



Medicines Control Authority of Zimbabwe

MEDIA RELEASE

Public Alert On The Recall Of Benylin Paediatric Formulation

Embargo: Immediate Release

Harare, 15 April 2024: The Medicines Control Authority of Zimbabwe (MCAZ) would like to inform all stakeholders of a critical communication received from National Agency for Food and Drug Administration (NAFDAC) of Nigeria regarding the recall of Benylin Paediatric 100ml Syrup, batch number 329304, manufactured by Johnson and Johnson, South Africa.

According to NAFDAC, recent laboratory analysis has revealed unacceptably high levels of Diethylene glycol in this formulation. Diethylene glycol is a contaminant which is toxic for humans when consumed. Toxic effects can include abdominal pain, vomiting, diarrhoea, inability to pass urine, headache, altered mental state, and acute kidney injury, potentially leading to death.

Additionally, the South African Health Products Regulatory Authority (SAHPRA) and the manufacturer identified an additional batch that is affected bringing the affected batches to two; 329303 and 329304.

While the Authority confirms that this product was registered in 2023 for use in Zimbabwe, our import database does not show a record of the importation of this product and more specifically these two batches. However, there is a concern that through illegal means, the aforementioned batches of Benylin Paediatric Syrup may find their way into the local market. As a precautionary measure, the Authority is issuing a recall notice of this product.

In the unlikely event that members of the public are in possession of and/or come across this product, please notify the Authority and/or healthcare provider immediately and desist from administering them to children. The cooperation of all stakeholders is essential in ensuring the right of citizens to safe and good quality medicines is protected. Meanwhile, the Authority will intensify its market surveillance activities through strict premises inspections and public awareness to ensure that these products are not circulated.

The mandate of the MCAZ is to protect public health by ensuring that all medicines and medical devices on the market are safe, effective, and of good quality and will continue to monitor the situation in line with the WHO guidelines. The Authority also urges members of the public to access medicines from licenced persons and premises for easier monitoring. The Authority and law enforcement agencies continue to work together to eradicate any substandard and falsified health products.

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About MCAZ:

Medicines Control Authority of Zimbabwe (MCAZ) is a statutory body established by an Act of Parliament, The Medicines and Allied Substances Control Act (MASCA) [Chapter 15.03]. MCAZ is a successor of the Drugs Control Council (DCC) and the Zimbabwe Regional Drug Control Laboratory (ZRDCL). DCC was established by an Act of Parliament in 1969: Drugs and Allied Substances Control Act [Chapter 15.03] following which ZRDCL became operational in 1989.

MCAZ is responsible for protecting public and animal health by ensuring that accessible medicines and allied substances and medical devices are safe, effective and of good quality through enforcement and adherence to standards by manufacturers and distributors.

The mandate of MCAZ is to protect public health ensuring that medicines and medical devices on the market are safe, effective, and of good quality.

Notes to Editors:

MCAZ will post this media release on our website. Navigate to the Publications section on the website.

Should you request an interview for television, please send your request to mcaz@mcaz.co.zw and copy dkaiyo@mcaz.co.zw . Include your discussion points in your request.

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