Medicines & Healthcare products Regulatory Agency

MHRA Central Freedom of Information Team
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MHRA Website

[redacted]

Our Ref: **FOI2025/00076**

18 February 2025

Dear [redacted]

Thank you for your Freedom of Information (FOI) request received on 28 January 2025. You wrote:

> *Applicant intends to develop a new formulation of Famotidine as an active substance for the UK market. We seek clarification regarding the reference listed drug (RLD). Below are the specific points we would appreciate your guidance on:*
> *1. Applicant has identified some products listed in the MHRA drug database (details provided in the table below) that may potentially serve as reference listed drugs (RLDs) for Famotidine. However, we were unable to locate public assessment reports (PAR) confirming their RLD status.*
> *2. Kindly verify if these products are indeed RLDs also please help to provide their respective public assessment reports (PAR)?*
> *3. Furthermore, we would appreciate confirmation from the agency regarding whether these identified products qualify as RLDs, or if there are additional RLDs we should consider for Famotidine.*
>
> *1. Famotidine 40mg tablet Tillomed Laboratories Limited PL 11311/0478 12/08/2009*
> *2. Famotidine 40mg tablet Teva UK Limited, PL 00289/0345 01/04/2010.*
>
> *can we used both the above product as reference product.*

MHRA Response

Famotidine 40mg tablet (PL 11311/0478) was authorised to Tillomed Laboratories Limited following a Change of Authorisation holder (CoA). The initial marketing authorisation was authorised to Roger Oakes Limited following an abridged simple procedure on 03 July 2009 (PL 32019/0034). A link to the Public Assessment Report (PAR) is provided below: https://mhraproducts4853.blob.core.windows.net/docs/b59864af34c5680496493f1c5c6063cf9a1b79c7

Famotidine 40mg tablet (PL 00289/0345) was authorised to Teva UK Limited on 04 August 2000 following an incoming mutual recognition procedure for an abridged application (generic medicine) with Germany as the reference member state (DE/H/0238/002/MR). As this

medicinal product was authorised before it was a requirement for European regulators to publish PARs, no PAR is available for this product.

Regarding your enquiry about a suitable reference product, the purpose of FOI is to provide information that we hold on request, it is not to provide advice. Please contact the Regulatory Information Service (RIS): RIS.NA@mhra.gov.uk, for information on suitable reference products in the UK. Alternatively, you may wish to request a scientific advice meeting if you think this would be helpful. Further information on how to do this is available on our website: https://www.gov.uk/guidance/medicines-get-scientific-advice-from-mhra

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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