



Medicines & Healthcare products  
Regulatory Agency

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[MHRA Website](#)

Our Ref: **FOI2025/00298**

7 August 2025

Dear [REDACTED]

Thank you for your Freedom of Information (FoI) request received on 9 July. You wrote:

*Please provide me with the most comprehensive dataset available relating to all adverse drug reactions (ADRs) and side effects reported to the Yellow Card scheme in connection with tirzepatide, including but not limited to its UK brand names Mounjaro and Zepbound, from the date of first report to the present.*

*I am specifically requesting:*

- *Raw (but fully anonymised) Yellow Card data related to tirzepatide*
- *Including, where available:*
  - o *Reaction terms (preferred terms and SOCs)*
  - o *Outcome (e.g. fatal, recovered, ongoing)*
  - o *Patient demographics (age group, sex, etc. where not identifying)*
  - o *Source of report (e.g. healthcare professional, patient)*
  - o *Date of onset and report*
  - o *Indication for use*
  - o *Dose, route, and duration of use*
  - o *Concomitant medications (where applicable)*

*Please provide the data in a format suitable for statistical analysis, such as CSV or Excel. I understand that some elements of the data may be redacted to protect confidentiality or comply with s.40 (personal data) or s.43 (commercial interests) of the FOIA. However, I request that you provide the fullest dataset possible within the limits of the law, and clearly indicate where any information has been withheld and under which exemption(s).*

## **MHRA Response**

We can confirm that we hold some of the information you have requested. However, some of the information is exempt under Section 21(1) of the Freedom of Information Act because the information is accessible to you, as it is already in the public domain.

You can view all suspected adverse reactions reported to the MHRA via the Yellow Card scheme on our website as [interactive Drug Analysis Profiles \(iDAPs\)](#). We currently publish data on reports processed up to 6 June 2025. Please be aware that there is a time lag of around one month from receipt of a report to it appearing in the iDAP.

Mounjaro (tirzepatide) is indicated for both type 2 diabetes and weight management in adults with obesity or overweight and at least one weight-related comorbidity. Zepbound is not licensed for use in the UK.

The iDAP for tirzepatide can be viewed [here](#). The reactions within the selected reports are displayed by primary System Organ Class (SOC) as defined by MedDRA. You can right-click on the left-hand column and select 'Expand All' or 'Expand Current' to view all reactions (preferred terms) reported within a specific SOC. Filter options are available to display reports by sex, age group, year of receipt, reporter type and route of administration. It is important to note that each individual iDAP on our website is accompanied by additional context for interpreting the Yellow Card data displayed in the iDAP.

Further to your request, we have provided separate tables displaying data not specifically covered within the iDAP, as listed below:

- **Table 1.** UK spontaneous suspected adverse reaction reports for tirzepatide and reaction outcomes
- **Table 2.** UK spontaneous suspected adverse reaction reports for tirzepatide and indication for use
- **Table 3.** UK spontaneous suspected adverse reaction reports for tirzepatide and tirzepatide dose
- **Table 4.** UK spontaneous suspected adverse reaction reports for tirzepatide and time to reaction onset
- **Table 5.** UK spontaneous suspected adverse reaction reports for tirzepatide and reported concomitant medications (excludes co-suspected medications)

It is important to be aware that it is not mandatory to provide reaction outcomes, suspect drug indication and dosage, reaction dates or concomitant medications when submitting a Yellow Card report to the MHRA, therefore the data provided only includes reports where these data was specifically reported. If discrepancies are noted during routine assessment in the data provided, we are able to follow-up with the reporter for further information should it be deemed necessary.

Patient safety is our top priority, and no medicine would be approved unless it met our expected standards of safety, quality, and effectiveness. Our role is to continually monitor the safety of medicines during their use, including GLP-1 receptor agonists (RAs). We have robust, safety monitoring and surveillance systems in place for all healthcare products. When a safety issue is confirmed, we always act promptly to inform patients and healthcare professionals and take appropriate steps to mitigate any identified risk. New medicines, such as GLP-1 RAs, are more intensively monitored to ensure that any new safety issues are identified promptly. Additionally, the MHRA recently published some guidance for patients taking GLP-1 RAs for diabetes and/or weight loss which can be viewed [here](#).

It is important to note that a reaction reported to the Yellow Card scheme does not necessarily mean it has been caused by the medicine, only that the reporter had a suspicion it may have. Underlying or concurrent illnesses may be responsible, or the events could be coincidental.

As the use of the GLP-1 RAs increases, so have the number of Yellow Card reports associated with these medicines. Yellow Card 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 publicity and awareness about a product.

If you have any queries about this letter, please contact us quoting the reference number above.

Yours sincerely,

MHRA Central Freedom of Information Team  
Medicines & Healthcare products Regulatory Agency

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### **Your right to complain under the Freedom of Information Act**

If you are not happy with this response you may request an internal review by e-mailing [foi.request@mhra.gov.uk](mailto:foi.request@mhra.gov.uk) or by writing to: MHRA Central Freedom of Information Team, 10 South, Colonnade, Canary Wharf, London, E14 4PU

Any request for an internal review must be received by us within 40 working days of the date of this letter. Please note we are not obliged to provide a review if it is requested after more than 40 working days.

If you are not content with the outcome of the internal review, you may apply directly to the Information Commissioner's Office for a decision. Generally, the Commissioner cannot make a decision unless you have exhausted our own complaints procedure. The Information Commissioner can be contacted at: The Information Commissioner's Office, Wycliffe House, Water Lane, Wilmslow, Cheshire SK9 5AF.

Website: [ICO FOI and EIR complaints](#) or telephone 0303 123 1113.

### **Re-use of our information**

The MHRA information supplied in response to your request is subject to Crown copyright. Information created by the MHRA which is disclosed under the Freedom of Information Act is made available for re-use under the Open Government Licence (OGL) v3.0, except where this is otherwise stated. There are some restrictions on re-use under the OGL and these can be viewed here:

<https://www.nationalarchives.gov.uk/doc/open-government-licence/version/3/>