

FOI 23/834

Dear

Thank you for your request for information dated, 31 October 2023, where you asked:

“I found information about the granted market authorization by month in the period 2014 to 2023. However, I am also interested in applications that were either refused or withdrawn. Is this data available? If yes, is it possible to access it?”

Response:

Please find attached a list of marketing authorisation applications for the period 2014-2023 that have been refused, the other columns can be filtered as needed.

The individual details of the withdrawn applications or those refused cases which may be at appeal are exempt from release under Sections 41 and 43(2) of the Freedom of Information Act (FOIA). If we were to release these details, this information could be used to alert current marketing authorisation holders to a potential competitor who is trying to enter the marketplace. Although MHRA believes in the principles of transparency for showing good governance and regulation of medicinal products, to release specific information on these applications would undermine the trust between MHRA and the companies concerned, as these companies expect such applications to be submitted in confidence.

Section 41 is an absolute exemption, and no consideration of the public interest is required, except to state that we consider the release of specific information on marketing authorisation applications submitted to MHRA that were subsequently withdrawn or refused cases at appeal, to be an actionable breach of confidence.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argument that outweighs the commercial harm in alerting competitors to whether an application may have been made and withdrawn, or refused and are at the appeal stage, for the reasons already stated above. Please note that in line with the guidance from the Information Commissioner’s Office (ICO), we consider a response for disclosure under the FOIA to be made to the world at large, which in due course will be published (in a redacted form to remove personal information) on our website. So, whilst we are not referring to you as a competitor, any response or information we give to you or anyone else under the FOIA will in due course become publicly available.

We trust that you will find this information of use.

Your right to seek a review

If you disagree with how we have interpreted the Freedom of Information Act 2000 in answering your request, you can ask us to review our actions and decisions by writing to: info@mhra.gov.uk, and requesting an internal review.

Please note that your internal review request must be in a recordable format (email, letter, audio tape etc.), and that you have 40 working days upon receipt of this letter to ask for a review. We aim to provide a full response to your review request within 20 working days of its receipt. Please quote the reference number above in any future communications.

If you are not content 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 online via an electronic form: <https://ico.org.uk/make-a-complaint/foi-and-eir-complaints/foi-and-eir-complaints/>

*Or in writing to:
Information Commissioner's Office,
Wycliffe House,
Water Lane,
Wilmslow,
Cheshire,
SK9 5AF*

Yours sincerely,

HQA FOI Team