marketing authorisation holder was Alcon Laboratories (UK) Ltd. This was later transferred to Novartis Europharm Limited in 2018. Following this, the product was grandfathered in the UK post-brexit with the licence number PLGB 00101/1110-1111.

Therefore, we would like to request the following:

- * *Confirmation of Original Date of Approval in UK*
- * *Legal Basis of Original Application in UK*
- * *Public Assessment Reports for the Original Approval in UK*

MHRA Response

Nevanac was originally authorised through a centralised procedure done through the European Medicines Agency (EMA). Further information on this, including the Public Assessment Report (PAR) for the initial grant of this marketing authorisation can be obtained through the EMA website. A link to this information is provided below:

<https://www.ema.europa.eu/en/medicines/human/EPAR/nevanac>

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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<https://www.nationalarchives.gov.uk/doc/open-government-licence/version/3/>