Medicines & Healthcare products Regulatory Agency

MHRA
Regulating Medicines and Medical Devices

[redacted]

MHRA

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United Kingdom

www.gov.uk/mhra

2nd May 2024

Dear [redacted]

FOI 24/327

Thank you for your phone call on 4th April 2024 where you requested the following information:

"What is the correlation between the product Pethidine injections and autism, any ADR reports?
All autism cases in the UK linking to product (ADRs)?
All autism cases globally linking to product (ADRs)?"

It may be helpful to firstly provide some background information to allow interpretation of this data. The Yellow Card scheme is the UK system for collecting and monitoring information on suspected adverse drug reactions (ADRs). The scheme is run by the MHRA and currently relies on voluntary reporting of suspected ADRs by health professionals and patients. There is also a legal obligation for pharmaceutical companies to report serious ADR reports to their drugs. All reports, including from patients, are reviewed through a signal detection process to identify previously unrecognised concerns about medicines and consider if further action is necessary.

Pethidine is an opioid which is authorised for pain relief during labour and it's effect only lasts between 2 to 4 hours. Pethidine can cross the placenta and can have a similar effect on the baby. Adults digest pethidine quicker than babies, although this can vary. The most appropriate use for pethidine is earlier in labour, when it can be digested by the mother. The causes of autism spectrum disorders are not fully known and are likely associated with multiple factors. The MHRA has received 307 Yellow Card reports for Pethidine, of which 3 have reported Autism as a suspected adverse drug reaction.

Please find attached Drug Analysis Print (DAP) for Pethidine. This DAP contains complete data for all UK spontaneous suspected adverse reactions, or side effects, since the start of the Yellow Card Scheme, 01/07/1963 until 22/04/2023. Please refer to the attached information sheet for guidelines on how to interpret these DAPs.

When considering the spontaneous ADR data detailed above, it is important to be aware of the following points:

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

- It is also important to note that Yellow Card data cannot be used to determine the incidence of a reaction or to compare the side effect profiles of different medicines or vaccines. ADR reporting rates are influenced by the seriousness of ADRs, their ease of recognition, the extent of use of a particular drug or vaccine and may be stimulated by promotion and publicity about a drug. Reporting tends to be highest for newly introduced medicines or vaccines during the first one to two years on the market and then falls over time.

I can confirm that the MHRA does not hold all global suspected ADR reports for any medicine, including Pethidine. The World Health Organization (WHO) database covers approximately 99% of the world and can be accessed here https://www.vigiaccess.org/.

I have attached the Patient Information Leaflet for Pethidine which includes a list of known side effects of this medication.

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 this response's date and can be addressed to this email address.

Yours sincerely,

FOI Team,
Safety and Surveillance Division

If you have a query about this email, please contact us. If you are unhappy with our decision, you may ask for it to be reviewed. That review will be undertaken by a senior member of the Agency who has not previously been involved in your request. If you wish to pursue that option please write to the Communications Directorate, 4-T, Medicines and Healthcare products Regulatory Agency, (via this email address). After that, if you remain dissatisfied, you may ask the Information Commissioner at:

The Information Commissioner's Office
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