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PUBLIC NOTICE 006/2021

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 confirmation with a RT-PCR test. For this reason they are not recommended for use in home or office settings except for clinic or casualty settings where their use is controlled. On the other hand, the Ag-RDTs have advantages including, shorter turn-around time; less expensive than the rt-PCR; simplicity to perform anywhere.

All COVID-19 Ag-RDT kits (imported and locally manufactured), must undergo verification by a **locally** accredited laboratory that performs PCR tests. This is to assess the performance of the Ag-RDT kit against an existing validated rt-PCR method in use in that laboratory.

The results of the verification conducted by the laboratories will inform the decision to issue an authorization for the sale, distribution and use of a COVID-19 AG-RDT kit.

DOCUMENTS TO BE SUBMITTED

The following documents must be submitted upon application:

1. Cover letter on company letterhead indicating intention to apply for authorization to sell and distribute the Covid-19 Ag-RDT kits.
2. Supportive evidence for each COVID-19 test kit(s) including:
    - Evidence of pre-market approval/registration/evidence of emergency use authorisation for each listed COVID-19 test kit by at least one of the authorities recognised by NMRC (see regulatory authorities that NMRC aligns with) or pre-qualification by the World Health Organization.
    - Written declaration of sameness by the original manufacturer that each COVID-19 test kit(s) being imported is the same as the product listed or registered by any of the authorities recognized by NMRC.
    - Evidence of ISO13485:2016 certification of the original manufacturer for each listed COVID-19 Ag-RDT kit.
3. A validation report by an accredited laboratory.
4. Copy of Instructions for Use (IFU) in English language for each listed COVID-19 Ag-RDT kit(s).

5. Copy of labelling and packaging of each listed COVID-19 Ag-RDT kit(s).

AUTHORISATION APPLICATION PROCESS AND TIMELINES

1. The application letter should be submitted via email to NMRC (covid.regulatory@mhss.gov.na) only.
2. A letter of acknowledgment of receipt of the application will be sent to the applicant.
3. A primary review of each application will be performed to determine if the above requirements are met.
4. Each application will be reviewed by a committee of the NMRC.
5. An observation letter will be sent to the applicant in the event that the application does not meet the evaluation criteria. The deficiencies identified within the application will be documented in the observation letter.
6. The applicant is required to respond to the deficiencies noted in the observation letter within 30 days. NOTE: Only 2 cycles will be permitted. Failure to respond will result in the rejection of the application.
7. If the application meets the evaluation criteria, the listed Ag-RDT kit(s) will be approved for use in Namibia in the diagnosis of COVID-19 under set conditions.

CUSTOM CLEARANCE OF THE TEST KITS FOR IMPORT

1. NMRC may issue a clearance letter to allow import of the test kits for validation purposes. Only test kits that have met all the requirements stated above can be imported.
2. Clearance to import will only be for the quantity required for validation.

CONDITIONS UNDER WHICH THE ANTIGEN RAPID TEST KITS MAY BE APPROVED FOR USE

1. The rapid test kits should only be supplied to and used in health facilities (as defined in the Health Facility Act No 36 of 1994) or institutions where medical personnel certified and trained in the use

of test kits is/are present to perform the test. The supplier should therefore provide the NMRC with the list of recipients of the test kits.

2. It is the responsibility of the supplier to ensure that the medical personnel to be performing the tests have received training on specimen collection, Ag-RDT testing and biosafety measures. Therefore, only trained and certified users are permitted to perform the tests.
3. Medical personnel conducting tests should adhere to the most recent MoHSS *Guidance on Rapid Diagnostic Testing for Covid-19 Response.*
4. The supplier and/or medical personnel (end-users of the test kits) should provide the NMRC with a report on any activities after one month of testing as well as the use of the kits, operational or diagnostic challenges or successes experienced.
5. End-users, distributors and/or manufacturers must report any adverse event or product problem or suspected falsified product or suspected unapproved devices to NMRC.

Authorization for any Ag-RDT may be revoked if the condition(s) under which it was issued are not met or if new evidence that do not support use emerges.

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