

FOI 23/625

Dear

Thank you for your request of 21 August 2023, where you asked,

“We would like to request a copy of Public Assessment report (UK PAR) and information if its Initial application of the following product under the Freedom of Information Act (FOIA) of MHRA:

*Product name: **Ondansetron 2mg/ml Solution for Injection-PL 43801/0001***

*MAH name: **Sciecare Pharma Limited***

*PL number: **PL 43801/0001***

*Authorised on: **21 August 2018**”*

We have located the relevant public assessment report (PAR) online, and provide you with a link this document below.

<https://mhraproducts4853.blob.core.windows.net/docs/eb5eeee2b4d5a7a1a9138ca88d91b1c77ca66b38>

Given that this document is reasonably accessible in the public domain the formal position under FOIA is Section 21 (information reasonably accessible by other means). However, we have also noted ‘and information’ is mentioned in your request, please could you clarify or if this was an error, if so an onward reply is *not* needed.

If you disagree with how we have interpreted the Freedom of Information Act 2000 in answering your request, you can ask for an internal review. Please reply to this email, within two months of this reply, specifying that you would like an Internal Review to be carried out.

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

by 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