

Medicines & Healthcare products Regulatory Agency

10 South Colonnade
Canary Wharf
London
E14 4PU
United Kingdom
gov.uk/mhra



27 October 2023

FOI 23/771

Dear

Thank you for your letter of 8th June where you have asked "I write to inquire what the status of the licence for treatment of motor neurone disease is and if it applies to UK. If it has been licensed for use in the UK, how can treatment with the drug for motor neurone disease can be accessed? What plans if any there are to make the treatment of motor neurone disease with interleukin 2 available on the NHS?"

The Medicines and Healthcare Products Regulatory Agency (MHRA) can confirm that Interleukin-2 is not currently licensed for motor neurone disease. 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 whether any applications have been received by MHRA for Interleukin-2, we need to refuse the request and neither 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 change in the indications for marketing authorisation are close or not.

Please be aware we publish redacted FOI replies on our website and these can be found at the following link:

https://www.gov.uk/government/collections/freedom-of-information-responses-from-the-mhra-2021

If you disagree with how we have interpreted the Freedom of Information Act 2000 in answering your request, you can ask for an internal review. Please reply to this email, within two months of this reply, specifying that you would like an Internal Review to be carried out.

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 online via an electronic form: https://ico.org.uk/make-a-complaint/foi-and-eir-complaints/foi-and-eir-complaints/

Or

by writing to:

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