NAMIBIA MEDICINES REGULATORY COUNCIL

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To: Marketing Authorisation Holders, Importers and Healthcare Professionals

WITHDRAWAL OF ALL RANITIDINE CONTAINING PRODUCTS FROM THE NAMIBIAN MARKET.

Background

Nitrosamine compounds are potent genotoxic agents in several animal species and some are classified as probable or possible 17 human carcinogens by the International Agency for Research on Cancer (IARC). They are referred to as "cohort of concern" compounds in the ICH guidance for industry M7(R1) Assessment and Control of DNA Reactive (Mutagenic) Impurities in Pharmaceuticals To Limit Potential Carcinogenic Risk (March 2018). The presence of these impurities appears to be generated by the reaction of a secondary amine (which may be present as an impurity or degradant in the solvents and reagents used) and sodium nitrite under acidic conditions where nitrous acid is formed.

Regulatory Authorities across the globe have been investigating the presence of nitrosamine impurities in certain drug products. Since 2018, several drug products including ranitidine have been found to contain unacceptable levels of nitrosamines. According to the United States Food and Drug Administration (USFDA), some common heartburn products (ranitidine, commonly known as Zantac, and nizatidine, commonly known as Axid) contained unacceptable levels of N-nitrosodimethylamine (NDMA).

Regulatory decision

The Namibia Medicines Regulatory Council (NMRC) has taken decisive action in response to the detection of N-Nitrosodimethylamine (NDMA), a probable human carcinogen, in ranitidine-containing products. The NMRC recognizes the potential risk associated with prolonged exposure to this impurity in ranitidine-containing medicines.

Ranitidine, a histamine-2 (H2) receptor blocker widely used to reduce stomach acid production in conditions such as heartburn and stomach ulcers, has been identified as high-risk for nitrosamine impurities. Notably, these impurities increase with the degradation of the product over time on the shelf.

In light of potential health risks and with public health in mind, the NMRC has decided that all products containing ranitidine should no longer be used in Namibia. This proactive step aims to prevent further exposure to NDMA impurities, particularly as impurity levels tend to increase with the duration of the shelf life.

The NMRC recommends that alternative products be used. The NMRC is committed to ensuring the safety and well-being of the public, and this decision reflects a precautionary approach to address the potential risks associated with ranitidine-containing products.

Yours sincerely,

FRANSINA NAMBAHU
REGISTRAR OF MEDICINES