Medicines & Healthcare products
Regulatory Agency

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[redacted]

6 February 2024

FOI 24/107

Dear [redacted],

Thank you for your Freedom of Information request dated 31 January 2024, where you requested data on medication errors for your research on overdoses of Glucagon-like Peptide-1 (GLP-1) agonists and SGLT2 inhibitors.

Firstly I would like to draw your attention to the interactive Drug Analysis Profiles (iDAPs) which are available on our website here: What is being reported | Making medicines and medical devices safer (mhra.gov.uk). 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 the year of receipt.

When reviewing the reported adverse events, it may be helpful to have some information on the dictionary that we use when classifying ADR reports and the process involved. MedDRA (Medical Dictionary for Regulatory Activities) is a clinically validated international medical terminology dictionary. It's organised by System Organ Class (SOC), divided into High-Level Group Terms (HLGT), High-Level Terms (HLT), Preferred Terms (PT) and finally into Lowest Level Terms (LLT). When patients and health care professionals are completing electronic Yellow Card reports they are able to type in the side effect which will populate a drop-down list containing suggested MedDRA LLT terms based on what they have entered. If the reporter cannot find a term which fits, then they can fill in this field with free text and one of our trained signal assessors will select an appropriate term or terms when evaluating the report. Similarly, if the reporter mentions an additional ADR in the report outside of the side effects section, then our assessor would add this too. If our

assessors are unsure on any ADR being reported, where possible, they follow up with the reporter to clarify this. Where information on overdoses and medication errors is provided, assessors ensure that the most appropriate term is coded within the case. For example, the PT prescribed overdose may be coded when a health care professional has intentionally prescribed a greater dose than the medicine is licensed for. All reactions at the PT level for a substance can be found within the iDAPs.

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.

I hope the information provided both here and in the iDAPs is helpful and fulfils your request, however, is there is any further information you require please detail this and we will be happy to log it as a further information request.

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

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If you have a query about the information provided, please reply to this email

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

If you were to remain dissatisfied with the outcome of the internal review, you would have the right to apply directly to the Information Commissioner for a decision. Please bear in mind that the Information Commissioner will not normally review our handling of your request unless you have first contacted us to conduct an internal review. The Information Commissioner can be contacted at:

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