Medicines & Healthcare products Regulatory Agency

[redacted]

10 South Colonnade
Canary Wharf
London
E14 4PU
United Kingdom
gov.uk/mhra

18th March 2024

Dear [redacted]

FOI 24/168

Thank you for your information request, dated 20th February 2024, where you requested Yellow Card data.

In response to your request, we can confirm that the MHRA does hold this information however most of the information is exempt from release under Section 21 of the FOIA (information accessible by other means), as this is already publicly available and can be found here: https://yellowcard.mhra.gov.uk/idaps. Each iDAP contains a complete listing of all suspected adverse reactions that have been reported to the MHRA via the Yellow Card scheme for a specific substance. This includes all reports received from healthcare professionals, members of the public, and pharmaceutical companies. The filters on the left-hand side of the page can be used to select a subset of reports such as age (10 year bands), sex, route of administration, report seriousness, year received, and source of report.

This information does not represent an overview of the potential side effects. A list of the recognised adverse effects is provided in the information for healthcare professionals and the recipient information MHRA Products | Home.

When using the Interactive Drug Analysis Profile, you should remember that:

- The likelihood of experiencing an adverse drug reaction when taking a medicine cannot be estimated from the data in the Interactive Drug Analysis Profile. This is because we have limited information about how many people have taken the medicine without experiencing a reaction.
- Reporters are asked to submit Yellow Card reports even if they only have a suspicion that the medicine may have caused the adverse drug reaction. The existence of an adverse drug reaction report in the Interactive Drug Analysis Profile does not necessarily mean that the medicine has caused the reaction.
- It may be difficult to tell the difference between something that has occurred naturally and an adverse drug reaction. Sometimes reactions can be part of the condition being treated rather than being caused by a medicine.

- Many factors have to be considered when assessing whether a medicine has caused a reported adverse drug reaction. When monitoring the safety of medicines, MHRA staff carry out careful analysis of these factors.
- It is not possible to compare the safety of different medicines by comparing the numbers presented in the Interactive Drug Analysis Profiles. Reporting rates can be influenced by many factors including the seriousness of the adverse drug reactions, their ease of recognition and the extent of use of a particular product. Reporting can also be stimulated by promotion and publicity about a product.

Data for vaccines other than COVID-19 vaccines is available on request, we would be happy to provide this in response to a new request once you specify which vaccines you are interested in.

I hope the information provided both here and in the iDAPs is helpful. 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

Please remember to quote the reference number above in any future communications.

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:

Information Commissioner's Office
Wycliffe House
Water Lane
Wilmslow
Cheshire
SK9 5AF