FOI 24/100 Adcirca (tadalafil) Module 2.7.2 PLGB 14895/0229

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

Tue 27/02/2024 16:47

To [redacted]

2 attachments (1 MB)

clin-pharm-summary-eu-pah-redacted.pdf; clin-pharm-summary-appendix-eu-pah.pdf;

FOI 24/100

Dear [redacted],

Thank you for your request for information dated 30 January 2024 where you requested '*Module 2.7.2 Summary of Clinical Pharmacology Studies for Adcirca (tadalafil) 20mg film coated tablets (PLGB 14895/0229) that was submitted to the MHRA for the initial MAA.'*

We confirm we hold the information related to your request, please find attached the Summary of Clinical Pharmacology Studies and the associated appendix.

Please note, a single redaction has been made to page 14 under Section 41(1) and 43(2).

Section 41(1) - information provided in confidence
This is an absolute exemption and no consideration of the public interest is required. The withheld information was provided to the MHRA in confidence by a third-party for the purposes of assessment. This information has the necessary quality of confidence as it is more than trivial and not otherwise accessible; the preservation of confidences is recognised by the courts to be an important matter and one in which there is a strong public interest. In this case, the information was provided to the MHRA with explicit conditions on its use by the MHRA (including further disclosure) and an obligation of confidence therefore exists. For these reasons, disclosure would be likely to have a detrimental impact on the party who provided the information. In such circumstances, our view is that disclosure would be an actionable breach of that confidence, and this engages the section 41(1) exemption.

Section 43(2)
Release of the redacted information would be likely to cause harm to the third party's commercial interests. We have considered the balance of the public interest when applying this exemption. The exemption is to safeguard the commercially sensitive information. As a qualified exemption, 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. In this case we have not identified any issues which would benefit the public as a whole by being brought to their attention (examples of issues would be a major public health risk or a major procedural failure or irregularity).

We now consider this FOI request closed. However, If you disagree with how we have interpreted the Freedom of Information Act 2000 in answering your request, you can ask us to review our actions and decisions by writing to: info@mhra.gov.uk, and requesting an internal review.

Please note that your internal review request must be in a recordable format (email, letter, audio tape etc.), and that you have 40 working days upon receipt of this letter to ask for a review. We aim to provide a full response to your review request within 20 working days of its receipt. Please quote the reference number **FOI 24/100** in any future communications.

If you are not content 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,

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, January 30, 2024 10:09 AM
To: MHRA Customer Services <MHRACustomerServices@mhra.gov.uk>
Cc: [redacted]
Subject: FOI 24/100 - FOI Request: Adcirca (tadalafil) Module 2.7.2 PLGB 14895/0229

You don't often get email from [redacted]

Re: Freedom of Information Request for Adcirca (tadalafil) PLGB 14895/0229, Module 2.7.2

Dear MHRA,

We write to issue a Freedom of Information request for **Module 2.7.2 Summary of Clinical Pharmacology Studies for Adcirca (tadalafil) 20mg film coated tablets (PLGB 14895/0229)** that was submitted to the MHRA for the **initial MAA.**

We kindly request a PDF attachment of this document, within the 20-day timeline stipulated on gov.uk, via reply to this email. We confirm that we have reviewed the MHRA's list of published responses to FOI requests in the first instance, before issuing this request.

Should you require any further information for this Freedom of Information request, please let us know.

Kindest regards,

[redacted]