

REF: B/279/35/12/2023

CIRCULAR 12 of 2023

20th June, 2023.

To: Pharmaceutical Wholesalers Association (PWA) Members
Community Pharmacists Association (CPA) Members
All Community Pharmacists and Wholesale Dealers
All Medical and Pharmacy Practitioners

RE: REGULATORY ALERT REGARDING THE SELLING OF SPECIALLY RESTRICTED PREPARATIONS AND THALIDOMIDE

The Authority notes with concern increasing reports concerning buying and selling of Specially Restricted Preparations, particularly Isotretinoin and Thalidomide. Your attention is drawn to section 67 and 69 of the Medicines and Allied Substances Control (General) Regulations, SI, 150 of 1991 (*"the Regulations"*) which restrict the buying and selling of Specially Restricted Preparations. Section 67 of the Regulations reads:

"(1) No person shall acquire or possess a specially restricted preparation other than (a) a pharmacist who controls, or is employed at premises where-

(i) the manufacturer of specially restricted preparation is authorized in terms of subsection (2) of section sixty-eight; or

(ii) the storage and distribution of specially restricted preparations is authorized in terms of section sixty-nine:

Provided that such person may possess a specially restricted preparation solely for the purposes of and to the extent that is necessary for the execution of his duties on such premises; or

(b) a person for whom a specially restricted preparation has been prescribed by a medical practitioner in a prescription issued to him in terms of section seventy to the extent permitted by such prescription".

Section 69 of the regulations reads :

" No person shall store or dispense a specially restricted preparation in or from any premises other than premises specified in Part II of the Eighth Schedule i.e. Premises where specially restricted preparations may be stored, and from which they may be dispensed: The Pharmacy Department at the following hospitals –

(1) Bulawayo Central (2) Gweru General (3) Harare Central (4) Masvingo General (5) Mpilo Central (6) Mutare General (7) Parirenyatwa

(2) The Authority may, subject to such conditions as it considers fit, authorize, in writing, any person to store for distribution a Specially Restricted Preparation on premises licensed in terms of Part VI of the Act"

Practitioners, retail pharmacies and wholesale dealers are not authorised to possess and dispense Specially Restricted Preparations and Thalidomide and can only do so after written authorisation from the Authority is acquired in terms of section 69(2) of the Regulations.

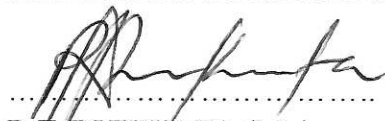
The Medicines and Control Authority of Zimbabwe (MCAZ) is strongly advising general medical practitioners, community pharmacists and wholesale dealers against buying and selling of Specially Restricted Preparations and Thalidomide without written authorisation from the Authority

All medical practitioners, pharmacies and wholesale dealers in possession of Specially Restricted Preparations and Thalidomide are **immediately required to surrender all stocks to the Authority within twenty-four (24) hours**. Upon verification of stocks, further arrangements will be made with respect to the licit possession and dispensing of these products.

The Authority would like to caution all practitioners, licence and permit holders that drastic actions including immediate cessation of operations as well as prosecution may be imposed without further warning if practitioners, licence and permit holders are found in possession of Thalidomide and any Specially Restricted Preparations **without written authorisation from MCAZ after the 24 hours which expire on 22nd June 2023 at 1630 hrs.**

Yours faithfully

MEDICINES CONTROL AUTHORITY OF ZIMBABWE



R.T. RUKWATA (Mr.)

DIRECTOR-GENERAL