Medicines & Healthcare products Regulatory Agency

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[redacted]

27 October 2023

FOI 23/727

Dear [redacted]

Thank you for your enquiry of 30 September detailed below which has been classified as a Freedom of Information request with the reference number FOI 23/727.

‘[redacted] I am attempting to collate data about adverse drug reactions, specifically 'congenital, familial and genetic disorders', however filtering the results by 'male' is showing me the results for affected male babies/children, as opposed to fathers. I was wondering if there is any way I can access data relating to sodium valproate exposure via the father, and this specific reaction group? Or alternatively, if there is any way to filter on your website to find the results I'm looking for? “

When considering the below Adverse Drug Reaction (ADR) data, it is important to be aware of the following points:

- A reported reaction does not necessarily mean it has been caused by the medicine or vaccine, only that the reporter had a suspicion it may have. The fact that symptoms occur after use of a vaccine or medicine, and are reported via the Yellow Card scheme, does not in itself mean that they are proven to have been caused by it. Underlying or concurrent illnesses may be responsible and such events can also be coincidental.

- It is also important to note that the number of reports received via the Yellow Card scheme does not directly equate to the number of people who suffer adverse reactions and therefore cannot be used to determine the incidence of a reaction or compare the safety profile of different vaccines. ADR reporting rates are influenced by the seriousness of ADRs, their ease of recognition, the extent of use of a particular medicine, and may be stimulated by promotion

and publicity about a drug. Reporting tends to be highest for newly introduced vaccines during the first one to two years on the market and then falls over time.

Data reported through the Yellow Card scheme relating to sodium valproate exposure via the father is provided below from a search of the MHRA internal database using the following search strategy terms:

Exposure via father,
Exposure via partner,
Maternal exposure via partner during pregnancy,
Paternal drugs affecting foetus,
Paternal exposure before pregnancy,
Paternal exposure during pregnancy,
Paternal exposure timing unspecified
Exposure via semen,
Transmission of drug via semen

This search strategy retrieves 5 UK ADR reports which report the following 3 events in children born to fathers taking valproate:

- Cleft palate
- “Minor” epilepsy
- Otospondylomegaepiphyseal dysplasia

In addition, one case reported a spontaneous abortion (miscarriage) and in one case the report is of male infertility.

We 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: info@mhra.gov.uk

Yours sincerely,

FOI Team
Safety and Surveillance
Medicines and Healthcare products Regulatory Agency

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