REPUBLIC OF KENYA

**MINISTRY OF HEALTH**

**PHARMACY AND POISONS BOARD**

# RAPID ALERT NOTIFICATION OF A QUALITY DEFECT/RECALL

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| | Reference Number : **2024/001** |
| 1. To: **World Health Organisation, Market Autorisation Holders, Distributors, Retailers and Consumers** | |
| 2. Product Class of Defect: **Class I** | 3. **Substandard** |
| 4. Product : **Benylin Paediatric** | 5. Marketing Authorisation Number: **1434**<br><br>For use in humans |
| 6. Brand/Trade Name : **Benylin Paediatric** | 7. INN or Generic Name: **Diphenhydramine Hydrochloride** |
| 8. Dosage Form : **Syrup** | 9. Strength: **7 mg per 5 ml** |
| 10. Batch number: **329304** | 11. Expiry Date: **04/2024** |
| 12. Pack size and Presentation: **100ml Syrup** | 13. Date Manufactured: **05/2021** |
| 14. Marketing Authorisation Holder: **Johnson & Johnson S.A. (Pty) Ltd** | |
| 15. Manufacturer : **Johnson & Johnson (Pty), South Africa**<br><br>Contact Person: **Dr. Janki Chauhan**<br>Telephone: +254 20 3749304 | 16. Recalling Firm (if different): **Surgipharm Ltd**<br><br>Contact Person: **Dr. Janki Chauhan**<br>Telephone: +254 20 3749304 |
| 15. Where the defect is attributed to a manufacturing site, site where defect occurred: **Johnson & Johnson Pty Ltd**<br><br>Contact Person: **Dr. Janki Chauhan**<br>Telephone: +254 20 3749304 | |
| 17. Recall Number Assigned (if available): **REC/2024/010** | |
| 18. Details of Defect/Reason for Recall: **Quality concerns arising from an unacceptable high level of diethylene glycol detected through laboratory analysis conducted by NAFDAC. Diethylene glycol is a contaminant which is toxic to** | |

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| **humans when consumed and can prove fatal. Toxic effects can include abdominal pain, vomiting, diarrhea, inability to pass urine, headache, altered mental state, and acute kidney injury which may lead to death.** |
| 19. Information on distribution including exports (type of customer, e.g. hospitals): **consumer/patients** |
| 20. Action taken by Issuing Authority: **Urgent mandatory recall of Benylin Pediatric 100mls cough syrup Batch No 329304** |
| 21. Proposed Action: **Healthcare Professionals to Quarantine all the remaining stock and stop further distribution, sale, issuing, or use of the batch immediately. Await contact from Surgipharm Limited to arrange the return and Patients and members of the public who have the product batch are advised to immediately return the product to the nearest healthcare facility.** |

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| 22. From (Issuing Authority):<br>**Kenya Pharmacy and Poisons Board** | 23. For **Feedback**<br><br>Contact: pms@ppb.go.ke<br><br>Telephone: **0795743049** |
| 24. Date: **11th April 2024** | |