

FOI 23/786

Dear

Thank you for your email where you have asked ***if there is a timeline on approval for the product Lyfnua.***

Unfortunately, we cannot provide information on whether there may or may not be an application for any particular product. This means that for your enquiry about Lyfnua, we need to refuse to confirm or deny whether 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 competitor is close to obtaining a marketing authorisation or not.

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

Yours sincerely

MHRA Customer Experience Centre
Communications and engagement team
Medicines and Healthcare products Regulatory Agency
10 South Colonnade, Canary Wharf, London E14 4PU