FOI 23/893 - Alzheimer's - Leqembi (Lecanemab)

Dear

Thank you for your request for information dated, 18 November 2023, we have identified the following questions within your email:

> *"**Alzheimer's - Leqembi (Lecanemab***
>
> *I appreciate that this medication will require the approval of the UK Health authorities before it is available for prescription in the UK and that this process may take some time to conclude.*
>
> *I shall be very pleased if you can advise me of the progress that is being made in the UK regarding the suitability and efficacy of making this medication available in the UK."*

We can advise that the MHRA holds a marketing authorisation application for Lecanemab, and this has been made public by the company please refer to the below press release:

EISAI SUBMITS MARKETING AUTHORIZATION APPLICATION FOR LECANEMAB AS TREATMENT FOR EARLY ALZHEIMER'S DISEASE IN GREAT BRITAIN | Biogen

In terms of your request we hold information on the status of the application in the assessment process. However, we cannot divulge this information as it is considered to be commercially confidential / sensitive*. Nonetheless, you could approach the company as they may be able advise further on their intentions with regard to authorisation and their intentions for marketing the product.

*Section 43 is a qualified exemption and requires a consideration of the public interest. We have considered the public interest and cannot see any public interest argument that outweighs the commercial harm in alerting competitors to whether a company is close to obtaining a marketing authorisation or not. Please note that in line with the guidance from the Information Commissioner's Office (ICO) we consider a response or disclosure under FOI to be made to the world at large, which in due course will be published (in a redacted form to remove personal information) on our website. So, whilst we are not referring to you as a competitor, any response or information we give to you or anyone else via FOI will in due course become publicly available.

Other resources and information which may be of interest to you
Sometimes there are clinical situations when the use of an unlicensed medicine can be provided to a patient. Please note that Healthcare professionals may have more responsibility to accurately prescribe an unlicensed medicine than a licenced

medicine in the UK or GB. The following web link include an example on the use of an unlicensed medicine https://www.gov.uk/drug-safety-update/off-label-or-unlicensed-use-of-medicines-prescribers-responsibilities.

The General Medical Council (GMC) regulate doctors and how they prescribe. Guidance about prescribing unlicensed medicines is provided by the GMC.

Our role is to regulate medicines, medical devices, blood components for transfusion and to ensure that they are safe for the public to use in the UK. We do not provide medical advice and suggest you speak to your doctor or Healthcare professional on best treatment options.

National Institute for Clinical Excellence (NICE) Lecanemab update:
NICE gets ready to assess new dementia treatments. | News | News | NICE
Project information | Lecanemab for treating mild cognitive impairment or mild dementia caused by Alzheimer's disease [ID4043] | Guidance | NICE

A list of on-going trials which are recruiting in the UK is available here, this website can be searched for the specific condition of interest e.g. Alzheimer's disease.
Be Part Of Research (nihr.ac.uk)

[,,,] please be assured that the MHRA works hard to ensure patient access to safe, effective, quality medicines.

We trust that you will find this background information of use. However, If you disagree with how we have interpreted the Freedom of Information Act 2000 in answering your request, you can ask us to review our actions and decisions by writing to: info@mhra.gov.uk, and requesting an internal review.

Please note that your internal review request must be in a recordable format (email, letter, audio tape etc.), and that you have 40 working days upon receipt of this letter to ask for a review. We aim to provide a full response to your review request within 20 working days of its receipt. Please quote the reference number above in any future communications.

If you are not content 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 online via an electronic form: https://ico.org.uk/make-a-complaint/foi-and-eir-complaints/foi-and-eir-complaints/

Or in writing to:
Information Commissioner's Office,
Wycliffe House,

Water Lane,
Wilmslow,
Cheshire,
SK9 5AF

Yours sincerely,

HQA FOI Team