

MEDICINES CONTROL COUNCIL



SUBSTITUTION OF MEDICINES

This document has been prepared to serve as a recommendation to authorised health practitioners involved in the dispensing and administration of medicines. It represents the Medicines Control Council's current thinking on the safety, quality and efficacy of medicines. The MCC is committed to ensure that all medicines in use will be of the required quality, safety and efficacy. It is important for all who deal with medicines to adhere to the administrative and technical requirements to avoid unwanted or adverse events that may compromise the health of the population. This guideline must be read in conjunction with the definition of "interchangeable multi-source medicine"; Section 22F; and Regulation 2 of the Medicines and Related Substances Act, 1965 (Act 101 of 1965), as amended.

This guideline will be updated on a regular basis as new information becomes available.

REGISTRAR OF MEDICINES
MS M HELA

GROUPS OF MEDICINES AND INDIVIDUAL MEDICINES THAT HAVE BEEN DECLARED NOT SUBSTITUTABLE BY COUNCIL

1 INTRODUCTION

This guideline replaces the **GUIDELINE ON GENERIC SUBSTITUTION** (Document 2.10 Generic substitution Dec03v1) published in December 2003.

The current guideline will be updated as new information on substitution and interchangeability becomes available. The Council registers medicines on the basis of their quality, safety and efficacy in terms of the current guidelines, standards and policies published from time to time. General conditions are appended to each registration certificate, while specific conditions may be imposed by Council on any particular medicine or group of medicines.

Section 22F of the Medicines and Related Substances Act, 1965 (Act 101 of 1965), as amended, provides for the pharmacist or any person licensed in terms of Section 22C (1) (a) to dispense an alternative medicine to the one prescribed, subject to specific conditions.

In terms of Section 22F (4) (c) of the Act Council may declare any medicine or group of medicines not substitutable. Such medicines or group of medicines shall be reflected in this guideline until the Council determines otherwise, based on evidence and information that is available to it.

2 GROUPS OF MEDICINES THAT ARE NOT SUBSTITUTABLE

Biosimilars are not generic products and cannot be identical to their reference products. Further, the formulations may be different and this can have a profound effect on their clinical profiles.

In addition, a biosimilar does not necessarily have the same indications or clinical use as the reference product. Therefore, given current science, they cannot be considered interchangeable with the reference product or products of the same class.

Equally, automatic substitution (i.e. the practice by which a different product to that specified on the prescription is dispensed to the patient without the prior informed consent of the treating physician) cannot apply to biosimilars.

This approach ensures that treating physicians can make informed decisions to ensure that treatment is in the interest of patients' safety.

This guideline is effective from the date of publication of this document.

REFERENCES

1. Medicines and Related Substances Act, 1965 (Act 101 of 1965), as amended, Section 22F.
2. Current MCC Guideline on ***Biosimilar Medicines***, item 5.3 .

UPDATE HISTORY

Date	Reason for update	Version & publication
1994	Circular 16 of 1994 (List of Non-Substitutable Medicines)	
November 2003	Guideline on Generic Substitution	2.10 Version 1 December 2003
January 2010	Substitution of Medicines	2.10 Version2 April 2010