REPUBLIC OF KENYA

MINISTRY OF HEALTH

PHARMACY AND POISONS BOARD

RAPID ALERT NOTIFICATION OF A QUALITY DEFECT / RECALL

	Reference Number : **2025/007**
1. To: **World Health Organization, Market Authorization Holders, Distributors, Retailers and Consumers**	
2. Product Class of Defect: **Class I**	3. **Substandard**
4. Product : **Paracetamol 1% W/V injection**	5. Marketing Authorization Number : **N/A** ***For use in humans***
6. Brand/Trade Name : **Lumidol injection**	7. INN or Generic Name: **Paracetamol**
8. Dosage Form : **Injection**	9. Strength : **Paracetamol 1% W/V injection**
10. Batch Numbers**: CM4594007, CM4594008 and CM4594009**	11. Expiry Date: **10/2026**
12. Pack size and Presentation : **Clear colorless solution in a 100ml Bottle**	13. Date of Manufacture: **11/2024**
14. Marketing Authorization Holder : **KamlaAmrut Pharmaceutical LLP, India.**	
15. Manufacturer **: KamlaAmrut Pharmaceutical LLP, India.**	16. Recalling Firm (if different): **Zawadi Healthcare Ltd, Nairobi, Kenya.** Contact Person: **Devanshi Desai** Telephone: **0784 882278 / 0784 882279**
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/2025/016**	
18. Details of Falsification : **N/A**	
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 Lumidol (Paracetamol 1%W/V) Injection Batch No. CM4594007, CM4594008 and CM4594009**
21. Proposed Action : **Healthcare Professional to 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**	