**MEDIA RELEASE**

**SAHPRA alerts the public about contaminated health products**

**Embargo: Immediate release**

**Pretoria, 10 October 2022 –** The South African Health Products Regulatory Authority (SAHPRA), like other regulators globally, has been alerted to dubious health products being traded by an Indian company, Maiden Pharmaceuticals.

The products as they appear on the World Health Organisation (WHO) product list ( Medical Product Alert N°6/2022: Substandard (contaminated) paediatric medicines (who.int))are NOT registered for use in South Africa. These products have been identified in The Gambia, but there is a possibility that these products may be distributed to other countries.

The four products are *Promethazine Oral Solution, Kofexmalin Baby Cough Syrup*, *Makoff Baby Cough Syrup* and *Magrip N Cold Syrup* manufactured by Maiden Pharmaceuticals. Thirty-three children in The Gambia died of kidney-related illness. The WHO conducted laboratory tests which linked the medication to those deaths.

The four products contain unacceptable amounts of diethylene glycol and ethylene glycol which are toxic substances and can prove to be fatal. The fact that these medicines were administered to children makes the matter far more serious. Toxic effects following consumption of the product(s) can include abdominal pain, vomiting, diarrhoea, inability to pass urine, headache, altered mental state, and acute kidney injury which may lead to death.

If you are in possession or come across any of these products, please ensure that you do not consume these products, nor should you administer it to children. If you know of such instances, please contact our Regulatory Compliance unit at:

Mokgadi.fafudi@sahpra.org.za

012 015 5434

“SAHPRA’s mandate is to ensure that the public has access to quality, safe and effective health products. The safety of the public is of paramount importance. Our Regulatory Compliance unit will work with law enforcements agencies to eradicate any substandard and falsified health products,” 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 (Act No 101 of 1965 as amended) as well as the Hazardous Substances Act (Act No 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 down the home page to "**SAHPRA TV and Podcasts**". Podcasts appear on the right-hand side.

Should you request an interview for television, please send your request to media@sahpra.org.za and copy yuveng@sahpra.org.za. Include your discussion points in your request.