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NAMIBIA MEDICINES REGULATORY COUNCIL
OFFICE OF THE REGISTRAR

DEAR HEALTHCARE PROFESSIONAL

COMMUNICATION ON N-NITROSODIMETHYLAMINE (NDMA) IMPURITIES DETECTED IN RANITIDINE-CONTAINING MEDICINES

Background

It has come to the attention of the Namibia Medicines Regulatory Council (NMRC) that an impurity, N-Nitrosodimethylamine (NDMA) has been detected in several ranitidine-containing medicines, leading to recalls of these medicines from various markets including Namibia. (See **Table 1** on page 3).

Nitrosamines including NDMA are believed to be probable human carcinogens (cancer-causing agents). NDMA is found in water and food, including meat, dairy products and vegetables as environmental contaminants, however, no harm is expected when ingested in small quantities.

Ranitidine medicines, which belong to a class of medicines known as histamine-2 (H_2) receptor blockers are used widely to reduce the production of stomach acid in patients with conditions such as heartburn and stomach ulcers. They are scheduled medicines available over-the-counter (NS1) for short-term symptomatic relief of heartburn and hyperacidity and on prescription (NS2) for the treatment and prevention of various indications such as stomach and intestinal ulcers, and gastroesophageal reflux disease.

Action by the Namibia Medicines Regulatory Council (NMRC)

In order to ensure that registered ranitidine-containing medicines on the Namibian market have no impurities present, the NMRC has engaged the manufacturers of ranitidine active pharmaceutical ingredients (APIs) and final pharmaceutical products (FPPs). The NMRC will provide more information on the outcome of the investigations and any regulatory actions to be taken upon completion of this task.

Meanwhile, healthcare professionals are encouraged to advise patients who are on ranitidine-containing medications to continue with their treatment. However, if necessary to stop or substitute a ranitidine-containing medicine (e.g. due to product recall), the decision should be guided by a healthcare professional and alternative medicines approved for the similar indication(s) should be considered.

Adverse medicines reactions suspected to be caused by these medications must be reported to the Therapeutics Information and Pharmacovigilance Centre (TIPC) using the Adverse Drug Reaction Reporting form (Safety yellow form) via email: info.TIPC@mhss.gov.na or Fax2mail: 0886606781.

Yours faithfully,

REGISTRAR OF MEDICINES
REPUBLIC OF NAMIBIA

MR. JOHANNES GAESEB
REGISTRAR OF MEDICINES

TABLE 1: LIST OF RANITIDINE-CONTAINING MEDICINES RECALLED FROM THE NAMIBIAN MARKET TO DATE

MANUFACTURER	PRODUCT NAME	BATCH NUMBER	EXPIRY DATE
GlaxoSmithKline SA (Pty) Ltd	Zantac 50mg/2mL Injection	V67R	19-Aug-2021
		H35R	15-Jun-2021
		JR7C	14-Dec-2020
		7M4G-A	09-Jan-2020
		7M4G	
		H87J	17-Sept-2021
		XT8J	26-Oct-2021
	Zantac 15mg/mL Syrup	B58118C	31-Mar-2020
		B30819A	31-Jan-2021
		B23517J	31-Oct-2019
Sandoz SA (Pty) Ltd	RaniHexal 150mg Tablets	FW6277	31-Aug-2020
		FW7659	
		FW7656	
		FW7682	
	RaniHexal 300mg Tablets	FW6223	30-Sep-2020
		FW6238	
		FW6240	
		FW6241	