Medicines & Healthcare products
Regulatory Agency

10 South Colonnade
Canary Wharf
London
E14 4PU
United Kingdom
gov.uk/mhra

[redacted]

10 May 2024

MHRA reference FOI2024/00077

Dear [redacted],

Thank you for your information request, which we received on 30 April 2024. You asked for:

"We are currently undertaking a review of Ceyesto 1mg/ml oral solution for use in line with its marketing authorisation. The aim of this review is to consider the inclusion of this product in the Devon joint formulary. The Devon joint formulary makes recommendations for approaches to treatment for a range of indications. To assess the suitability of this product it would be helpful to review the public assessment report.

At present it appears that the public assessment report has not been published on the MHRA website. Would it be possible for a copy to be shared, alternatively is it possible to advise when the report will be publicly available on the MHRA website?"

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.

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

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(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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