FW: FOI 23/993

FOILicensing <FOILicensing@mhra.gov.uk>
Fri 19/01/2024 13:06

To:FOILicensing <FOILicensing@mhra.gov.uk>;MHRA Customer Services <MHRACustomerServices@mhra.gov.uk>[redacted]
>
Cc[redacted]

Hi all,

This one has been sent out.

Thanks,
[redacted]

From: FOILicensing <FOILicensing@mhra.gov.uk>
Sent: Friday, January 19, 2024 1:05 PM
To:[redacted]
Subject: FOI 23/993

Dear [redacted]

Thank you for your request for information, dated 18 December 2023, where you asked the following:

What Famotidine Marketing Authorisation is considered the reference product in the UK?
Is Pepcid 40 mg (PL 00025/0216), or the UK reference product if it's a different MA, part of the same global marketing authorisation of the German Pepdul 40 mg licence (MA number: 5775.00.00 Date of Authorisation: 1985-08-07)?
When was Pepcid 40 mg (PL 00025/0216) first approved in the UK? When was it withdrawn? Has there been a MA transfer of the Pepcid 40 mg MA (PL 00025/0216) since original MA application until MA withdrawal? If so, please provide a history of MA transfers?
Has there ever been a Pepcid 20 mg MA? If so, when was it approved, what was the MA number and who was the original MA holder?
As Pepcid 40 mg (PL 00025/0216) is now withdrawn and assuming this was the reference product for famotidine in the UK, which other MA can be used as the reference product in terms of product information?

Our response:

The UK reference products for famotidine are Pepcid Tablets 20 mg and Pepcid Tablets 40 mg (PL 00025/0215 and PL 00025/0216), which were granted Marketing Authorisations to Merck Sharp & Dohme Limited on 8 September 1987. These marketing authorisations were cancelled on 12 December 2013. They were not subsequently transferred to another company. Unfortunately, we do not hold any information on the product in Germany (Pepdul 40 mg Tablets).

Pepcid Tablets 20 mg and Pepcid Tablets 40 mg (PL 00025/0215-0216) can be cited as regulatory reference medicinal products, however as they are no longer marketed, they could not be used as comparator products.

The other current UK marketing authorisations for famotidine are generics and could not be used as a reference products.

If additional information on how to proceed with a marketing authorisation application is required, you may wish to apply for regulatory advice.

We hope you find this information useful. If you are dissatisfied with the handling of your request, you have the right to ask for an internal review. Internal review requests should be submitted within two months of the date you receive this response and addressed to: info@mhra.gov.uk

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 at:

Information Commissioner's Office
Wycliffe House
Water Lane
Wilmslow
Cheshire
SK9 5AF

Or online via: https://ico.org.uk/make-a-complaint/foi-and-eir-complaints/foi-and-eir-complaints/"

Your sincerely,
HQA FOI Team