NAMIBIA MEDICINES REGULATORY COUNCIL

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03 May 2023

PUBLIC NOTICE 002/2023

To: Marketing Authorisation Holders, Importers and Healthcare Professionals

WITHDRAWAL OF ALL PHOLCODINE CONTAINING PRODUCTS ON THE NAMIBIAN MARKET

The office of the Registrar of Medicines would like to provide guidance on the significant safety issue concerning pholcodine containing products.

Preliminary findings from the ALPHO study have triggered a safety signal due to increased risk of perioperative anaphylaxis to neuromuscular blocking agents (NMBAs) after consumption of pholcodine. In light of the above, the European Pharmacovigilance Risk Assessment Committee (PRAC) evaluated all available data including final results of the ALPHO study, post-marketing safety data and information submitted by third parties. The review showed that the use of pholcodine in the 12 months before general anaesthesia with NMBAs is a risk factor for developing an anaphylactic reaction. Several medicines regulatory authorities have taken actions including withdrawal and deregistration of pholcodine continuing products.

As a precautionary measure considering the seriousness of the safety risk as well as the lack of risk minimisation measures, the office of the Registrar of Medicines is hereby requesting all marketing authorisation holders, importers and healthcare professionals to implement the following procedures pending the Namibia Medicines Regulatory Council's decision:

1. Withdraw and quarantine all pholcodine containing products

2. Suspend the prescribing, issuance or sale of pholcodine containing products and consider alternative options to treat patient symptoms
3. Advise patients to stop taking the pholcodine containing products

Further information will be provided by the Council in due course.

Yours sincerely,

FRANSINA NAMBAHU
REGISTRAR OF MEDICINES