FW: FOI 24/008 - Freedom of Information Request - Valproate pregnancies

Pharmacovigilanceser < vigilanceservice@mhra.gov.uk >

Fri 05/01/2024 16:33

To

Hi All,

For your records.

Many thanks,

From: Pharmacovigilanceser

Sent: Friday, January 5, 2024 4:32 PM

To:

Cc:

Subject: RE: FOI 24/008 - Freedom of Information Request - Valproate pregnancies

## FOI 24/008

Dear

Thank you for your email dated 2nd January 2024, where you requested:

- Total Valproate conceptions to date
- Total number of Valproate pregnancies from November 2022 to November 2023
- Total number of Valproate births from November 2022 to November 2023

The MHRA does not hold this information, however it is publicly available at the following link: <a href="https://digital.nhs.uk/data-and-information/publications/statistical/mi-medicines-and-pregnancy-registry">https://digital.nhs.uk/data-and-information/publications/statistical/mi-medicines-and-pregnancy-registry</a>

Although the link to the <u>Valproate use by women and girls</u> was updated/moved on 28<sup>th</sup> November 2023, the embedded link to the Medicines and Pregnancy Register links to the report published on 11 Feb 2021 rather than the home page for the registry. It can be easily accessed by clicking on the <u>link</u> at the top of the webpage or by using the search function on the NHS Digital website.

The summary page makes it clear that NHS Digital publish updates twice a year with the last one published on 28 September 2023 and that there is a 6-month delay between the end of the time period and publication. Therefore, data on exposed pregnancies in England are only available between April 2018 and March 2023. The MHRA worked in partnership with NHS Digital on the registry but do not hold or have access to the patient level data.

I hope the information provided is helpful, but 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 of this response; and can be addressed to this email address.

Yours sincerely,

## **FOI Team**

Safety & Surveillance Group

Medicines and Healthcare Products Regulatory Agency 10 South Colonnade, Canary Wharf, London E14 4PU

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From:

Sent: Tuesday, January 2, 2024 1:42 PM

To: MHRA Customer Services < MHRACustomerServices@mhra.gov.uk >

Cc:

Subject: FOI 24/008 - Freedom of Information Request - Valproate pregnancies

Dear MHRA

Due to INFACT's work with the MHRA and the Patient Safety Commissioner on the subject of Valproate and Pregnancy, we have found that the link to the Valproate Registry on the MHRA website, although updated in November 2023, is taking people to NHS Digital figures dated April 2018 – 30<sup>th</sup> March 2020, therefore we are writing to request the true and up to date figures for the following

- Total Valproate conceptions to date
- Total number of Valproate pregnancies from November 2022 to November 2023
- Total number of Valproate births from November 2022 to November 2023

We look forward to your reply Yours sincerely



