

FOI 23/716

Dear

Thank you for your email.

“we are interested in particular to know if MAA are pending for biosimilars containing tocilizumab (cimzia).”

The Medicines and Healthcare Products Regulatory Agency (MHRA) does not have a list of pending Marketing Authorisation Applications on its website and advise it is not possible to access a list from us.

Unfortunately, we cannot provide information on whether an application for biosimilars containing tocilizumab (cimzia) has been received. We refuse to confirm or deny that 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

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