



Quality Medicines for Malawi

PUBLIC NOTICE

ALERT ON RECALL OF TWO BATCHES OF BENYLIN PAEDIATRIC COUGH SYRUP 100ML, BATCH NUMBERS 329303 AND 329304

Lilongwe, Sunday, 14th April, 2024: The Pharmacy and Medicines Regulatory Authority (PMRA) has taken note of the public notice dated 10th April 2024 from the National Agency for Food and Drugs Administration and Control (NAFDAC) of Nigeria alerting the general public of the recall of Benylin Paediatric Cough Syrup Batch No. 329304. Further review of the proceedings of the engagement between the South African Health Products Regulatory Authority (SAHPRA) and the South African manufacturer of the product (Johnson & Johnson (Pty), South Africa) has indicated that an additional batch (Batch No. 329303) also requires immediate recall.

This recall has been necessitated after the detection of higher than permissible levels of Diethylene glycol in the two batches of Benylin Paediatric Cough Syrup. High levels of Diethylene glycol when consumed may lead to toxic effects which include abdominal pain, vomiting, diarrhea, inability to pass urine, headache, altered mental state, and acute kidney injury which may lead to death.

Below are details and pictorial presentation of the recalled product:

Description	Batch No.	Manufacturer	Manufacture Date	Expiry Date	Quality Issue	Pictorial presentation
Benylin Paediatric Cough Syrup	329303 329304	Johnson & Johnson (Pvt), South Africa	May 2021	April 2024	Higher than permissible levels of Diethylene glycol	

In a communication to PMRA, the manufacturer, Johnson & Johnson (Pty), South Africa, has confirmed that the affected batch numbers were manufactured in May 2021 and distributed to Nigeria, Kenya, Tanzania, Rwanda, Swaziland, Zambia and South Africa between June 2021 and August 2022.

However, in case any of the two affected batches are in circulation in Malawi, the PMRA is advising all outlets, pharmacies, medicine stores, healthcare facilities, to immediately quarantine the concerned batches and STOP distribution, sale, dispensing, or use of the two

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affected batches of Benylin Paediatric Syrup. The quarantined product should be reported to PMRA immediately.

Healthcare workers, patients and the public are also advised to return any of the affected batches to the premises where the product was sourced.

Meanwhile, the PMRA in collaboration with key medicine supply chain actors in Malawi will continue conducting post-market quality surveillance of pediatric cough syrups on market to screen for possible high levels of Diethylene glycol in these products.

PMRA reminds healthcare workers as well as pharmacy businesses to report any suspected poor quality products as well as suspected adverse drug reactions using the existing pharmacovigilance system.

Further, PMRA would like to urge all members of the public to report any suspected poor quality products or adverse drug reactions to the nearest hospitals or pharmacies; or report directly to the National Pharmacovigilance Centre through Medsafe-360 by dialing *360# for free on TNM and Airtel networks.

For media enquiries contact PMRA Public Relations Officer on 0885313011 or email at jjosiah@pmra.mw.



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DIRECTOR GENERAL

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