FOI 24/127 - FOI request: PL 42289/0026 and PL 42289/0027

MHRA Customer Services <MHRACustomerServices@mhra.gov.uk>
Tue 05/03/2024 16:21

[redacted]

FOI 24/127

Dear [redacted]

Regarding your request for the Public Assessment Report (PAR) for Varenicline Film-Coated Tablets (PL 42289/0026-27), the PAR is currently being prepared for publishing. We anticipate that this will be available in the next 60 calendar 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

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: Tuesday, February 6, 2024 9:08 PM
To: MHRA Customer Services <MHRACustomerServices@mhra.gov.uk>
Cc: [redacted]
Subject: FOI request: PL 42289/0026 and PL 42289/0027

FOI request: PL 42289/0026 and PL 42289/0027

Dear MHRA,

The above licences were granted on 30/11/2023 and normally, one would have expected the PAR to have been published online by now but it has not.

Usually when there is no PAR, it means that the licence was granted following a change of ownership procedure or an informed consent application.

My question is this: Is a PAR available and if not, on what grounds?

Best regards,

[redacted]

[redacted]

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