	Reference Number: Case 50
Rapid Alert Notification of a Quality Defect	
1. To: The Regulatory Authority	
2. Product Recall Class & Type of Defect: **Class: I Type: A**	3. Falsification / Fraud (specify) Not Applicable
4. Product: **Benylin Paediatric Syrup**	5. Marketing Authorisation Number: **H/10.1/12**
6. Brand/Trade Name: **Benylin Paediatric Syrup**	7. INN or Generic Name: **Diphenhydramine Hydrochloride**
8. Dosage Form: **Syrup**	9. Strength: **Each 5 ml syrup contains 7 mg Diphenhydramine HCl**
10. Batch number(s): (**329304 & 329303**)	11. Expiry Date: **April 2024**
12. Pack size and Presentation: **100 ml syrup**	13. Date Manufactured: **May 2021**
14. Marketing Authorisation Holder (MAH): **Johnson & Johnson (Kenvue), 241 Main Road, Retreat 7945, Cape Town, South Africa** Contact Person: **Mr. Sello Malete** Telephone: **+27 82 825 5931**	
15.1 Manufacturer: **Johnson & Johnson (Kenvue), 241 Main Road, Retreat 7945, Cape Town, South Africa**	16. Recalling Firm (if different from 15.1): Contact Person: **Mr. Sello Malete** Telephone: **+27 82 825 5931** Email: SMalet01@kenvue.com
15.2 Where the defect is attributed to a manufacturing site, site where defect occurred (if different from 15.1):	
17. Recall Number Assigned (if available): Case 50	
18. Summary of Quality Defect and Reason for Recall: As per reported information from NAFDAC, Benylin Paediatric was sampled among other paediatric formulations and analyzed using an in-house method. The Laboratory analysis reports show that the product contains Diethylene glycol above the acceptable limit (Not more than 0.1%). https://nafdac.gov.ng/public-alert-no-011-2024-alert-on-the-sale-of-counterfeit-tandak-injection-in-nigeria/. The manufacturer in South Africa in collaboration with SAHPRA is currently investigating.	

19. Distribution including export to other markets:
According to the MAH, distribution of affected batches was as follows:

Batch **329304** was sent to other countries, as indicated below:
Distributed to **Nigeria**, **Kenya**, **Tanzania** and **Rwanda** as follows (**no. of Units & shipped date**): **Nigeria:** 432 units, 11-Aug-2022; **Kenya:** 11 184 units, 25-Aug-2021; **Tanzania:** 5 376 units 24/25-Jan 2022; and **Rwanda:** 1 824 units 25-May-2022.

Batch **329303** was sent to three other countries as indicated: **Swaziland**: 144 units, 15-Jun-2021; **Zambia**: 5 760 units, 15-Jul-2021; **South Africa**: 4 638 units, 15-Jun-2021.

The above pack lots originated from one bulk lot. According to the MAH, countries not listed above did not receive these batches.

For more information about exporting or batch destination, please contact Marketing Authorisation Holder and/ or local Regulatory Authority (SAHPRA) *maphutheho.selikane@sahpra.org.za and mokgadi.fafudi@sahpra.org.za* and copy *deon.poovan@sahpra.org.za*

20. Action taken by Issuing Authority: Conduct a recall (Class I, Type A)
The information is published on the SAHPRA recall webpage
https://www.sahpra.org.za/product-recalls/

21. Proposed Action: SAHPRA is monitoring the recall.

22. From (Issuing Authority):

South Africa Health Products Regulatory Authority (SAHPRA) Loftus Park, Building A, 402 Kirkness St, Arcadia, Pretoria, 0083, South Africa.

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Signed: Deon Poovan SIGNIFLOW Date: 12 April 2024

Deon Poovan – Senior Manager: Inspectorate & Regulatory Compliance