

FOI 23-436 – position on pending MAAs

REQUEST

13 June 2023

If a company submits an MAA for Market Approval and already has completed MIA acceptance and certification requirements, along with PIP certification would MHRA have a public reference that MAA has been submitted and pending review ?

Basically what to know if a company has submitted an MAA?

MHRA RESPONSE

12 JULY 2023

Thank you for your email.

Regarding your enquiry “would MHRA have a public reference that MAA has been submitted and pending review”, we do not publish any information on whether a Marketing Authorisation Application (MAA) is submitted and pending assessment.

Regarding whether any applications have been received by MHRA, we would refuse to confirm or deny under Section 41 (S41) and Section 43 (S43) of the FOI 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 in alerting competitors to whether a competitor is close to obtaining a marketing authorisation or not.

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
Communications and engagement team
Medicines and Healthcare products Regulatory Agency
10 South Colonnade, Canary Wharf, London E14 4PU
Telephone 020 3080 6000