



Medicines & Healthcare products
Regulatory Agency

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[gov.uk/mhra](https://www.gov.uk/mhra)

[REDACTED]

07 July 2023

FOI 23/405

Dear [REDACTED]

Thank you for your information request, dated 9 June 2023, where you asked for a copy of the final study report for “A post-authorisation safety study (PASS) to evaluate the paternal exposure to valproate and the risk of neurodevelopmental disorders including autism spectrum disorders as well as congenital abnormalities in offspring - a population-based retrospective study”, reference EUPAS34201, that was commissioned by the European Medicines Agency and then supplied to the MHRA.

Unfortunately, the information is exempt from release under section:

Section 41 – Information provided in confidence: information provided to us in confidence, with the expectation that it will not be released, is exempt from disclosure under the FOI Act. Information will be covered by Section 41 if: it was obtained by the authority from any other person; its disclosure would constitute a breach of confidence; a person or organisation could bring a court action for that breach of confidence; and that court action would be likely to succeed.

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.



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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,
Safety & Surveillance