MEDIA RELEASE

SAHPRA recalls two batches of Benylin Paediatric Syrup

Embargo: Immediate release

Pretoria, 13 April 2024 – On 10 April 2024, the South African Health Products Regulatory Authority (SAHPRA) received a report from the Nigerian National Agency for Food and Drug Administration and Control (NAFDAC) regarding the detection of high levels of diethylene glycol in a batch of Benylin Paediatric Syrup. SAHPRA immediately contacted the South African manufacturer, Kenvue (formerly Johnson and Johnson) for a response. Following engagements with the manufacturer and in the best interest of the public, it was resolved that affected batches would immediately be recalled while an investigation is ongoing.

SAHPRA, in collaboration with Kenvue, have identified the affected batch numbers as 329304 and 329303. These affected batches have been distributed to the following countries: South Africa, Eswatini, Rwanda, Kenya, Tanzania and Nigeria.

Benylin Paediatric presents as a clear, bright red syrup having a raspberry odour and taste, packed in amber glass bottles containing 100 mL with a plastic measuring cup. It is indicated for the relief of cough and its congestive symptoms and for the treatment of hay fever and other allergic conditions affecting the upper respiratory tract.

SAHPRA wishes to inform the public not to panic as the matter is being handled with priority. Batch recalls are batch-specific and do not necessarily apply to other batches/similar products. The manufacturer is a SAHPRA-licenced manufacturer and complies with Good

Manufacturing Practices. The public is reminded that the recall is limited to two batches and should not panic regarding the range of products bearing the same name.

SAHPRA is alerting healthcare professionals and the public to discontinue the use of the two batches mentioned, remove them from their inventory and return them to their normal distribution channel(s) with immediate effect.

Classification of the recalls

The recall is classified as a Class 1, Type A recall, which is associated with a serious product quality concern that may have severe consequences. This is a country-wide recall. The product is being recalled from hospitals, retail outlets, healthcare professionals, authorised prescribers and individual customers or patients.

What the public should know

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

Members of the public who have consumed these two batches who experience any adverse reaction or witness it in children should consult their healthcare professional and report this using the Med Safety App or send an email to: adr@sahpra.org.za.

The recall is limited to batch numbers 329304 and 329303 of Benylin Paediatric Syrup.

“As a national regulatory authority, the recalling of medical products is a crucial measure to address safety concerns or quality issues so that we protect the health of the public. SAHPRA is recalling these two batches from the market due to reported high levels of diethylene glycol, with the potential to cause serious adverse events,” indicates SAHPRA CEO, Dr Boitumelo Semete-Makokotlela.

Issued by:

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About SAHPRA:

SAHPRA is tasked with regulating (monitoring, evaluating, investigating, inspecting and registering) all health products. This includes clinical trials, complementary medicines, medical devices and in-vitro diagnostics (IVDs). Furthermore, SAHPRA has the added responsibility of overseeing radiation control in South Africa. SAHPRA's mandate is outlined in the Medicines and Related Substances Act, 101 of 1965 (as amended) as well as the Hazardous Substances Act, 15 of 1973.

SAHPRA has three pillars to ensure that medicines, medical devices and IVDs meet the requisite standards to protect the health and well-being of all who reside in South Africa:

- Safety
- Efficacy
- Quality

It is these three pillars that define the ethos of SAHPRA.

Notes to Editors:

SAHPRA will post this media release on our website. Navigate to the News section on the website.

A podcast will be recorded and posted on the home page. Scroll don the home page to "**SAHPRA TV and Podcasts**". Podcasts appear on the right-hand side.

Should you wish to request an interview, please send your request to media@sahpra.org.za and copy Madimetja.Mashishi@sahpra.org.za.

Updates on vaccine registration can be accessed here:

Vaccines - News and updates (sahpra.org.za) - https://www.sahpra.org.za/news-and-updates/vaccines-news-and-updates/