Medicines & Healthcare products
Regulatory Agency

10 South Colonnade
Canary Wharf
London
E14 4PU
United Kingdom
gov.uk/mhra

[redacted]

13 March 2024

Dear [redacted]

RE: FOI 24/160

Thank you for your email dated 16th February 2024 where you requested:

- *Under the UKs Freedom of Information Act, copies of the full reports made to the MHRA for semaglutide specifically for the following reports:*
  GB-NOVOPROD-1119997
  GB-NOVOPROD-1106743
  GB-NOVOPROD-1034070
- *A summary of the number of reports of people hospitalised or died as a result of taking suspected counterfeit semaglutide in 2023.*

I can confirm that we hold the information requested, however provision of full copies of the reports requested is exempt from release under Section 40 (personal information) and Section 41 (information provided in confidence) of the FOI Act. Supplying you with this information could lead to patient or reporter identification. Further to the use of Section 40 and 41, as outlined in our Privacy Policy, the MHRA will not share the identity of anyone submitting a Yellow Card report with any person outside the MHRA without their explicit consent, unless we are required or permitted to do so by law. As this is personal data in relation to an individuals' health, this would be of detriment to them and may damage the engagement with the scheme.

Further to your second request I can confirm, in 2023 we received 12 UK spontaneous suspected Adverse Drug Reaction (ADR) reports for semaglutide associated with counterfeit-related[1] reported reaction terms. Please be aware the 3 reports you've listed above are included within the 12 ADR reports found on our system. Of these 12 ADR reports, 3 stated that the patient was hospitalised, however none of the reports included a fatal outcome.

[1] counterfeit product administered, product counterfeit, product label counterfeit, product packaging counterfeit, suspected counterfeit product, product administered from unauthorised provider, adulterated product, poor quality product administered, product quality issue, product substitution issue, product tampering, suspected product quality issue, suspected product tampering.

Please see the attached Drug Analysis Print (DAP) for semaglutide associated with the counterfeit-related reactions listed above. The DAP lists all the reactions which were reported within the 12 ADR reports up to and including 04 March 2024. The attached guidance sheet provides you with further information on how to interpret the print.

When considering the spontaneous data within this response, it is important to be aware of the following points:

- The inclusion of a particular reaction on our system does not necessarily mean that it has been caused by the suspect drug. Many factors must be considered in assessing causal relationships, including temporal association, the possible contribution of concomitant medication, and the underlying disease. We encourage reporters to report suspected ADRs i.e., the reporter does not have to be sure of a causal association between the drug and the reactions – a suspicion will suffice.
- It is 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 to drugs for several reasons. 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.
- The number of reports received should not be used as a basis for determining the incidence of a reaction as neither the total number of reactions occurring, nor the number of patients using the drug is known.

As these data do not necessarily refer to proven side effects, you should refer to the product information for details on the possible side effects.

We 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

dissatisfied, you may ask the Information Commissioner at: Information Commissioner’s Office Wycliffe House Water Lane Wilmslow Cheshire SK9 5AF.