FOI 24/162 - Melatonin PAR

MHRA Customer Services <MHRACustomerServices@mhra.gov.uk>

Fri 08/03/2024 09:11

[redacted]

FOI 24/162

Dear [redacted]

Regarding your request under the Freedom of Information Act (FOIA) for the Public Assessment Report (PAR) for “Ceyesto 3 mg tablets (PL 44490/0007) and Ceyesto 1mg/ml Oral Solution (PL 44490/0001)”, please see our response below:

Ceyesto 3mg Tablets (PL 44490/0007) was authorised by a Change of Authorisation Holder (CoA) on 15 January 2021. The original marketing authorisation (PL 16784/0004) was granted to HK Pharma Limited by an incoming decentralised procedure (FI/H/1051/001/DC) with the UK as a Concerned Member State (CMS). As MHRA was not the Reference Member State (RMS) for this product, no PAR will have been published by MHRA, as any PAR for this product should be published by the RMS country (Finland). A link to the PAR on the Heads of Medicines Agencies (HMA) Mutual Recognition Information (MRI) Product Index is below:
https://mri.cts-mrp.eu/portal/details?productnumber=FI/H/1051/001

Ceyesto 1mg/ml Oral Solution (PL 44490/0001) was authorised on 07 September 2023. We are currently preparing a PAR for this, which will be published in the next 20 working days. All Public Assessment Reports 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 information is 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 Public Assessment Report 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.

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 two 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 at:

Information Commissioner's Office
Wycliffe House
Water Lane
Wilmslow
Cheshire
SK9 5AF

Or online via: https://ico.org.uk/make-a-complaint/foi-and-eir-complaints/foi-and-eir-complaints/

Yours sincerely,

MHRA Customer Experience Centre
Communications and engagement team
Medicines and Healthcare products Regulatory Agency
10 South Colonnade, Canary Wharf, London E14 4PU

From: [redacted]
Sent: Monday, February 12, 2024 12:46 PM
To: FOI_Policy <FOI_Policy@mhra.gov.uk>
Subject: Melatonin PAR

Dear MHRA,

Under FOI Act, we request the MHRA to provide UK PAR for below mentioned licensed products: Ceyesto 3 mg tablets (PL 44490/0007), and/or Ceyesto 1mg/ml Oral Solution-(PL 44490/0001)ALTURiX Ltd.

Thank you !

Kind regards

[redacted]