Medicines & Healthcare products
Regulatory Agency

10 South Colonnade
Canary Wharf
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United Kingdom
gov.uk/mhra

[redacted]

10 May 2024

MHRA reference FOI2024/00056

Dear [redacted],

Thank you for your information request, which we received on 24 April 2024. You asked for:

“I am searching for product information about CEYESTO 1 MG/ML ORAL SOLUTION

On the MHRA Products webpage, I can only find PIL and SPC for this product. However, I am looking for a copy of the Public Assessment Report, PAR. It does not seem to be published.

In fact, I cannot find the PAR for the Ceyesto tablets either (even though it has been approved for several years). Does the MHRA not publish PARs or is there another reason for why this does not seem to be the case for Ceyesto?

I hereby request a copy of the Public Assessment Report, PAR, for CEYESTO 1 MG/ML ORAL SOLUTION”

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

The Public Assessment Report (PAR) for Ceyesto 1 mg/ml Oral Solution (PL 44490/0001) is currently being prepared and should be published in the next 60 calendar days. As it will be published in the future, we are exempting the release of any further information under Section 22(1) of the Freedom of Information Act (FOIA) – Information intended for future publication.

It is both reasonable and in the public interest to maintain this established schedule of proactive publication.

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It may be of interest to you that Ceyesto 3 mg tablets is also authorised in the UK, following a decentralised procedure with Finland as the Reference Member State (FI/H/1051/001/DC). The PAR for this product is published on the Heads of Medicines Agencies (HMA) MRI Product Index. A link to this is provided below: https://mri.cts-mrp.eu/portal/details?productnumber=FI/H/1051/001

This concludes our response to your request.

If you have a query about this response, please contact us at foi.request@mhra.gov.uk

Please remember to quote the reference number at the top of this letter in any future communications. Details of your appeal rights are below.

Yours sincerely,

Health Quality and Access Division
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

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/

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

Re-use of our information

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