Medicines & Healthcare products Regulatory Agency

MHRA Central Freedom of Information Team
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E14 4PU

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MHRA Website

[redacted]

Our Ref: **FOI2024/00798**

16 January 2025

Dear [redacted]

Thank you for your Freedom of Information (FoI) request received on 16 December. You wrote:

> *In January 2024, the MHRA changed its guidance to doctors who wish to start males aged under 55 on a new course of valproate to treat epilepsy. In September 2024, further guidance to men was issued, which included the need to use contraception if taking valproate, and to stop valproate before trying to father a child.*
>
> *Both measures were based upon the EMA's safety committee's (PRAC) recommending certain precautionary measures for the treatment of male patients with valproate medicines, based upon a retrospective observational study carried out by companies that market valproate. This study was shared with the MHRA.*
>
> *This post-authorization safety study (PASS) evaluating the paternal exposure to valproate and the risk of neurodevelopmental disorders has the EU PAS number EUPAS34201 and the Study ID: 50599*
>
> *I would like to request a copy of the above study upon which the MHRA based its decision. Thus far, only an assessment report has been placed in the public domain. (https://www.gov.uk/government/publications/valproate-paternal-exposure-to-valproate-and-risk-of-neurodevelopmental-disorders-and-congenital-malformations-in-offspring)*

MHRA Response

We can confirm that the Agency holds this information which was provided in confidence by the marketing authorisation holders (MAHs) when it was provided to the European Medicines Agency (EMA).

Please note that the regulatory changes communicated in January 2024 were not based on the PASS study evaluating the paternal exposure to valproate and the risk of neurodevelopmental disorders. The evidence underpinning the regulatory changes communicated in January 2024 is outlined in the Public Assessment Report dated November 2023.

The EMA published details of the PASS (EUPAS34201) and subsequently published the outcome of the PASS including the data submitted by the MAHs which consisted of the Final

report, Corrigendum to the final report and an Addendum. This information is available on the EMA website here: Outcomes of imposed non-interventional post-authorisation safety studies.

The MHRA do not routinely publish original study data and will not be providing a hard copy of the final report as the information is exempt under Section 21(1) of the Freedom of Information Act because the information is reasonably accessible to you, as it is already in the public domain.

If you have any queries about this letter, please contact us quoting the reference number above.

Your right to complain under the Freedom of Information Act

If you are not happy with this response you may request an internal review by e-mailing foi.request@mhra.gov.uk or by writing to: MHRA Central Freedom of Information Team, 10 South, Colonnade, Canary Wharf, London, E14 4PU

Any request for an internal review must be received by us within 40 working days of the date of this letter. Please note we are not obliged to provide a review if it is requested after more than 40 working days.

Yours sincerely,

MHRA Central Freedom of Information Team
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