Medicines & Healthcare products Regulatory Agency

MHRA
Regulating Medicines and Medical Devices

[redacted]

MHRA

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www.gov.uk/mhra

16 May 2024

Dear [redacted]

RE: FOI2024/00064

Thank you for your information request, received 22nd April 2024. As you may be aware your request for information was logged as an FOI twice, please accept our apologies for the confusion caused. Your request for FOI 2024/00064 is detailed below:

> *I obtained a case listing from UMC/VigiBase platform and I am trying to match up their records of fatal cases to the 5 entries in the Yellow Card system. The screenshot shows the output from the .csv file exported from the Yellow Card platform. I realize that one entry in the yellow card system was reported by a consumer (#408) and not a healthcare provider. I would like to know if entry #408 is a duplicate of #395 as it is very unusual to see brain injury as an adverse drug report associated with Patent Blue V. Do you have de-identified individual case safety summary reports for these that can be shared (similar to what is posted through EudraVigilance)?*

Your request for FOI 2024/00070 is detailed below:

> *I ran a query on the Yellow Card database for Patent Blue V and it returned 5 fatal cases. The reason that I am asking is that I am a medical writer contracted to prepare safety summaries for a client who is interested in Patent Blue V and it is very important that I am able to identify and describe any fatal cases reported for Patent Blue V as very few have been reported in literature publications. I attended a meeting recently with my client and representatives from the US FDA and we were asked by the FDA to reach out to the various Pharmacovigilance authorities around the globe to make every effort to obtain information on fatal outcomes, including PHI removed/de-identified narratives, where possible. During this meeting, they identified 2 fatal cases with MHRA in the identifiers: Case 1 with worldwide Unique ID: GBMHRA- MED- 20230622164 5088490- HYJQM (Safety Report ID: GB-MHRA-ADR 28000024) and Case 2 with worldwide unique ID: GB-MHRA- MED-20230412154 231885è_0- VJYLZ (Safety Report ID: GB-MHRA- ADR 27834330) - both reported in 2023. I have matched the high-level terms as best as I can and*

linked these to the ADR #419 and #408, respectively, from the Yellow Card system database download csv file for event listing. Is there any further information available on the fatal cases reported to MHRA? Any information that you can provide is much appreciated.

You will have received our response to FOI 2024/00070, which provided all the information we can share in relation to the 5 UK spontaneous suspected adverse drug reaction reports for Patent Blue V with a fatal outcome, as referenced in your request.

Further to your additional questions enquiring whether two of the reports which included brain injury as suspected adverse reactions were duplicates, I can confirm after review of additional information that these reports have been identified as duplicates and will be merged on our system, thank you for bringing this to our attention. This will be reflected on our published iDAP data by next month.

Lastly, In FOI 2024/00070 you also mention you have tried to match two reports from the FDA database to that show in iDAPs published on the Yellow Card website. I can confirm the reports you've linked match the information we hold.

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 and Surveillance

If you have a query about the information provided, please reply to this email

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. 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

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