Medicines & Healthcare products Regulatory Agency

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

[redacted]

29 December 2023

Dear [redacted]

FOI 23/812

Thank you for your communication, dated 24 October 2023, in which you requested Module 2.7.1 Summary of Biopharmaceutics for Adcirca (tadalafil) 20 mg film coated tablets (PLGB 14895/0229) that was submitted to the MHRA for the initial Marketing Authorisation Application (MAA).

We are responding to your request by providing the attached, submitted to support the initial application for Adcirca (tadalafil) 20 mg film coated tablets (PLGB 14895/0229):

(i) **Module 2.7.1 Biopharm-summary-eu-pah,** redacted under Section 41 (Information given in confidence) and Section 43 (Commercial interests) of the Freedom of Information (FOI) Act
(ii) **Module 2.7.1.4 Biopharm-summary-appendix-eu-pah,** redacted under Section 41 (Information given in confidence) and Section 43 (Commercial interests) of the FOI Act.

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.

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.