Medicines Control Authority of Zimbabwe

GUIDELINES TO APPLICATIONS FOR BULK IMPORTATIONS OF MEDICINES UNDER SECTION 75

1.0 Preamble

In a bid to ensure that essential medicines are readily available to the public, the Authority approved the proposals made by the Retail Pharmacists Association, Public Institutions and Private Hospitals Association of Zimbabwe to import essential unregistered medicines in bulk from named manufacturers by named wholesale dealers. This was done to ensure that only safe, efficacious and good quality medicines are accessible to the people of Zimbabwe.

2.1 Who can import unregistered medicines in bulk?

2.1.1 Approved Wholesale Dealers

2.1.2 Any person or organisation approved by the Authority

2.2 Application for issue of a bulk Section 75 authorisation letter

2.2.1 An application to import an unregistered medicine shall be made in the Form LEF 19

2.2.2 Every application for bulk importation of an unregistered medicine shall be accompanied by:

2.2.2.1A copy of the pro forma invoice.

2.2.2.2An application fee as stated in the current fee schedule

2.2.3 Incomplete applications will not be processed. Applications unaccompanied by the relevant fees will be deemed incomplete.

2.2.4 All applications shall be submitted and authorization acquired prior to purchase and shipment of consignments.

2.2.5 All applications will be processed within five (5) working days from the date of submission, thus the importer is advised to make provisions for this.

2.2.6 If the application is approved, a letter of authorization shall be issued.

2.2.7 Each letter of authorization will be restricted to one product.

2.3 The role of the MCAZ

2.3.1 To ascertain whether the specified product is authorized for bulk importation under section 75

2.3.2 To issue a letter within five (5) working days for approved applications

2.3.3 To verify and clear the consignment

2.4 The role of the Importer

2.4.1 To apply for a Section 75 authorisation letter and submit documentation in time.

2.4.2 To notify the Authority of importation of consignment.

2.4.3 To submit returns on sale of imported unregistered medicines in the form LEF18 on a monthly basis.

2.5 The role of the retailer

2.5.1 To purchase unregistered medicines under the bulk importation program from authorised distributors

2.5.2 Acquire and retain prescription records and individual application forms from the medical practitioners.

2.5.3 Submit records of all unregistered medicines acquired and dispensed on a monthly basis to the MCAZ.

2.5.4 Maintain records in the Dangerous Drugs register format.

ANNEXURE 1

Guidance document to filling out application for bulk importation of unregistered medicine form

NB* It should be noted that the forms should be filled in correctly and completely. No section should be left blank.

Completing form LEF 19 –Application for bulk importation of medicines

Section 1

Full name and address of importer- This section require the details of the authorised importer of the medicine.

Section 2

Full name and address of supplier in exporting country- This section will require the details of supplier of the medicines, which might be the principal or the authorized distributor in the exporting country.

Section 3

The applicant is required to specify the mode of transport through which the medicines will be imported as well as the customs office that will clear the medicines (port of entry of the medicines).

Section 4

Approximate date of arrival - the expected date of arrival of the consignment so that arrangements for the verification and clearance of the consignment can be made on time.

Section 5

Particulars of medicines to be imported-This table should give the full details of the medicines to be imported from the trade name, International Non-Proprietary Name (INN) of medicine, strength, Quantity, Name and Address of Supplier and Manufacturer, and the Cost, insurance and freight value (CIF). The CIF can be reflected once as the total invoice value. This table should be filled in completely and correctly, failure of which will delay the processing of the permit.

Section 6

Declaration by the applicant- This is where the applicant would put their name and sign as a declaration that information provided is correct.

Section 7

Position of the person applying on behalf of the company- It would be preferable that applications be done by technical personnel.