



Medicines & Healthcare products Regulatory Agency

MHRA Central Freedom of
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[MHRA Website](https://www.mhra.gov.uk)

Our Ref: **FOI2024/00672**

29th November 2024

Dear [REDACTED]

Thank you for your Freedom of Information (Fol) request received on 1st November 2024.
You wrote:

I'd like to make the following freedom of information request. Please could you provide the following:

In the MHRA reminder concerning the potential side effects of GLP-1 receptor agonists (published 24th October 2024) it is reported that of the 7228 reports of 'common gastrointestinal reactions of nausea, vomiting and diarrhoea in association with GLP-1RAs indicated for weight management', 68 reports involved hospitalisation. (Source: <https://www.gov.uk/drug-safety-update/glp-1-receptor-agonists-reminder-of-the-potential-side-effects-and-to-be-aware-of-the-potential-for-misuse#fn:2>)

*Please may you provide further information concerning these 68 cases, including:
Name of hospital into which they were admitted
Reactions by MedDRA System Organ Class*

MHRA Response

We can confirm that the Agency holds the information you are seeking.

However, we are engaging an exemption from disclosure under Section 41(1) of the Fol Act, which protects information provided in confidence.

The information you have requested relating to the names of hospitals where patients were admitted was obtained by the Agency from another person. The Agency believes that if this information would be released it would breach the confidence of the person(s) the information pertains to, actionable by them or any other person. Therefore, we are not going to be releasing the requested information. However, if you are interested in regional data then

please specify this. At this time, I can confirm the majority of the 68 reports were received from reporters within England.

Further to your request, please see Table 1 below which displays the reactions within these 68 reports by MedDRA system organ class (SOC). 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 per SOC.

Table 1: Number of reports for GLP-1RAs indicated for weight management which reported nausea, vomiting and/or diarrhoea up to and including 28th October 2024, broken down by MedDRA SOC.

Reaction MedDRA SOC	Number of Reactions
Cardiac disorders	6
Endocrine disorders	3
Eye disorders	1
Gastrointestinal disorders	138
General disorders and administration site conditions	18
Hepatobiliary disorders	2
Immune system disorders	1
Infections and infestations	8
Injury, poisoning and procedural complications	13
Investigations	13
Metabolism and nutrition disorders	25
Musculoskeletal and connective tissue disorders	2
Nervous system disorders	21
Product issues	3
Psychiatric disorders	13
Renal and urinary disorders	3
Reproductive system and breast disorders	1
Respiratory, thoracic and mediastinal disorders	5
Skin and subcutaneous tissue disorders	5
Vascular disorders	20
Total Reactions	301
Total Reports	68

When considering this spontaneous Adverse Drug Reaction (ADR) data, it is important to be aware of the following points:

- A reported reaction does not necessarily mean it has been caused by the drug, only that the reporter had a suspicion it may have. The fact that symptoms occur after use of a drug, and are reported via the Yellow Card scheme, does not in itself mean that they are proven to have been caused by the drug. 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 drug, and may be stimulated by promotion and publicity about a drug. 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.

Please be aware that the data provided should not be used as a list of side effects to the available GLP-1RAs, 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 the available GLP-1RAs 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](#).

The MHRA continuously monitors the safety of medicines 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 individually assessed and cumulative information reviewed at regular intervals. If appropriate, regulatory action would be taken if any serious risks were confirmed.

If you have any queries about this letter, please contact us quoting the reference number above. If you are planning a media story, please contact the MHRA News Team on 02030807651 or by email at newscentre@mhra.gov.uk.

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.