ZAMBIA MEDICINES REGULATORY AUTHORITY

PUBLIC NOTICE

Date: 12th April, 2024

To: Distributors, Wholesalers, Retailers, Healthcare Professionals, Parents, General Public

MEDICAL PRODUCT ALERT:
RECALL OF BENYLIN PAEDIATRIC COUGH SYRUP 100ML BATCH NO. 329304 MANUFACTURED BY JOHNSON & JOHNSON (PTY), SOUTH AFRICA

The Zambia Medicines Regulatory Authority (ZAMRA) is a statutory body established under an Act of Parliament, the Medicines and Allied Substances Act No. 3 of 2013 of the Laws of Zambia. The main mandate of ZAMRA is to regulate and control the manufacture, importation, storage, distribution, supply, sale and use of medicines and allied substances for human and animal health protection.

ZAMRA wishes to alert healthcare professionals and the general public that it has been notified by the National Agency for Food and Drug Administration and Control (NAFDAC) of Nigeria about **RECALL** of **Benylin Paediatric Cough Syrup Batch No. 329304.** The recall has been necessitated by detection of high levels of Diethylene glycol following laboratory analysis.

Benylin Paediatric Syrup is used for the relief of cough and its congestive symptoms, hay fever and other allergic conditions in children aged 2 to 12 years.

Product details

Product Name	**Manufacturer**	**Batch No.**	**Manufacture Date**	**Expiry Date**
Benylin Paediatric Syrup	Johnson & Johnson (Pvt), South Africa	329304	May- 2021	April- 2024

Risk

Diethylene glycol is toxic to humans when consumed in amounts above the acceptable limits, resulting in serious injury or death, especially in children. Toxic effects following use of this product may include but not limited to abdominal pain, vomiting, diarrhoea, inability to pass urine, headache, altered mental state and acute kidney injury which may lead to death.

Based on the above information, ZAMRA has instituted a **batch specific recall** of Benylin Paediatric Cough Syrup Batch No**. 329304**. All pharmaceutical outlets and health facilities should check their inventory and quarantine the affected batch should it be in their possession. Parents who might have this batch in their possession should not administer it to their children.

In the event that you are in possession of the above-mentioned product, please return it to your healthcare provider or supplier who should in turn notify ZAMRA.

Further, by this notice, importers and distributors of this product are notified to conduct market surveillance and facilitate the recall and disposal of the affected batch should it be in circulation. ZAMRA will closely monitor the recall to ensure that the product is completely removed from circulation in the interest of public health.

Last year, ZAMRA published Medical Product Alerts including a World Health Organisation (WHO) Medical Product Advisory in relation to syrups contaminated with diethylene and ethylene glycol that caused deaths of children in many regions of the world including Africa.

If you suffer any adverse drug reaction/event having used this product, you are advised to seek immediate medical advice and report the incident to the National Pharmacovigilance Unit at Zambia Medicines Regulatory Authority by phone: +260 211 432 356/+260 //956 521 094 or email address at: npvu@zamra.co.zm or pharmacy@zamra.co.zm.

Should the public need further clarification, please do not hesitate to contact the Secretariat.

Makomani Siyanga (Mr.)
DIRECTOR-GENERAL