POLICY FOR CLASSIFYING MEDICINES INTO THERAPEUTIC CLASSES FOR PURPOSES OF THERAPEUTIC INTERCHANGE

VERSION 9.0; 6 July 2021

1 Purpose

The purpose of this policy is to provide guidance for the placement of medicines in therapeutic classes

Subject to subsections (2), (3) and (4) of Section 22F, a pharmacist or a person licensed in terms of section 22C (1) (a) shall -

(1) (a) inform all members of the public who visit the pharmacy or any other place where dispensing takes place, as the case may be, with a prescription for dispensing, of the benefits of the substitution for a branded medicine by an interchangeable multi-source medicine, and shall, in the case of a substitution, take reasonable steps to inform the person who prescribed the medicine of such substitution;

(b) dispense an interchangeable multi-source medicine instead of the medicine prescribed by a medical practitioner, dentist, practitioner, nurse or other person registered under the Health Professions Act, 1974, unless expressly forbidden by the patient to do so.

(2) If a pharmacist is forbidden as contemplated in subsection (1) (b), that fact shall be noted by the pharmacist on the prescription.

(3) When an interchangeable multi-source medicine is dispensed by a pharmacist he or she shall note the brand name or where no such brand name exists, the name of the manufacturer of that interchangeable multi-source medicine in the prescription book.

(4) A pharmacist shall not sell an interchangeable multi-

which may be informed by the designation of a therapeutic class in the Standard Treatment Guidelines.

7 Designation and use of therapeutic classes

7.1 The NEMLC will designate therapeutic classes for a condition, where appropriate.

7.2 The NEMLC will identify a list of medicines by INN, dosage form and dose that fall into each therapeutic class.

8.2.7 Potential risks, such as contraindications, warnings, and precautions (including high risk patient populations e.g. elderly patients, pregnancy, liver and kidney disease and co-morbidities);

8.2.8 Requirements for clinical monitoring and patient management;

8.2.9 Availability of product, including but not limited to registration of the product in terms of the Medicines and Related Substances Act (Act 101 of 1965); and

8.2.10 Any additional monitoring and management requirements relating to management of the supply chain, prescribing and dispensing.

8.3 If the evidence based review shows the medicines have a comparable therapeutic effect, and that the therapies are similar with regard to the parameters on which they were compared, the expert review committee will make a recommendation to NEMLC for the designation of these agents into a therapeutic class, providing an appropriate dose and administration recommendation for each therapeutic alternative.

8.4 Supporting evidence should be preferably derived from meta-analyses, systematic reviews or randomised clinical trials published in peer-reviewed literature.

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9.3.2.1 which items on a tender may be awarded per therapeutic class, and cases where the same medicine should be awarded across classes to facilitate dose titration and/or adjustment;

9.3.2.2 advice on the importance of monitoring patients when switching from one member of a therapeutic class to another;

9.3.2.3 monitoring

and PTCs, prescribers, persons dispensing medicine and patients must report any adverse effects in accordance with normal requirements for