

FOI 23/090

14th March 2023

Dear

Thank you for your email.

Regarding whether applications have been approved by MHRA to date that have been included in the Innovative Licensing & Access Pathway, including both new marketing authorisation approvals and variations to existing approved authorisations, we refuse to confirm or deny we hold any information under Section 41 (S41 – information provided in confidence) and Section 43 (S43 – commercial interests) of the Freedom of Information Act (FOIA).

S41 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. S43 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 caused in releasing this information, which would constitute a breach of trust between MHRA and those companies coming to us to apply for ILAP. This breach of trust would result in fewer companies wanting to engage with MHRA in ILAP and would inhibit the good advice that we provide companies, which would be detrimental to their product development and ultimately to patients.

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

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
Telephone 0203 080 6000

