REPUBLIC OF KENYA

MINISTRY OF HEALTH

PHARMACY AND POISONS BOARD

RAPID ALERT NOTIFICATION OF A QUALITY DEFECT/RECALL

	Reference Number : **2024/002**
1. To: **World Health Organisation, Market Autorisation Holders, Distributors, Retailers and Consumers**	
2. Product Class of Defect: **Class I**	3. **Falsification**
4. Product : **Herceptin 440mg (*Trastuzumab 440mg*)**	5. Marketing Authorisation Number : **20372** For use in humans
6. Brand/Trade Name : **Herceptin 440mg**	7. INN or Generic Name : **Trastuzumab 440mg**
8. Dosage Form : **Injection**	9. Strength : **440mg**
10. Batch Number : **C5830083**	11. Expiry Date : **11/2024.**
12. Pack size and Presentation: **1 Vial**	13. Date Manufactured : **12/2021**
14. Marketing Authorisation Holder: **F. Hoffman-La Roche Ltd**	
15. Manufacturer : **Claimed to be manufactured in Germany by Roche Products Ltd** 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 market concerning the falsification of Herceptin 440mg (*Trastuzumab 440mg*) where the product batch was claimed to be manufactured in Germany by Roche Products Ltd.**
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 Herceptin 440mg (*Trastuzumab 440mg*) 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 Herceptin 440mg (*Trastuzumab 440mg Batch C5830083*, 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 Herceptin 440mg (*Trastuzumab 440mg* 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 : **11th May 2024**	