Medicines & Healthcare products Regulatory Agency

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www.gov.uk/mhra

4 August 2023

FOI 23/499

Dear

Thank you for your email dated 12 July 2023 in which you requested the following information under the Freedom of Information (FOI) Act:

- *The number of Yellow Card reports that mention the term "suicide" or "suicidal ideation" or "suicidal risk" for semaglutide and liraglutide.*
- *Does the MHRA typically formulate reports on such matters? If so, can you please provide them?*

The Yellow Card scheme, run by the MHRA, is the UK system for collecting and monitoring information on safety concerns such as suspected side effects involving medicines. The fact that symptoms occur after use of a medicine, and are reported via the Yellow Card scheme, does not in itself mean that they are proven to have been caused by the medicine, and should not be interpreted as a list of known side effects. Please refer to the guidance given later in this response to ensure that the Yellow Card data is interpreted in the correct way.

As of 6 July 2023, we have received 5 suspected adverse drug reactions involving semaglutide that are associated with ‘suicidal and self-injurious behaviour’. As of 6 July 2023, we have received 12 suspected adverse drug reactions involving liraglutide that are associated with ‘suicidal and self-injurious behaviour’. ‘Suicidal and self-injurious behaviour’ includes the suspected adverse drug reactions of suicidal behaviour, suicidal ideation, suicidal attempt, and self-injury.

Patient safety is our top priority. GLP-1 receptor agonists available in the UK are exenatide, liraglutide, lixisenatide, dulaglutide and semaglutide. As with all medicines, the safety of GLP-1 receptor agonists is kept under continual review by the MHRA to ensure that the benefits outweigh the risks. We are currently reviewing safety data on the risk of suicidal thoughts and thoughts of self-harm associated with medicines known as GLP-1 receptor agonists, used for treating both type 2 diabetes and weight loss. We will carefully consider all available evidence and communicate any further advice to patients and healthcare professionals as appropriate.

We advise any individual experiencing suicidal thoughts or thoughts of self-harm to seek immediate medical assistance. We ask everyone to continue to report any suspected side effects using our Yellow Card scheme website.

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The MHRA routinely publishes interactive Drug Analysis Profiles (iDAPs) on our website which contain a complete listing of all suspected adverse reactions that have been reported to the MHRA via the Yellow Card scheme. This includes all reports received from healthcare professionals, members of the public, and pharmaceutical companies. I can confirm that the MHRA publishes an iDAP for both semaglutide and liraglutide which are regularly updated in line with all other iDAPs for other medicines.

Guidance on Yellow Card reporting:

- The likelihood of experiencing an adverse drug reaction when taking a medicine cannot be estimated from the Yellow Card data. 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 fact that an adverse drug reaction has been reported 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 need to be considered when assessing whether a medicine has caused a reported adverse drug reaction. When monitoring the safety of medicines, the MHRA carries out a careful analysis of these factors.
- It is not possible to compare the safety of different medicines by comparing the number of reports received through the Yellow Card scheme. Reporting rates are variable and 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. For that reason, we use a range of tools and approaches to ensure that events are not occurring more frequently than they would in the general population, or in Clinical Trials. The Yellow Card scheme is one of several sources of evidence we use when evaluating the safety of medicines.

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,
Safety and Surveillance
Medicines and Healthcare products Regulatory Agency

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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, 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
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