Medicines & Healthcare products Regulatory Agency

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gov.uk/mhra

[redacted]

14 December 2023

Dear [redacted]
,

FOI 23/706

Thank you for your communication, dated 26 September 2023, in which you requested copies of the clinical overview, the assessment report issued by the MHRA and the public assessment report regarding Ceyesto 1 mg/ml Oral Solution (PL 44490/0001). We have now concluded our public interest considerations for section 43 of the Freedom of information Act.

MHRA response:

Clinical overview
In response to your request, please find attached the clinical overview submitted for the initial application for Ceyesto 1 mg/ml Oral Solution (PL 44490/0001), redacted under Section 40 (Personal information), Section 41 (Information given in confidence) and Section 43 (Commercial interests) of the information Act.

Disclosure of information subject to Section 40 (Personal information) would be an infringement of personal data. Section 40 (Personal information) is an absolute exemption and no consideration of the public interest is required.

Section 41 (Information given in confidence) is an absolute exemption, and no consideration of the public interest is necessary, except to state that the release of this information

withheld under this section of the FOI Act would be considered an actionable breach by the MHRA.

We have redacted some parts of the attached documentation under Section 43 (Commercial interests) of the FOI Act because the release of all, or part of, the information would, or would be likely to, cause harm to the third party's commercial interests. The exemption is to safeguard the commercially sensitive information/commercial enterprise. In this case, release of information would enable the competitors to overcome several regulatory hurdles in the research and development of their own products. This exemption is conditional on the public interest in releasing it not outweighing the company's/commercial enterprise's right to confidentiality and the probable damage that the company/commercial enterprise could suffer as a result of the information being released. We have considered the balance of the public interest when applying this exemption. In this case, we have not identified any issues which would benefit the public, as a whole, by being brought to their attention.

Public Assessment Report (PAR)
We are currently in the process of producing a PAR for publication on the MHRA website for this product.

All PARs are routinely published by the MHRA. We are therefore applying section 22(1) of the FOI; this information is exempt from disclosure because it is intended for future publication.

> Section 22
> (1) Information is exempt information if—
> (a) the information is held by the public authority with a view to its publication, by the authority or any other person, at some future date (whether determined or not),
> (b) the information was already held with a view to such publication at the time when the request for information was made, and
> (c) it is reasonable in all the circumstances that the information should be withheld from disclosure until the date referred to in paragraph (a).

Each of the three criteria must be met for section 22(1) to be engaged. The assessment reports are held by the MHRA with the settled expectation that this PAR will be published at a future date; in this case, this expectation is based on the section 64 of the Human Medicines Regulations 2012, which sets out the duties of the MHRA for the publication of PARs:

> ***Duties of licensing authority in connection with determination***
>
> *(6) The licensing authority must—*
> *(b) make the assessment report publicly available (with the omission of information of a commercially confidential nature) as soon as is reasonably practicable after it has been prepared or revised; and*
> *(c) include in the assessment report a summary, written in a manner that is understandable to the public, that contains, in particular, a section relating to the conditions of use of the medicinal product.*

As stated in section 22(1)(a), it is not necessary for the date of publication to be determined for section 22(1) to apply.

We take a consistent approach to support the scheduled publication of PARs for wider public benefit. We believe it is reasonable in all the circumstances, fair, and in line with accepted practices, to withhold the information requested ahead of the wider schedule of publication. In this case, there is a settled intent to publish the PAR at a future date, and it is reasonable to maintain the schedule for this planned publication.

Public interest

We have considered the public interest within the process of engaging Section 22. A factor in favour is the general principle in transparency, to provide for earlier release of this particular information. We also understand there is a public interest in making the information available for public scrutiny. However, responding to individual requests on an ad hoc basis while the information requested forms part of the scheduled approach to wider publication, creates an additional burden for staff and disrupts the existing approach to the process. This factor strongly favours maintaining the exemption.

We therefore consider that section 22(1) applies to the requested information at this time.

Please also note, the Patient Information Leaflet (PIL) is available to patients and the public and the summary of product characteristics (SmPC), although, primarily intended for healthcare professionals is also available for the public to view. The SmPC, among other important information, describes the key safety and efficacy data which supported the grant of the marketing authorisation of this medicine.

MHRA assessment report
The MHRA assessment report is being withheld under Section 41 (Information given in confidence), Section 43 (Commercial interests) and Section 22 (Information for future publication) of the FOI Act, as this information is considered commercially confidential or is to be published on our website in the PAR for Ceyesto 1 mg/ml Oral Solution (PL 44490/0001).

We now consider this FOI request closed.

If you are dissatisfied with the handling of your request, you have the right to ask for an internal review. Internal review requests should be submitted within 2 months of the date you receive this response and addressed to: info@mhra.gov.uk.

Please remember to quote the reference number above in any future communications.

If you were to remain dissatisfied with the outcome of the internal review, you would 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 your request, unless you have first contacted us to conduct an internal review. The Information Commissioner can be contacted online via an electronic form: 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.

Yours sincerely,

The FOI Team,
Healthcare Quality and Access.