Medicines & Healthcare products Regulatory Agency

MHRA Central Freedom of Information Team
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MHRA Website

[redacted]

Our Ref: **FOI2026/00324**

20 April 2026

Dear [redacted]

Thank you for your Freedom of Information (FoI) request received on 24 March 2026. You wrote:

> *'With reference to our ongoing Freedom of Information (FOI) request (Our Ref: FOI2026/00152), we kindly request the agency to provide the Clinical Overview for the following Marketing Authorisation.*
>
> *Product Name: Doxazosin Tablets 8 mg*
> *MAH: Ennogen IP Ltd, UK*
> *MA No.: PL 55612/0034*
> *Requested Document: Clinical Overview*
>
> *For the agency's reference, the FOI response previously received from MHRA has been attached.*
>
> *We would appreciate your assistance in providing the requested document at your earliest convenience.*
>
> *Thank you for your support.'*

MHRA Response

Following a search of our paper and electronic records, we have established that the information you requested is not held by this Agency.

Advice and assistance

In searching for the information you seek we have tracked the licence history. To be as helpful as possible, we have included the history below.

Doxazosin Tablets 8 mg was first approved on 10 April 2001 to Lagap Pharmaceuticals Ltd as PL 04416/0355. Lagap Pharmaceuticals Ltd was later acquired by Novartis and became part of Sandoz Limited.

In February 2009, the licence was transferred from Sandoz via a change of ownership to ENNOGEN LIMITED as PL 34007/0032. In November 2024, the licence underwent another change of ownership to ENNOGEN IP LTD as the current granted form PL 55612/0034.

During searches for this request, we have identified ~14 boxes of paper records in the MHRA archives that may relate to the original Lagap/Sandoz authorisation. As the historical records are not for the requested licence, these were considered outside the scope of the current request.

Before the early 2000s, the MHRA did not require quality, non-clinical or clinical overviews. Instead, there were clinical, pharmacological-toxicological and pharmaceutical expert reports. Due to the age of the licence, it is unlikely a clinical overview is present in the archive records for the original iteration of the product licence.

We hope this helps to inform any future requests.

If you have any queries about this letter, please contact us quoting the reference number above.

Yours sincerely,

MHRA Central Freedom of Information Team
Medicines & Healthcare products Regulatory Agency

Your right to complain under the Freedom of Information Act

If you are not happy with this response you may request an internal review by e-mailing foi.request@mhra.gov.uk or by writing to: MHRA Central Freedom of Information Team, 10 South, Colonnade, Canary Wharf, London, E14 4PU
Any request for an internal review must be received by us within 40 working days of the date of this letter. Please note we are not obliged to provide a review if it is requested after more than 40 working days.

If you are not content with the outcome of the internal review you may apply directly to the Information Commissioner's Office for a decision. Generally, the Commissioner cannot make a decision unless you have exhausted our own complaints procedure. The Information Commissioner can be contacted at: The Information Commissioner's Office, Wycliffe House, Water Lane, Wilmslow, Cheshire SK9 5AF.
Website: ICO FOI and EIR complaints or telephone 0303 123 1113.

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