REPUBLIC OF KENYA

MINISTRY OF HEALTH

PHARMACY AND POISONS BOARD

RAPID ALERT NOTIFICATION OF A FALSIFIED HEPKEN-5000 (HEPARIN INJECTION BP 5000 IU/ML), BATCH NO. ML29053

	Reference Number : **2025/004**
1. To: **World Health Organization, Market Authorization Holders, Distributors, Retailers and Consumers**	
2. Product Class of Defect: **Class 1**	3. **Falsified**
4. Product: **Hepken-5000**	5. Marketing Authorization Number: **N/A** ***For use in humans***
6. Brand/Trade Name: **Hepken-5000**	7. INN or Generic Name: **Heparin Injection BP 5000 IU/ML**
8. Dosage Form: **IV/SC**	9. Strength: **5000 IU/ML**
10. Batch Numbers: **ML29053**	11. Expiry Date: **06/2026**
12. Pack size and Presentation: **5ml vial**	13. Date of Manufacture : **07/2024**
14. Marketing Authorization Holder: **KNVM Medicare Pvt. Ltd**	
15. Manufacturer**: Stated as Makcur Laboratory Limited, India**	16. Recalling Firm (if different): **N/A**
15.1 Where the defect is attributed to a manufacturing site, site where defect occurred: **N/A**	
17. Recall Number Assigned (if available): **N/A**	
18. Details of Falsification : **The batch was falsely purporting to be manufactured by Makcur Laboratory Limited, India**	
19. Information on distribution including exports (type of customer, e.g. hospitals): **Hospitals**	

20. Action taken by Issuing Authority: **Rapid Alert Issuance**
21. Proposed Action: • **Procurement agencies, distributors, pharmacists, pharmaceutical technologists, and members of the public to remain vigilant and report immediately any encounter with the falsified batch.** • **All stakeholders in the supply chain to procure HPTs only from licensed manufacturers, importers, distributors, and retailers. Procuring from unlicensed sources places patients at risk and will attract severe regulatory and legal sanctions**.

22. From (Issuing Authority): **Kenya Pharmacy and Poisons Board**	23. For **Feedback** Contact: pms@ppb.go.ke Telephone: **0795743049**
24. Date : **10th September 2025**	