REPUBLIC OF KENYA

MINISTRY OF HEALTH

PHARMACY AND POISONS BOARD

RAPID ALERT NOTIFICATION OF A QUALITY DEFECT/RECALL

	Reference Number : **2024/003**
1. To: **World Health Organisation, Market Autorisation Holders, Distributors, Retailers and Consumers**	
2. Product Class of Defect: **Class 1**	3. **Falsification**
4. Product : **Ozempic solution for injection in pre-filled pen**	5. Marketing Authorisation Number: **currently NOT registered** 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 Authorisation Holder: **currently NOT registered**	
15. Manufacturer: **Not Applicable** Contact Person: **Not Applicable** Telephone: **Not Applicable**	16. Recalling Firm (if different): **Not Applicable** Contact Person: **Not Applicable** Telephone: **Not Applicable**
15.1 Where the defect is attributed to a manufacturing site, site where defect occurred (if different from 15): **Not Applicable** Contact Person: **Not Applicable** Telephone: **Not Applicable**	
17. Recall Number Assigned (if available): **Not Applicable**	

18. Details of Defect/Reason for Recall: **The Pharmacy and Poisons Board "the board" received an alert from the INTERPOL concerning the falsification of Ozempic Pens (Semaglutide) where Apidra Solostar pens (glulisine) used to treat both type 1 and type 2 diabetes has been falsely relabelled as Ozempic (Semaglutide) Pens.**
19. Information on distribution including exports (type of customer, e.g. hospitals): **Not Applicable**
20. Action taken by Issuing Authority: **The Board has initiated a rapid response and heightened surveillance to verify whether the falsified Ozempic (Semaglutide) Pens is presently circulating in the Kenyan market.**
21. Proposed Action: **The Board cautions the public and healthcare professionals AGAINST trading, distribution, wholesaling, retailing, issuing, dispensing, use or administration to patients of the falsified Ozempic (Semaglutide) Pens, as such actions are illegal and jeopardise public health and safety. The Board encourages the public and healthcare professionals to immediately share any information regarding Ozempic pens with the Pharmacy and Poisons Board.**

22. From (Issuing Authority): **Kenya Pharmacy and Poisons Board**	23. For **Feedback** Contact: pms@ppb.go.ke Telephone: **0795743049**
24. Date: **17th July 2024**	