MEDIA RELEASE

Warning: Use of ranitidine-containing medicine- UPDATE

For immediate release

Pretoria, 31 October 2019 - The South African Health Products Regulatory Authority (SAHPRA) has learned about the safety concerns regarding the presence of a nitrosamine impurity called NDMA in ranitidine-containing medicines. NDMA is classified as a probable human carcinogen (a substance that could cause cancer) based on the results of animal studies. NDMA is a known environmental carcinogen and it is present in some foods and in water supplies in small quantities. NDMA is not expected to cause any harm when very small quantities are ingested.

Ranitidine is used to treat the production of stomach acid in patients with conditions such as heartburn and stomach ulcers. It is available as an over-the-counter (OTC) and prescription medicine. OTC ranitidine has been approved by SAHPRA to prevent and treat symptoms of heartburn due to acid indigestion and excess stomach acid, while prescription ranitidine has been approved for treatment and prevention of various indications such as ulcers (stomach and intestinal) and gastroesophageal reflux disease.

SAHPRA has issued a media release and the subsequent media articles and interviews have been informative to the public. SAHPRA also issued “Dear Healthcare Professional” letters, informing pharmacies about this safety concern. Some Ranitidine-containing products have been removed from the market or temporarily recalled while investigations are being undertaken. The following actions were taken by manufacturers:

Manufacturer	**Product Name**	**Action**
Cipla Medpro	Ultak	Product recalled
GlaxoSmithKline	Zantac	Product recalled
Sandoz South Africa	Ranihexal	Product recalled
Pharma-Q	CPL Alliance Ranitidine	Product recalled
Biotech Laboratories	Ranitidine 300 Biotech	Batches of medicines under quarantine
Gulf Drug Company	Gulf-Ranatidine	Batches of medicines under quarantine

“Pharmacies have been advised to stop dispensing these products immediately, and to return the remaining stock to the manufacturers. Patients are advised to also stop taking these products and to consult their healthcare professional for alternative treatment and advice.

SAHPRA is working with international regulators and manufacturers on this issue to ensure that all Ranitidine-containing products in the country are safe, effective and of the highest quality," indicates SAHPRA's Acting CEO, Ms Portia Nkambule.

Healthcare professionals and patients are encouraged to report and suspected adverse reactions and product quality issues to the SAHPRA Pharmacovigilance Unit via telephone on (012) 842 7609/10 or by email: adr@sahpra.org.za or to the National Adverse Events Monitoring Centre (NADEMC) on (021) 447 1618 or fax (021) 448 6181. The adverse drug reaction (ADR) reporting form can be accessed via the SAHPRA website at: https://www.sahpra.org.za/documents/12e54dcaADRForms.pdf.

Issued by:
Ms Portia Nkambule
012 842 7582/7583
portia.nkambule@sahpra.org.za

For more information:
Mafora Matlala
Mafora.matlala@sahpra.org.za
083 387 3358

Media Contact:
Yuven Gounden
012 842 7628
066 1202 669
yuveng@sahpra.org.za

About SAHPRA

SAHPRA is tasked with regulating (monitoring, evaluating, investigating, inspecting and registering) all health products and clinical trials in South Africa. Health products include complementary medicines, medical devices and *in vitro* diagnostics (IVDs). SAHPRA also has the responsibility of overseeing radiation control in South Africa. SAHPRA's mandate is outlined in the Medicines and Related Substances Act (Act 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 South Africans:

- Safety
- Efficacy
- Quality

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