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NAMIBIA MEDICINES REGULATORY COUNCIL

PUBLIC NOTICE 004/2021

UPDATED REGULATORY REQUIREMENTS FOR THE SALE, DISTRIBUTION AND USE OF COVID-19 ANTIGEN-RAPID DIAGNOSTIC TEST KITS

This document provides an update to the *PUBLIC NOTICE 003/2021*, issued on the 04 February 2021.

Background:

The Namibia Medicines Regulatory Council (NMRC) has a mandate to regulate medical devices as per the *Medicines and Related Substance Control Act, 2003 (Act 13 of 2003)*. Rapid diagnostic tests (RDTs) for COVID-19 fall within the definition of medical devices as per the *Act*.

The use of Nucleic Acid Amplification tests (NAATs), such as real time reverse transcription polymerase chain reaction (rt-PCR) assays, has been the gold standard to detect SARS-CoV-2 infection. Antigen-detection diagnostic tests have recently been developed to directly detect SARS-CoV-2 proteins produced by replicating viruses in respiratory secretions and are available as both laboratory-based tests, and for near-patient use, commonly known as Rapid Diagnostic Tests (RDTs).

The Antigen-Rapid Diagnostic tests (Ag-RDTs) have demonstrated a lower sensitivity compared to the rt-PCRs and are much more likely to give false-negative results in individuals with a low viral load. Negative results for the Ag-RDTs are therefore considered presumptive negative and in most cases requires