REPUBLIC OF KENYA

MINISTRY OF HEALTH

PHARMACY AND POISONS BOARD

RAPID ALERT NOTIFICATION OF A QUALITY DEFECT / RECALL

	Reference Number : **2025/006**
1. To: **World Health Organisation, Market Autorisation Holders, Distributors, Retailers and Consumers**	
2. Product Class of Defect: **Class I**	3. **Substandard**
4. Product : **Paragen Injection**	5. Marketing Authorisation Number: **H2021/CTD8671/20126** For use in humans
6. Brand/Trade Name : **Paragen Injection**	7. INN or Generic Name: **Paracetamol**
8. Dosage Form : **Injection**	9. Strength: **1% W/V**
10. Batch number: **K4290027**	11. Expiry Date: **02/2026**
12. Pack size and Presentation: **Clear and colourless solution filled in a 100ml bottle**	13. Date Manufactured: **03/2024**
14. Marketing Authorisation Holder: **Pro Med Pharmaceuticals Limited**	
15. Manufacturer: **KamlaAmrut Pharmaceutical LLP, India**	16. Recalling Firm (if different): **Pro Med Pharmaceuticals Limited** Contact Person: **Dr. Ivy Nellie** Telephone: **+254 722 203 700**
15.1 Where the defect is attributed to a manufacturing site, site where defect occurred: **KamlaAmrut Pharmaceutical LLP, India**	
17. Recall Number Assigned (if available): **REC/2025/015**	
18. Details of Defect/Reason for Recall: **Color change of the product to black**	

19. Information on distribution including exports (type of customer, e.g. hospitals): **consumer/patients**
20. Action taken by Issuing Authority: **Issue of a Mandatory Recall notice for Paragen (Paracetamol 1%W/V) Injection Batch No. K4290027**
21. Proposed Action: **Healthcare Professionals to Quarantine all the remaining stock and stop further distribution, sale, issuing, or use of the batch immediately.**

22. From (Issuing Authority): **Kenya Pharmacy and Poisons Board**	23. For **Feedback** Contact: pms@ppb.go.ke Telephone: **0795743049**
24. Date: **24th April 2025**	