



Medicines & Healthcare products
Regulatory Agency



MHRA
10 South Colonnade
Canary Wharf
London
E14 4PU
United Kingdom

www.gov.uk/mhra

18th August 2023

Dear [REDACTED]

FOI 23/543

Thank you of your email dated 20th July 2023, where you requested:

“Suspected adverse reactions to benzodiazepines through the Yellow Card scheme including dementia, neurological disorders or cancers, and details of the suspected adverse reactions reported on the MHRA website - please provide links to the relevant pages on the MHRA website.

Details of which published literature the MHRA has considered on the impact of benzodiazepines on dementia risk, brain health and cancer risk.”

For suspected side effects being reported for medicines, the MHRA publishes this information in the form of interactive Drug Analysis Profiles (iDAPs) which can be accessed using the link below:

<https://yellowcard.mhra.gov.uk/idaps>

This will allow you to see the types of reactions that have been reported to benzodiazepines. Therefore, this information is exempt from release under the FOI Act under Section 21 (information accessible by other means). The information you have requested is already in the public domain and can be accessed using the link above. However, if you require further details, please respond with the exact information you require and for which benzodiazepine specifically.

Regarding the second part of your request, all data relating to the safety of a medicine must be held by the Marketing Authorisation Holder (MAH) and the MHRA must be notified about any data which impacts on the safety of their products and this includes published literature. Published literature on the impact on dementia risk, brain health and cancer risk is not specifically held by the MHRA but can be accessed to support safety evaluations and would be included in the Periodic Safety Update Reports (PSURs) produced by MAHs for each active substance for which they hold product licences.

The European Union Reference Dates (EURD) list provides a list of active substances in medicinal products and includes the frequencies for submission of these PSURs and can be found here:
<https://www.ema.europa.eu/en/news/european-medicines-agency-publishes-list-eu-reference-dates-frequency-psur-submission>



Please note that every active substance may have a different PSUR cycle and therefore each of the benzodiazepine PSURs will be submitted according to their individual timetable. These PSURs are then assessed by both the UK and EU Regulatory Authorities and necessary actions arising from new safety concerns are addressed as appropriate.

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,
Vigilance and Risk Management of Medicines Division

The MHRA information supplied in response to your request is subject to Crown copyright. The FOIA only entitles you to access to MHRA information.

For information on the reproduction or re-use of MHRA information, please visit
<https://www.gov.uk/government/publications/reproduce-or-re-use-mhra-information/reproduce-or-re-use-mhra-information>

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
Wycliffe House
Water Lane
Wilmslow
Cheshire
SK9 5AF

Copyright notice

The information supplied in response to your request is the copyright of MHRA and/or a third party or parties, and has been supplied for your personal use only. You may not sell, resell or otherwise use any information provided without prior agreement from the copyright holder.