

FOI 23/524

Dear

Thank you for your request under the Freedom of Information Act of 19 July 2023.
You requested:

Betnesol Eye, Ear and Nose Drops Solution 0.1% w/v -Generics [UK]

In lieu of Public Assessment Reports (PARs), Assessment Reports will also do. Request you to provide the same.

This request followed from a reply we sent to you on 18 July 2023 confirming that no Public Assessment Report (PAR) exists for marketing authorisation PL 36301/0003. Our reply of 18 July 2023 was in response to your earlier request of 07 June 2023. In your 07 June request.

Referencing:

user testing bridging proposals

From this reference to user testing bridging proposals we understand that in your request of 19 July 2023, the reference to 'assessment reports' is to an assessment report that would include information about user testing.

User test reports are part of the confidential information that Marketing Authorisation Holders (MAHs) submit to the MHRA with a new application or as part of a variation to a licence. User test reports contain confidential information about the way the leaflet was designed and tested, often by third parties, the type of questions asked in testing and the methodology adopted. This information is commercially confidential to either the MAH or third parties that write, design or user test leaflets for MAHs. This commercially confidential information appears in all sections of the report and it is not therefore possible to redact certain sections of user test reports. We are therefore exempting release of the information you requested under Section 43 (Commercial interests) of the Freedom of Information (FOI) Act. We have considered the public interest and do not consider that the reasons for disclosing a user test report outweigh those for disclosure.

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