



Medicines & Healthcare products  
Regulatory Agency

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London  
E14 4PU  
United Kingdom  
[gov.uk/mhra](https://gov.uk/mhra)

[REDACTED]

**17 October 2024**

MHRA reference: **FOI2024/00585**

Dear [REDACTED]

Thank you for your information request, which we received on 22 September. You asked for:

*"On behalf all psoriasis patients please let us know when can Uk is going to allow "Topical Tapinarof" medicine?  
Please let us know whom should i request about this ?"*

We have dealt with your request under the Freedom of Information Act 2000 (FOIA).

We can confirm that no product named Topical Tapinarof or containing the active ingredient tapinarof has been authorised by MHRA.

Unfortunately, we cannot provide information on whether there may or may not be an application in progress for any particular product. When we need to refuse a written request for information in this way, we need to do this under the provisions of the Freedom of Information Act 2000 (FOIA) so that we include the relevant exemptions and the reasons why we are applying them. This means that for your enquiry about Topical Tapinarof", we need to refuse to confirm or deny whether we hold this information under Section 41(2) (S41 – information provided in confidence) and Section 43(3) (S43 – prejudice to commercial interests) of the FOIA.

We will explain these exemptions below.

Section 41 –

(2) The duty to confirm or deny does not arise if, or to the extent that, the confirmation or denial that would have to be given to comply with section 1(1)(a) would (apart from this Act) constitute an actionable breach of confidence.



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### Section 43 –

- (1) Information is exempt information if it constitutes a trade secret.
- (2) Information is exempt information if its disclosure under this Act would, or would be likely to, prejudice the commercial interests of any person (including the public authority holding it).
- (3) The duty to confirm or deny does not arise if, or to the extent that, compliance with section 1(1)(a) would, or would be likely to, prejudice the interests mentioned in subsection (2).

### **Public interest test**

Section 17(3) of the Act requires us to conduct a Public Interest Test (PIT) when considering the neither confirm nor deny provision of a qualified exemption. In applying this exemption, we are required to consider whether, in all the circumstances of the case, the public interest in neither confirming nor denying that the information is held outweighs the public interest in confirming or denying whether the MHRA holds the information you have requested. The ‘public interest’ is not the same as what interests the public. In carrying out a PIT, we consider the greater good or benefit to the community as a whole in saying whether information is held or not. The ‘right to know’ must be balanced against the need to enable effective procedural governance and to serve the best interests of the public. The FOI Act is ‘applicant blind’. This means that we cannot, and do not, ask about the motives of anyone who asks for information. In providing a response to one person, we are expressing a willingness to provide the same response to anyone.

### **Considerations in favour of confirming whether or not we hold the information**

To confirm or deny whether or not an application has been received by MHRA would be of interest to patient groups and healthcare professionals in knowing and understanding whether a relevant treatment could soon be available to patients. It would also be of benefit in general to show transparency in MHRA’s day-to-day work for the public to see what applications are currently being considered by MHRA.

### **Considerations in favour of neither confirming nor denying whether we hold the information**

To confirm or deny whether we are currently considering an application for a particular medicine would be of great interest to rival companies who are marketing or looking to market their own products. Knowledge of whether an application is being considered by MHRA can be used as market intelligence in order to gauge when a new product is likely to come onto the market so strategies can be employed to prevent that product getting a foothold in the market. Further, to confirm or deny that we may hold any information on applications that are not yet authorised in the UK can make companies reluctant or unwilling to submit applications for their products to the UK. This would result in fewer medicines being available for patients.

When licensed medicines are not available to meet the needs of individual patients, prescribers may prescribe unlicensed medicinal products. If a prescriber, in the



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exercise of their professional judgement, considers a medicinal product containing tapinarof as required to treat their patient, they may prescribe it, even if it is not licensed or available in the UK. The healthcare system in the UK, both NHS and private, have well established mechanisms in place to source unlicensed medicines which may be necessary to meet the clinical needs of individual patients. Prescribers should always satisfy themselves that the medicinal products they consider appropriate for their patients can be safely prescribed.

The General Medical Council has issued advice to doctors on prescribing unlicensed medicines: <https://www.gmc-uk.org/guidance/28349.asp>.

I would recommend that your constituents contact their doctors to discuss possible treatment options.

Further information from the MHRA on the supply of unlicensed medicinal products can be found at: [www.gov.uk/government/publications/supply-unlicensed-medicinal-products-specials](http://www.gov.uk/government/publications/supply-unlicensed-medicinal-products-specials).

Your constituents may also find the published guidance from the Royal Pharmaceutical Society (RPS) useful:  
<https://www.rpharms.com/Portals/0/RPS%20document%20library/Open%20access/Support/toolkit/specials-professional-guidance.pdf>

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

Yours sincerely,

**Healthcare, Quality and Access Group**

**Medicines and Healthcare products Regulatory Agency**

### **Appeal rights**

If you are dissatisfied with the handling of your request, you can ask us to conduct an internal review. Internal review requests should be submitted within two months of the date you receive this response and addressed to: [foi.request@mhra.gov.uk](mailto:foi.request@mhra.gov.uk)

If you remain dissatisfied with the outcome of the internal review, you have the right to apply directly to the Information Commissioner for a decision. Please bear in mind that the Information Commissioner will not normally review our handling of a request unless the requester has first asked us to conduct an internal review.

The Information Commissioner can be contacted through their online webform at: <https://ico.org.uk/make-a-complaint/foi-and-eir-complaints/foi-and-eir-complaints/>



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Or in writing to: Information Commissioner's Office, Wycliffe House, Water Lane, Wilmslow, Cheshire, SK9 5AF

### **Re-use of our information**

The MHRA information supplied in response to your request is subject to Crown copyright. Information created by the MHRA which is disclosed under the Freedom of Information Act is made available for re-use under the Open Government Licence (OGL) v3.0, except where this is otherwise stated. There are some restrictions on re-use under the OGL and these can be viewed here:

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