FOI 23/275 – public assessment report for Dulcolax Adult 5 mg Gastro-resistant Tablets

REQUEST
12 April 2023

I would like to request the **public assessment report** for licence PL 53886/0025 Dulcolax Adult 5 mg Gastro-resistant Tablets.

MHRA RESPONSE
10 May 2023

Dear

Thank you for your email of 12 April 2023 made under the Freedom of Information Act (FOIA), requesting the following information:

“The public assessment report for licence PL 53886/0025 Dulcolax Adult 5 mg Gastro-resistant Tablets.”

The marketing authorisation for Dulcolax Adult 5 mg Gastro-resistant Tablets (PL 53886/0025) was authorised by a Change of Authorisation Holder (CoA) on 01 November 2021. The original marketing authorisation for this product was granted by an abridged simple application on 01 June 1992 (PL 06772/0006).

As the original grant date for this product predates when MHRA would have been required to prepare a Public Assessment Report (PAR), no PAR has been published for this product.

We now consider this request closed.

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.