

**FOI 23/103**

**20<sup>th</sup> March 2023**

Dear

Thank you for your email and we apologise for delay in response.

The review of new drugs reviews the benefit-risk in relation to quality, safety and efficacy. Only when this is found to be positive, would a drug be approved, including for new antiviral drugs and monoclonal antibodies.

The MHRA website provides detailed information on licensing process: [Medicines, medical devices and blood regulation and safety: Marketing authorisations, variations and licensing guidance - detailed information - GOV.UK \(www.gov.uk\)](https://www.gov.uk/guidance/medicines-medical-devices-and-blood-regulation-and-safety-marketing-authorisations-variations-and-licensing-guidance-detailed-information)

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 at:

Information Commissioner's Office  
Wycliffe House  
Water Lane  
Wilmslow  
Cheshire  
SK9 5AF

Yours sincerely

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