

FOI 24/247

FOILicensing <FOILicensing@mhra.gov.uk>

Thu 04/04/2024 10:42

To [REDACTED]

Dear [REDACTED]

Regarding your request for information on Mavenclad® (cladribine), please see our response to your questions below.

1. In the course of the review of the Marketing Authorisation application for Mavenclad by the EMA, was the EMA or MHRA made aware of any existing or previous commercial relationships between the applicant, [REDACTED] and [REDACTED] (or an affiliate or company from the [REDACTED])
2. If so, can you provide documentation in which [REDACTED] provided details on any such commercial relationships as well as the EMA's response?  
**Mavenclad (cladribine) was authorised by the European Commission (EC) on 22 August 2017 following a centralised procedure. The UK was not rapporteur or co-rapporteur for this procedure, and we hold no documentation on the commercial relationships between [REDACTED]**
3. In the course of the review of the Marketing Authorisation application for Mavenclad by the EMA, was any assessment made regarding whether Mavenclad belonged to the global marketing authorisation of any previously-approved cladribine-containing product, including Leustat?
4. If so, can you provide documentation in which [REDACTED] made submissions on this question, as well as the EMA's response?  
**We hold no documentation concerning an assessment made regarding whether Mavenclad belonged to the global marketing authorisation of any previously-approved cladribine-containing product, including Leustat.**

If you have a query about the information provided, please reply to this email.

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](mailto: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

Yours sincerely,  
FOI Team