

FOI 23/574

Dear

Thank you for your email.

I would like to request a copy of the Public Assessment report (UK PAR) for the following product under the Freedom of Information Act (FOIA) of MHRA:

*Product name: **Zyloric Tablets 100mg and 300mg***

*MAH name: **Aspen***

3016 Lake Drive, Citywest Business Campus, Dublin 24, Ireland

PL number:

PL 39699/0001 – Zyloric 100 mg Tablets

PL 39699/0002 – Zyloric-300mg Tablets

We confirm that both above were granted by Change of ownership on 23/02/2012. The original Marketing Authorisations (MAs) are PL 00003/0092R (300mg) and PL 00003/5207R (100mg), which were authorised on 14/07/1980 and 20/03/1980, respectively.

As both MAs predate when MHRA would have been required to publish a PAR, no PAR has been published and none is available.

If you disagree with how we have interpreted the Freedom of Information Act 2000 with regards to your request, you can ask for the decision to be reviewed. The review will be carried out by a senior member of the Agency who was not involved with the original decision.

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