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FDA/HPT/VVC/SMD/VGU/24/0158 12th April 2024

Dear Healthcare Professional,

SAFETY ALERT: RECALL OF BENYLIN PAEDIATRIC 100 ML SYRUP (BATCH 329304)

The Food and Drugs Authority (FDA) wishes to bring to your attention the recall of Benylin 100 ml Paediatric Syrup **Batch No. 329304** from the Ghanaian market.

The details on the secondary package of the product are as follows:

- Product Name : **Benylin Paediatric 100 ml Syrup**
- Batch Number : **329304**
- Manufacturing date : **05/2021**
- Expiry date : **04/2024**
- Manufacturer : **Johnson & Johnson (PVT) South Africa**

The recall follows a communication by the National Agency for Food and Drugs Administration and Control (NAFDAC), Nigeria of the detection of unacceptable high levels of diethylene glycol in the affected batch.

Diethylene glycol is toxic to humans when consumed and can prove fatal. Toxic effects could include abdominal pain, vomiting, diarrhoea, inability to pass urine, headache, altered mental state and acute kidney injury which may lead to death.

Benylin Paediatric Syrup is indicated for the relief of cough and its congestive symptoms and for the treatment of hay fever and other allergic conditions in children aged two to 12 years.

Although the affected batch has not been imported into the country, the FDA wishes to advise all healthcare professionals who may have samples to:

- **Stop using Benylin 100 ml Paediatric Syrup with Batch No. 329304, Manufacturing date: 05/2021 and Expiry date: 04/2024 and return any samples to the nearest FDA offices for safe disposal.**
- Call the FDA on Mobile No: 024 431 0297/ 055 111 2224 or email to drug.safety@fda.gov.gh for enquiries or further guidance.

Meanwhile the FDA has strengthened its post market surveillance activities at the borders and across the country with the view to identify and withdraw the affected batch of Benylin Paediatric Cough Syrup on the Ghanaian market.

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Yours faithfully,

DR. DELESE A. A. DARKO
CHIEF EXECUTIVE OFFICER