

MEDICINES CONTROL COUNCIL



WOUND DRESSINGS – ACTIVE & PASSIVE

This guideline is intended to provide recommendations to applicants wishing to submit applications for the registration of medicines. It represents the Medicines Control Council's current thinking on the safety, quality and efficacy of medicines. It is not intended as an exclusive approach. Council reserves the right to request any additional information to establish the safety, quality and efficacy of a medicine in keeping with the knowledge current at the time of evaluation. Alternative approaches may be used but these should be scientifically and technically justified. The MCC is committed to ensure that all registered medicines will be of the required quality, safety and efficacy. It is important that applicants adhere to the administrative requirements to avoid delays in the processing and evaluation of applications.

Guidelines and application forms are available from the office of the Registrar of Medicines and the website.

Version 1 – Policy published in new guideline format	July 2012
Date of implementation	With immediate effect

REGISTRAR OF MEDICINES
MS M HELA

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1 INTRODUCTION

This guideline intends to distinguish active impregnated wound dressings from passive dressings and to assist when a decision is to be made whether a wound dressing is registerable as a medicine or not.

The following should be considered in the evaluation process:

- 1 Definition of a medicine in terms of Act 101 of 1965
- 2 Existence of pharmacological classifications for wound dressings (14.2) and emollients (13.4.2)
- 3 Medicinal claims made or not
- 4 Containing a chemical substance with
 - (a) Pharmacological action, or
 - (b) Absorbs wound fluids resulting in the changing of the chemical structure or/and forming a moist gel that has a number of benefits, or
 - (c) Prevents adhesion to wounds, or
 - (d) Any substance or chemical system which is dependent on being metabolised for the achievement of any of its principle intended purposes.

2 DEFINITIONS

- 2.1 With cognisance of the said specifications a definition for wound dressings was formulated and compiled as follows:

“Active Wound Dressing” in relation to the definition of a medicine, means any substance or mixture of substances used or purporting to be suitable for use or manufactured or sold for use in

- 1 wound healing through the application of materials and compounds with medicinal means in that it may be considered to be pharmacologically active or in some way directly influence the body's wound healing mechanism,
- 2 and excludes passive wound dressings and devices.

- 2.2 Word definitions in this definition

- 2.2.1 Materials and Compounds

Chemical substances with the following features:

- (a) pharmacological actions, or
- (b) absorbs wound fluids resulting in the changing of the chemical structure and/or forming a moist gel that has a number of benefits, or
- (c) prevents adhesion to wounds, or
- (d) any substance or chemical system which is dependent on being metabolised for the achievement of any of its principle intended purposes.

- 2.2.2 Passive wound dressings

A dressing which contains no active compound and the aim is rather to attempt to provide an optimum physical environment in the immediate vicinity of the wound conducive to wound healing for the particular type of wound in question.

Typical features which may be incorporated in a passive dressing include controlled vapour permeability of materials, formation of a physical barrier to the ingress of bacteria, prevention of a “wet” wound site but maintaining a moist wound environment through control of the absorbency of the dressing.

2.2.3 Device

An instrument, apparatus, appliance, implant or other similar or related article, which is intended for use in the treatment of humans, animals, which does not achieve any of its principle intended purposes through chemical action within or on the body of man or animal, and which is not dependent on being metabolised for the achievement of any of its principle intended purposes

3 REFERENCES

3.1 Government Gazette No. 3815, 23 March 1973

3.2 The Medicines and Related Substances Act, 1965 (Act 101 of 1965), as amended

4 UPDATE HISTORY

Date	Reason for update	Version & publication
23 March 1973	Wound dressings called up for registration, pharmacological classification 14.2	
Nov 2011	Existing guideline ratified by MCC	Version 1 July 2012
	Publication in new guideline format	
With immediate effect	Date of implementation	