

FOI 23/534 – publica assessment report for Ivermectin 3mg tablets (PL 23218/0227)

REQUEST

20 June 2023

We would like to submit a freedom of information request to MHRA for the following documents of Ivermectin 3mg tablets Marketing Authorisation (PL 23218/0227) granted to Laboratorios Liconsa S.A, Calle Dulcinea s/n 28805 Alcalá de Henares – Madrid-Spain

1. Public assessment report
2. Information on the legal basis used in this application for Marketing authorisation.
3. Information on reference standard used in this application for demonstrating bioequivalence.

MHRA RESPONSE

5 July 2023

This is a courtesy message to inform you that the PAR for Ivermectin 3mg tablets (PL 23218/0227) is now published on the MHRA products site.

The PAR should appear as the first item on this search page: <https://products.mhra.gov.uk/search/?search=PL+23218%2F0227&page=1&doc=Par&rerouteType=0>

The legal basis was Regulation 50, the MA was also supported by a BE study to the reference product, Stromectol 3mg Tablets.

As a formality, I've included the below FOI text in this email.

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 Service Centre
Medicines and Healthcare products Regulatory Agency
10 South Colonnade, Canary Wharf, London E14 4PU

Many thanks,

HQA FOI Team