Medicines & Healthcare products Regulatory Agency

MHRA Central Freedom of Information Team
10 South Colonnade
Canary Wharf
London
E14 4PU

foi.request@mhra.gov.uk.

MHRA Website

[redacted]

Our Ref: **FOI2025/00091**

03rd March 2025

Dear [redacted]

Thank you for your Freedom of Information (FoI) request received on 03rd February. You wrote:

I am looking to submit a freedom of information request regarding the MHRA yellowcard scheme. Specifically, I am looking to determine:

(1) The number of adverse events reported for any class of GLP-1 inhibitor injection (Mounjaro, Trulicity, Victoza, Ozempic and Wegovy) from January 1st 2023, to December 31st 2024, broken down by primary complaint/issue/reason for reporting, and…

(2) The number of adverse events for any of the above medicines which were reported by the marketing authorisation holder specifically, as opposed to a member of the public or healthcare professional, over the same period of time (January 1st 2023 to December 31st 2024).

MHRA Response

In response to your request, we can confirm that we hold the information you have requested.

Firstly, I feel it may be beneficial to provide some further context on the Yellow Card scheme. The Yellow Card Scheme is the UK system for collecting and monitoring information on suspected Adverse Drug Reactions (ADRs) and incidents in association with medicines, vaccines and medical devices. The Scheme is run by the Medicines and Healthcare products Regulatory Agency (MHRA) on behalf of the Commission on Human Medicines (CHM), and currently relies on voluntary reporting of suspected ADRs by health professionals and patients. It's vital to note that Yellow Card reports are made based on suspicion and are therefore not conclusive evidence that the medicine or vaccine caused the suspected reaction(s).

Further to your query, we have conducted a search of our database for all spontaneous suspected Adverse Drug Reaction (ADR) reports associated with the glucagon-like peptide-1 (GLP-1) receptor drug substances 'liraglutide', 'semaglutide' and 'tirzepatide' received between 1st January 2023 and 31st December 2024. Please note that these are the substances used in the products you have mentioned in your request (Mounjaro, Trulicity, Victoza, Ozempic and Wegovy) and therefore will include reports for all of these.

I can confirm that between 1st January 2023 and 31st December 2024 the MHRA received a total of 20,022 UK spontaneous suspected ADR reports relating to the substances 'liraglutide', ‘semaglutide’ and ‘tirzepatide’. Further to this, please find the Drug Analysis Print (DAP) attached for details of the reported reactions to all three substances, as well as the enclosed information sheet for guidelines on how to interpret the DAP. Please note that the total number of reactions in the table will not be equal to the total number of unique reports as one report may contain more than one reaction.

As you may be aware, Saxenda (liraglutide) and Wegovy (semaglutide) are both approved for weight management in adults with obesity or those who are overweight with at least one weight-related comorbidity, as well as in adolescents with obesity. Wegovy (semaglutide) is additionally indicated to reduce the risk of serious cardiovascular problems in adults. 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. Ozempic (semaglutide) has been authorised for the treatment of insufficiently controlled type 2 diabetes mellitus in adults. Ozempic is not authorised for weight loss but is sometimes used off-label for that purpose. The data provided here includes all UK spontaneous suspected ADR reports received regardless of the indication for each drug. Reports will be included in the data whether the patient was being treated for weight loss or diabetes.

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

- A reported reaction does not necessarily mean it has been caused by a medicine or vaccine, only that the reporter had a suspicion it may have been. Each year, millions of doses of routine vaccinations are given in the UK alone, and when any vaccine is administered to large numbers of people, some recipients will inevitably experience illness following vaccination. The fact that symptoms occur after use of a vaccine or medicine, and are reported via the Yellow Card scheme, does not in itself mean that they are proven to have been caused by it. Underlying or concurrent illnesses may be responsible and such events can also be coincidental.

- It is also important to note that the number of reports received via the Yellow Card scheme does not directly equate to the number of people who suffer adverse reactions and therefore cannot be used to determine the incidence of a reaction. ADR reporting rates are influenced by the seriousness of ADRs, their ease of recognition, the extent of use of a particular medicine or vaccine and may be stimulated by promotion and publicity about a medicine or vaccine. Reporting tends to be highest for newly introduced medicines during the first one to two years on the market and then falls over time. For these reasons the enclosed data should not be used as a basis for determining incidence of side effects.

- The MHRA continuously monitors the safety of medicines and vaccines through a variety of pharmacovigilance processes, including the Yellow Card scheme. As part of our signal detection processes, all adverse reaction reports received by the Yellow Card scheme are assessed, and cumulative information is reviewed at regular intervals. If appropriate, regulatory action would be taken if any serious risks were confirmed.

Please be aware that the DAP provided should not be used as a list of side effects to the available GLP-1 substances, nor should this data to be used to estimate the frequency of side effects or to compare the safety profile of different medicines. All established undesirable effects for each of the GLP-1 substances (liraglutide, semaglutide and tirzepatide) can be found in the Summary of Product Characteristics (SmPC) for healthcare

professionals and the Patient Information leaflet (PIL), both of which can be found on the MHRA products website.

I hope the information provided 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.

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

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 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.

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