

FOI 23/087

23rd February 2023

Dear

Thank you for your information request, dated 1 February 2023, where you asked for search in your database for adverse events for the Smoke Free 23 app

Unfortunately, the information is exempt from release under section **Section 43 – Commercial interests**:

Section 43 – Commercial interests: information where disclosure would be likely to prejudice the commercial interests of any person, including third parties or the public authority that holds the information. Section 43 is a qualified exemption, which means that we have considered whether the public interest in releasing the information is outweighed by the public interest in not giving the information. We consider that the public interest will be better served by not releasing the information as there have been fewer than five or no reports made to the MHRA involving this particular product. Releasing the information would also prejudice the Agency's commercial interests in this case and in future. As a market regulator, it is vital that the Agency can freely engage in dialogue with organisations about commercial activities.

If you disagree with how we have interpreted the Freedom of Information Act 2000 with regards to your request, you can ask for the decision to be reviewed. The review will be carried out by a senior member of the Agency who was not involved with the original decision.

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

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

Medicines and Healthcare products Regulatory Agency

10 South Colonnade, Canary Wharf, London E14 4PU