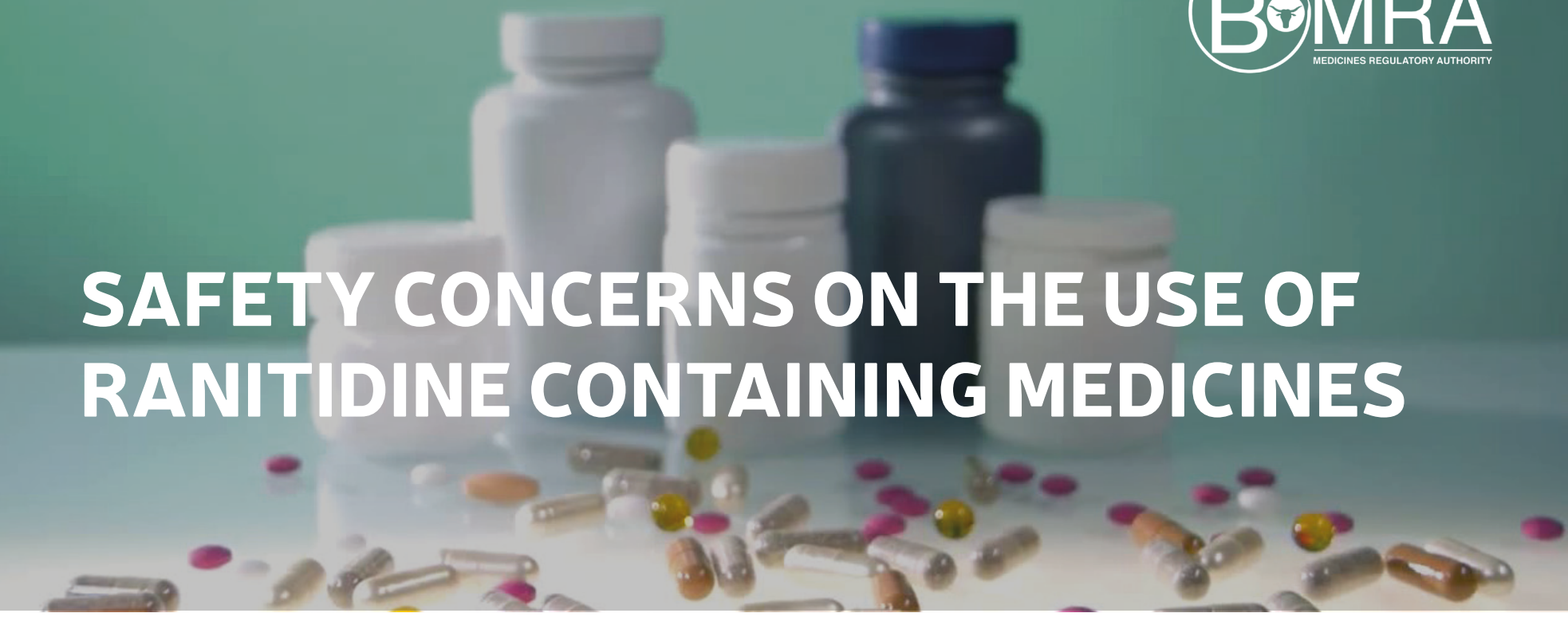
PRESS RELEASE:



SAFETY CONCERNS ON THE USE OF RANITIDINE CONTAINING MEDICINES

The Botswana Medicines Regulatory Authority wishes to inform the public of a potential safety issue in Ranitidine containing products.

The presence of nitrosamine impurity called N-nitrosodimethylamine (NDMA) has been identified in the products at low levels. NDMA is classified as a possible human carcinogen (**a substance that could cause cancer**) based on results of animal studies. NDMA is a known environmental contaminant and it is not expected to cause any harm when ingested in low quantities.

Ranitidine is widely used to reduce the production of stomach acid in patients with conditions such as heart burns and stomach ulcers. It is available as a prescription only medicine. Ranitidine has been approved by BoMRA for the treatment and prevention of various indications such as ulcers (stomach and intestinal) and gastroesophageal reflux disease.

BoMRA is working with the registered suppliers of Ranitidine containing medicines to further investigate this matter and will update the public on the outcomes of this investigation. Patients are advised to consult their health care providers before they stop taking Ranitidine or switch to other medicines that are approved and available in the market for similar indications as Ranitidine.

Patients are encouraged to report side effects to their Healthcare providers. Healthcare providers are encouraged to report side effects related to use of medicines including Ranitidine containing products to BoMRA Pharmacovigilance Department at **reportadr@bomra.co.bw**; **Tel; 373 1753** .

BoMRA regulates the supply chain of Human and veterinary medicines, medical devices and cosmetics to ensure that all medicines and related substances used in Botswana are in conformity with established criteria of quality, safety and efficacy.

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Botswana Medicines Regulatory Authority

- Integrity
- Customer Focus
- Efficiency
- TeamWork