

## 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: 2025/009 1. To: World Health Organization, Market Authorization Holders, Distributors, **Retailers and Consumers** 2. Product Class of Defect: Class 1 3. Falsified 5. Marketing Authorization Number: N/A 4. Product: **Hepken-5000** For use in humans 7. INN or Generic Name: Heparin Injection BP 6. Brand/Trade Name: Hepken-5000 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 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):	23. For <b>Feedback</b>
Kenya Pharmacy and Poisons Board	Contact:
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	0795743049
24. Date : <b>10<sup>th</sup> September 2025</b>	0130170073