FOI 23/154

28th February 2023

Dear

Thank you for your request under the Freedom of Information Act (FOIA).

Orkambi 100mg/125mg granules in a sachet (PLGB 22352/0006) and Orkambi 150mg/188mg granules in sachets (PLGB 22352/0007) are currently indicated for the treatment of cystic fibrosis (CF) in patients aged 2 years and older who are homozygous for the F508del mutation in the cystic fibrosis transmembrane conductance regulator (CFTR) gene. Orkambi 200mg/125mg film coated tablets (PLGB 22352/0004) and Orkambi 100mg/125mg film coated tablets (PLGB 22352/0005) are currently indicated for the treatment of cystic fibrosis (CF) in patients aged 6 years and older who are homozygous for the F508del mutation in the cystic fibrosis transmembrane conductance regulator (CFTR) gene.

Unfortunately, the Medicines and Healthcare Products Regulatory Agency cannot provide information on whether an application has been submitted to extend the use of Orkambi to 1-2 year olds. We refuse to confirm or deny that we hold this information under Section 41 (S41 – information provided in confidence) and Section 43 (S43 – commercial interests) of the Freedom of Information Act (FOIA).

Section 41 is an absolute exemption and no consideration of the public interest is required, except to state that we would consider the release of this information to be an actionable breach of confidence. Section 43 is a conditional 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 publishing this information, which would alert competitors to whether a change in the indications for marketing authorisation are close or not.

There are Clinical Trial databases available where records of clinical trials that are currently in progress, as well as completed trials, can be searched:
https://www.clinicaltrialsregister.eu/ctr-search/search
https://www.isrctn.com/

We also advise discussing your situation with your GP.

We do apologise that we cannot take this forward for you.

If you disagree with how we have interpreted the Freedom of Information Act 2000 with regards to your request, you can ask for the decision to be reviewed. The review will be carried out by a senior member of the Agency who was not involved with the original decision.

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

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

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