



MEDIA RELEASE

SAHPRA withdraws pholcodine-containing medicines from SA market

Embargo: Immediate release

Pretoria, 06 April 2023 – The South African Health Products Regulatory Authority (SAHPRA) has made the decision to withdraw pholcodine-containing medicines from the South African (SA) market due to the increased risk of sudden, severe, and life-threatening allergic reactions occurring during surgery. There is a link between the use of pholcodine-containing medicines and the risk of a sudden, severe, and life-threatening allergic (anaphylactic) reaction when neuromuscular blocking agents (NMBAs) are administered during general anaesthesia. NMBAs are used as muscle relaxants during surgery. The use of pholcodine-containing medicines, up to 12 months prior to surgery, increases the risk of anaphylactic reaction in patients who receive NMBAs.

The available data provides convincing evidence to support the association of pholcodine use with the risk of developing an anaphylactic reaction to NMBAs, particularly when used in the 12 months prior to general anaesthesia. Effective measures to minimise the risk of anaphylactic reactions to NMBAs, or to identify a patient population for whom the benefits of pholcodine outweigh its risks, have not been identified. As pholcodine is a non-prescription medicine, available patient records may not list its use, and patients may not always recall whether they have taken pholcodine-containing medicines in the past. Patients undergoing emergency surgery may not be able to provide information about their medical history to healthcare professionals.

Pholcodine is registered to treat non-productive (dry) cough and is available in a number of non-prescription medicines, either as a single active ingredient or in combination with other medicines.

In consideration of the nature of the adverse reaction, including its unpredictability and severity, SAHPRA has concluded that the potential risk outweighs the benefits. As a precautionary measure, SAHPRA has taken a regulatory decision to withdraw pholcodine-containing medicines from the SA market.

Alternative medicines to treat a dry cough are available on the South African market, and consumers are advised to seek advice from their doctor or pharmacist in this regard. Patients should inform healthcare professionals if they think they have taken a pholcodine-containing medicine, particularly

in the 12 months prior to surgery or general anaesthesia.

SAHPRA is working together with the manufacturers to ensure that all pholcodine-containing medicines (PHOLTEX FORTE®, PHOLTEX JUNIOR®, PROCOF®, FOLCOFEN®, PHOLTEX PLUS®, ADCO-PHOLCOLINT®, CONTRA-COFF®, DOCSSED®, TIXYLIX®) are removed from the market i.e., pharmacies, distributors, wholesalers or authorised health facilities. The public is urged to stop using these medicines and return them to the pharmacies.

For reporting of medicines/health products complaints, please contact SAHPRA at <https://www.sahpra.org.za/whistleblower/>

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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.