MEDIA RELEASE

SAHPRA releases results of investigation following recall of Benylin Paediatric syrup: No traces of diethylene glycol found

Embargo: Immediate Release

Pretoria, 05 June 2024 – On 13 April 2024, the South African Health Products Regulatory Authority (SAHPRA) initiated a precautionary recall of two batches of Benylin Paediatric Syrup (batch numbers 329303 and 329304), in response to reported high levels of diethylene glycol in an alert by the Nigerian National Agency for Food and Drug Administration and Control (NAFDAC). The recall was implemented as a precaution to protect lives while SAHPRA investigated the reported high levels of diethylene glycol.

As the national regulatory authority for health products in South Africa, SAHPRA implements health product recalls as a crucial measure to address safety concerns or quality issues in the interest of public health.

As part of the investigation of the reported high levels of diethylene glycol, SAHPRA tested samples of the two affected batches of Benylin Paediatric syrup through an independent laboratory and a method developed by the World Health Organisation for testing products for the presence of diethylene glycol. **The tests did not find traces of diethylene glycol in the recalled batches**. This indicates that units of batches 329303 and 329304 that were stored at the required temperature would not contain unacceptable levels of diethylene glycol.

SAHPRA also wishes to indicate that there is no record of any adverse drug reactions relating to diethylene glycol for the two recalled batches in South Africa or anywhere else where they were exported to on the continent.

SAHPRA is mandated to regulate and apply due diligence to health products to ensure that products in circulation in South Africa and those exported from SAHPRA-licensed manufacturers are safe for public consumption. SAHPRA applies this due diligence throughout the product life cycle, from registration through to post-market monitoring.

“SAHPRA will continue to closely monitor medical products that have the potential of containing unacceptable levels of diethylene glycol. And we will continue to address safety concerns or quality issues so that the health of the public is protected,” says 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:

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

SAHPRA will publish this media release on its website. Navigate to the News section on the website.

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