MINISTRY OF HEALTH AND SOCIAL SERVICES

NAMIBIA MEDICINES REGULATORY COUNCIL

GUIDELINE FOR APPROVAL OF SECTION 27 APPLICATIONS FOR MEDICINES AND VACCINE TO BE USED FOR COVID-19.

A) INTRODUCTION

The Namibia Medicines Regulatory Council (NMRC) is responsible for ensuring that medicines produced or imported into the country for human or animal use are safe, efficacious and of acceptable quality amongst other things. The NMRC's primary aim is to safeguard public health through a system of regulation. Unless authorized in terms of section 27 of the Medicines and Related Substances Control Act, 2003 (Act No.13 of 2003), medicines must be registered before being sold and used in Namibia. An unregistered medicine or vaccine may only be supplied in accordance with the provisions of **Section 27 of the Medicines and Related Substances Control Act, 2003 (Act No. 13 of 2003) and related regulations.**

Coronavirus disease (COVID-19) is an infectious disease caused by a novel coronavirus (SARS-CoV-2). On 30 January 2020, the World Health Organization (WHO) declared the outbreak a public health emergency of international concern. On 11 March 2020, WHO characterized COVID-19 as a pandemic. The pandemic presents an extraordinary challenge to global health. There are currently no NMRC-registered medicines and vaccines to treat and prevent COVID-19. This guidance describes NMRC's current requirements with regard to the data and documents needed to facilitate the approval of medicines and vaccines to treat and prevent COVID-19 on a compassionate basis.

It is equally important to note that the NMRC reserves the right to request information or material and define conditions not specifically described in this guideline, in order to enable the NMRC to adequately assess the safety, efficacy and quality of a medicine or vaccine for COVID-19 (SARS-COV-2). The NMRC is committed to ensuring that such requests are justifiable and that decisions and processes leading to such decisions are clearly documented. This guideline should be read in conjunction with the Medicines and Related Substances Control Act, 2003 (Act 13 of 2003) and its regulations.

In terms of Section 27:

1) The Council may authorise a person, in writing, to sell a specified quantity of a particular medicine, which is subject to registration, but is not registered, during a specified period and to a specified person or institution.
2) Such a medicine may be used for such purposes, in such manner and during such period, as the Council may determine in writing.
3) If effect is not given to a determination made in terms of subsection (2), or if the Council is of the opinion that the risks of selling a specified quantity of a particular medicine in terms of subsection (1), outweighs the potential benefits, the Council may at any time, in writing, withdraw any authority granted in terms of the said subsection (1).

This guideline provides requirements to approve the importation, distribution and sale of unregistered medicine for the diagnosis, treatment, mitigation, modification or prevention COVID-19 for an individual patient or group of patients (bulk supply for private or public institutions). In terms of this guideline, compassionate

clearance/use means the use of unregistered medicines for the treatment or prevention of a patient or group of patients with serious or life-threatening disease who has no satisfactory or no treatment options. It is the responsibility of the individual patient's doctor to decide that the available registered medicines are unable to meet the patient's therapeutic needs.

B) REQUIREMENTS FOR THE AUTHORISATION OF SALE OF UNREGISTERED MEDICINES IN TERMS OF SECTION 27 FOR COVID-19

1. QUALITY, SAFETY AND EFFICACY OF THE MEDICINE/ VACCINE – KEY CONSIDERATIONS

- The vaccine or medicine must be adequately characterized and its manufacture in compliance with applicable standards, including current Good Manufacturing Practice (cGMP).
- An application dossier (quality and clinical data) for verification and evaluation should accompany submission of a section 27 application, if it has not been submitted before.
- The dossier should follow the ICH CTD format. In the CTD dossier, sections for which no information is available at the time of the initial submission should be indicated as "data or information not available", "study ongoing" or "not applicable", as the case may be.
- Applicants should supply the data as per the WHO EUL requirements https://www.who.int/docs/default-source/medicines/eulprocedure.pdf?sfvrsn=55fe3ab8_7&download=true.
- NMRC will only consider section 27 applications for vaccines and medicines that are either WHO prequalified or WHO Emergency Use Listed or granted Emergency Use Authorisation or Conditional marketing authorisation from Stringent Regulatory Authorities (SRAs) that NMRC aligns with.
- NMRC will use a reliance approach to review COVID vaccines or medicines based on prior authorisations from WHO prequalification or from SRAs. For

this mechanism to operate or apply, the following additional information should be provided:

- The quality information summary (QIS), as approved/endorsed by the reference SRA or WHO.
- The unredacted full assessment reports from the reference SRA or WHO prequalification to enable NMRC verify the sameness of the product being applied for.

