MINISTRY OF HEALTH AND SOCIAL SERVICES

NAMIBIA MEDICINES REGULATORY COUNCIL

GUIDELINE FOR SECTION 27 APPLICATIONS

These guidelines are meant to provide assistance to industry and health care professionals on how to comply with the governing statutes and regulations. They also provide assistance to the Namibia Medicines Regulatory Council (NMRC) on how NMRC's mandates and objectives should be implemented in a manner that is fair, consistent and effective.

It is equally important to note that the NMRC reserves the right to request information or material or define conditions not specifically described in these guidelines, in order to allow the NMRC to adequately assess the safety, efficacy or quality of a medicinal product. NMRC is committed to ensuring that such requests are justifiable and that decisions are clearly documented.

A) INTRODUCTION

The Namibia Medicines Regulatory Council (NMRC) is responsible for ensuring that medicines are safe, efficacious and of quality amongst other things. The NMRC's primary aim is to safeguard public health through a system of regulation. Unless exempted, medicinal products must have marketing authorisation before being placed on the market. An unlicensed medicinal product may only be supplied in accordance with the provisions of **Section 27 of The Medicines and Related Substances Control Act, Act 13 of 2003 and related 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), outweigh 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 advice on the importation, distribution and supply of unregistered medicinal products for human use 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 medicinal products for the treatment 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, dentist or authorized prescriber to decide that the available licensed medicinal products are unable to meet the patient's medicinal needs. In this guideline, compassionate clearance/use does not refer to the use of an unlicensed medicinal product for an indication different from the one mentioned in the package insert and or patient information leaflet i.e. off-label use.

B) REQUIREMENTS FOR THE SALE OF UNREGISTERED MEDICINAL PRODUCTS IN TERMS OF SECTION 27

1) HEALTH CARE PRACTITIONER[1]

i. A valid prescription should be attached to the application. The Medicines and Related Substance Control Act 13 of 2003 section 29 subsection 9 (i) states that a prescription is repeatable for a maximum of 6 months only, therefore for repeat prescriptions, a new applications should be submitted every 6 months
ii. Inform the patient that the medicine is not registered with the NMRC
iii. A valid justification/ motivation stating why the currently registered alternative medicine[2] cannot be used.
iv. Inform patient about the possible benefits and risks of the medicinal product.
v. Ensure that the patient signs the informed consent. In case of a minor the parent or guardian must sign the informed consent. A copy of the consent form should accompany the application
vi. Ensure that 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 authorized unregistered medicinal product.
vii. Report all adverse events or unexpected events to the NMRC.
viii. The prescriber/practitioner is required to maintain all records on the authorized unregistered medicinal product for a period of 3years, in a manner that will enable inspection by the NMRC at any given time.

2) IMPORTER (APPLICANT)

i. A dully filled Section 27 application form to NMRC should be submitted
ii. A valid justification/ motivation stating why the currently registered alternative medicine[2] cannot be used should accompany the application
iii. Proof of valid GMP from authorities and organisations that NMRC aligns with or from NMRC should be attached for bulk applications
iv. A copy of the product information documents such as package insert, patient information leaflet and label should be attached to the application form.
v. The importer must ensure that for every section 27 bulk application submitted, a medicines registration application has been submitted to NMRC
vi. The applicant must be a holder of license in terms of section 31(5) of the Medicines and Related Substances Control Act 13 of 2003 and must comply with the condition 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. Applicant is expected to ensure that the product information documents such as labels, package insert 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 authorized unregistered medicinal products is made available to practitioners and the NMRC expeditiously.

x. Report any suspected adverse reactions of the authorized unregistered medicinal product to the NMRC.

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

xii. The applicant is required to maintain all records on the authorized unregistered medicinal product for a period of 3years, in a manner that will enable 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 the state facilities and for private market, applicant should attach a motivation from the practitioner(s).

C) FEES

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

[1]*For the purpose of this guideline: Practitioner refers to an authorized prescriber and/ or an authorized dispenser*

[2]*Registered alternative: any registered medicine with therapeutic equivalence*

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REGISTRAR OF MEDICINES

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REPUBLIC OF NAMIBIA