



[foi.request@mhra.gov.uk](mailto:foi.request@mhra.gov.uk).

[MHRA Website](#)

Our Refs:  
**FOI2026/00375**  
**FOI2026/00376**

29 April 2026

Dear [REDACTED]

Thank you for your Freedom of Information (FOI) requests received on 7 April 2026.

**For FOI2026/00375 you wrote:**

*I would like to submit freedom of information request in relation to 'Difflam 0.15% w/v Spray'.*

*I would like to know the date of approval when the age ranges '2 to 6 years' and '6 to 12 years' were added to the original license.*

*I would like a copy of the assessment report for this variation.*

*I would like a copy of the clinical overview for this application.*

*I would like to if the legal classification (pharmacy only) has changed (or not) since the original MA grant on 30 November 1984, dates of approval, and any assessment reports / public consultations that were carried out as part of any changes to the legal classification.*

**For FOI2026/00376 you wrote:**

*Please provide any internal scientific assessment reports, assessor summaries, or committee briefing documents held by MHRA relating to the assessment and approval of Difflam 0.15% w/v Spray, authorised 30 November 1984 in relation to:*

- Variation to add the age ranges '2 to 6 years' and '6 to 12 years' to the posology.
- Changes to the legal classification of this product since MA grant.

*If full disclosure is not possible, please provide confirmation of the existence of such documents and the exemptions relied upon.*

**MHRA Response**

Please find our response to each of your requests below.

FOI2026/00375

The Agency has completed its search for the information you have requested and we are able to confirm that we do hold some of the information you have requested.

I can confirm that a variation to amend the posology to add the age ranges 'children under 6' and 'children 6 to 12 years' were added to the license for Diffiam Oral Spray 0.15%, PL 00068/0112 on 15 January 1986. I can confirm the age range '2 to 6 years' was not approved as you have stated in your request, however, the age range of 'children under 6' was approved.

I can also confirm that the legal classification of 'Pharmacy Only' (P) has not changed since the original approval of Diffiam Oral Spray 0.15%, PL 00068/0112 granted on 30 November 1984.

Despite a thorough search of our electronic records, including a search for the product in our database which details what we hold in the paper archives, we have been unable to locate the requested assessment report for this variation and clinical overview for this application.

FOI2026/00376

Despite a thorough search of our electronic records, including a search for the product in our database which details what we hold in the paper archives, we have been unable to locate any internal scientific assessment reports, assessor summaries, or committee briefing documents for Diffiam Oral Spray 0.15% (PL 00068/0112) in relation to:

- Variation to add the age ranges '2 to 6 years' and '6 to 12 years' to the posology.
- Changes to the legal classification of this product since MA grant.

As clarified in the response to FOI2026/00375 above, the legal classification of 'Pharmacy Only' (P) for this product has not changed since the original approval on 30 November 1984.

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

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### **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](mailto: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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