

FOI 22/1174 – Brillique/Ticagrelor quality overview

REQUEST

18 October 2022

Please may I request the following in respect of Brillique (INN: Ticagrelor), PLGB 17901/0310.

Please can we have copies of the quality overview which accompanies the clinical and non-clinical overviews that support the grant of the MA.

MHRA RESPONSE

1 February 2023

Dear

Thank you for your email.

Regarding Quality Overview, 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 of releasing confidential and commercially sensitive data that could be used by competitors to facilitate the compiling and drafting of certain key aspects of an MAA application, e.g. details of the manufacturing process (including, for example, reference to starting materials, critical steps, and reprocessing) as well as the controls used to maintain the quality of a medicine—the main components of the QOS.

Further, we are also exempting information in the QOS under Section 21 of the FOI Act (Information accessible by other means), as the remainder of the information in this document which can be released is already available via the public domain in the public assessment report (PAR) and SmPC.

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

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