- Proof of cGMP compliance or inspection reports from the reference SRA or WHO prequalification.
- Risk Management Plan (which, at a minimum, should include the following):
  - Safety Specifications,
  - Pharmacovigilance Plan,
  - Plans for post-authorisation efficacy studies,
  - Summary of the Risk Management Plan, and
  - Information of a local or regional qualified person for pharmacovigilance (QPPV).

- Additionally, applicants should provide the bridging report, or justification for exemption, to address the benefit-risk of the vaccines and medicines in the local context. It is expected and is general practice that health products authorised, conditionally authorised or given emergency use authorisation by reference SRAs are approved for the conditions of use relevant for the respective reference SRA territory. When such a product is submitted for the regulatory approval, or compassionate use where conditions of use or the benefit– risk profile of the medicine or vaccine may differ, it is assumed that the applicant or manufacturer is able to support the application by providing evidence of a positive benefit–risk profile for the proposed conditions of use for the country concerned. The following should be addressed in the bridging report:
  - comparability of the studied population to the target population (e.g. ethnicity, gender representation, age groups) as regards.

- relevance of reference SRA-approved conditions of use as regards to epidemiology and disease pattern in the target countries as well as other implications for efficacy and safety, e.g. feasibility of monitoring and precautionary measures (e.g. resistance testing or therapeutic drug monitoring);

- interactions with food and with other medications relevant in the target countries that are not discussed in the reference SRA's assessment report;
- clinical role of a product and its recommended use according to relevant national and international treatment guidelines; and

- other related quality issues, including but not limited to, storage conditions and conditions of administration and use.

Note: Section 27 authorisation will not be granted until and unless the above requirements have been met.

2. HEALTH CARE PRACTITIONER

i. A valid prescription should be attached to the application for an individual patient. Section 29 subsection 9 (i) of the Medicines and Related Substance Control Act 2003, (Act No. 13 of 2003), states that a prescription is repeatable for a maximum of 6 months only, therefore for repeat prescriptions, a new application should be submitted every 6 months.
ii. Inform the patient that the medicine is not registered with the NMRC.
iii. Inform patient about the possible benefits and risks of the medicine.
iv. Ensure that the patient signs the informed consent document/form. In case of a minor, the parent or guardian must sign the informed consent document/form. A legal guardian or next of kin may give informed consent on behalf of an adult who does not have the capacity to consent. A copy of the consent form should accompany section 27 application.

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v. Ensure that an unregistered product shall only be used for the treatment of the patient in such a manner and for the approved period only. No other patient may receive the authorised unregistered medicine.
vi. Report all adverse events or unexpected events to the NMRC.
vii. The prescriber/practitioner is required to maintain all records on the authorised unregistered medicine for a period of three (3) years, in a manner that will enable data review or inspection by the NMRC at any given time.

3. IMPORTER (APPLICANT)

i. A dully filled Section 27 application form should be submitted to NMRC.
ii. Proof of valid GMP from authorities and organisations that NMRC aligns with or from NMRC should be attached to the application.
iii. A copy of the product information documents such as package insert, patient information leaflet and label should be attached to the application form.
iv. For vaccines, the package insert, patient information leaflet and label should be as per the WHO recommendations.
v. The importer must ensure that for every section 27 bulk application submitted, an application dossier (quality and clinical data) has been submitted to NMRC (refer to section 1 above).
vi. The applicant must be a holder of a license in terms of section 31(5) (c) of the Medicines and Related Substances Control Act 2003 (Act No. 13 of 2003), and must comply with the conditions set in that licence.
vii. The applicant is also responsible for providing all relevant information, such as a package insert, patient information leaflet or investigator's brochure, to requesting practitioners.
viii. The applicant is expected to ensure that the product information documents such as labels, package inserts and patient information leaflets are in the Namibian official language (English).

ix. The applicant is expected to ensure that significant new information with respect to the safety, efficacy and quality of authorised unregistered medicine is made available to practitioners and the NMRC expeditiously.

x. Report any suspected adverse reactions of the authorised unregistered medicine to the NMRC.

xi. The applicant shall not issue any advertisement, catalogue, price list or circular relating to the authorised unregistered medicine or make any representations in respect of that product.

xii. The applicant is required to maintain all records on the authorised unregistered medicine for a period of three (3) years, in a manner that will enable data review or inspection by the NMRC at any given time.

xiii. For medicine to be supplied to the state, the applicant is required to attach a copy of the purchase order from a state agency or office, or where a purchase order has not been issued, the applicant should attach a letter of support for the user state agency or office, and for the private sector, the applicant should attach a motivation letter from a practitioner(s).

4. FEES

Applicable fees payable to the Registrar of Medicines must be paid for processing of each application.

Effective date: 21 January 2021

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