	Reference Number **CASE_283**

Rapid Alert Notification of a Quality Defect

1. To: The Regulatory Authority	
2. Product Class of Defect: **Class: II**	3. **Falsification**
4. Product: **Ozempic Solution For Injection In Pre-Filled Pen**	5. Marketing Authorisation Number: **53/21.13/0497** For use in humans
6. Brand/Trade Name: **Ozempic Solution For Injection In Pre-Filled Pen**	7. INN or Generic Name: **semaglutide**
8. Dosage Form: **Injection In Pre-Filled Pen**	9. Strength: not established
10. Batch number: not established	11. Expiry Date: not established
12. Pack size and Presentation: not established	13. Date Manufactured: not established
14. Marketing Authorization Holder (MAH): Novo Nordisk (Pty) Ltd, 150 Rivonia Road 10 Marion Street Office Park, Building C1, Sandton, Johannesburg, 2196, South Africa Contact Person: Euganthri Pillay: eupi@novonordisk.com; Telephone: +27 11 202 0540 / +27 825266590	
15. Manufacturer: 15.1 Novo Nordisk (Pty) Ltd, 150 Rivonia Road 10 Marion Street Office Park, Building C1, Sandton, Johannesburg, 2196, South Africa	16. Recalling Firm (if different from 15.1): Not Applicable Contact Person: Not Applicable Telephone: Not Applicable
15.2 Where the defect is attributed to a manufacturing site, site where defect occurred (if different from 15.1): Not Applicable	
17. Recall Number Assigned (if available): Not Applicable	

18. Details of Quality defect:

In a notification sent to the South African Health Products Regulatory Authority (SAHPRA) by the company Novo Nordisk (Pty) Ltd, South Africa, a falsification report was confirmed about the products named **Ozempic.** The company stated that they received several notification about labeled vials and boxes that were released to the market by unknown source as counterfeit versions of Ozempic. One of the notifications was brought to Novo Nordisk's attention by a retail pharmacy based in Klerksdorp, in the North West part of South Africa. No physical sample was received for investigation, but just photos. The case has been reported to their Global Security partners for further processing and surveillance.

The summary of cases reported for potential counterfeit Novo Nordisk products in South Africa are therefore as follows: **9 cases on Ozempic falsification have been reported to Novo Nordisk South Africa to date:**

- 4 cases have been confirmed – no samples were retrieved, investigation was concluded by available pictures
- 2 cases were under investigation outcomes from their Headquarters in Denmark
- 3 cases were 'inconclusive' due to insufficient information available.

The company's confirmed counterfeit case reference is: 1168420

19. Information on distribution including exports (type of customer, e.g. hospitals): The MAH confirmed that the falsified products are distributed in South Africa.

For more information about exporting or batch destination, please contact the Marketing Authorization Holder and/ or local Regulatory Authority (SAHPRA). **portia.nkambule@sahpra.org.za / maphutheho.selikane@sahpra.org.za**

20. Action taken by Issuing Authority: Urgent actions have been initiated by the MAH for the examination and evaluation of product with the risk of falsification. The Authority will work closely with the MAH.

21. Proposed Action: Novo Nordisk (Pty) Ltd South Africa is committed to work closely with SAHPRA to combat the supply of counterfeit and illicit medicines.

22. From (Issuing Authority):

South Africa Health Products Regulatory Authority (SAHPRA) Loftus Park, Building A, 402 Kirkness St, Arcadia, Pretoria, 0083, South Africa.

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Signed:  Date: 19.June.2023

Deon Poovan – Senior Manager: Inspectorate & Regulatory Compliance