Medicines Control Authority of Zimbabwe

MCAZ/LED/GL-07

GUIDELINES FOR THE IMPORTATION OF VETERINARY MEDICINES IN TERMS OF SECTION 75 OF THE ACT

EFFECTIVE DATE: 02/2022

Medicines Control authority of Zimbabwe

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Reviewed by:	..... Signature	1/2/2022 ..... Date
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Approved by QM:	..... Signature	08/02/2022 ..... Date
Authorised by Director General:	..... Signature	9/2/2022 ..... Date

1.0 APPLICATION

These guidelines apply to all applicants who wish to import unregistered or unavailable veterinary medicines

2.0 PURPOSE

To define;

2.1 Categories of veterinary medicines
2.2 Requirements for applications to import the different categories of veterinary medicines
2.3 Applicable fees
2.4 Stakeholders roles in the application for importation of unregistered or unavailable veterinary medicines

3.0 BACKGROUND / INTRODUCTION

This facility is aimed at ensuring availability of lifesaving, essential veterinary medicines for animals which require them where there are no registered alternatives. The Authority is empowered to issue such authorisation in terms of section 75 of the Medicines and Allied Substances Control Act.

4.0 DEFINITIONS

The Authority has agreed to classify veterinary medicines into 4 categories

4.1 **Category I:** These are medicines that are registered in Zimbabwe and these will be imported via the normal import/export regulations. Applicants/ Principals are required to maintain these products on the register by payment of annual retention fees. For the list refer to the veterinary medicines register on the MCAZ website; www.mcaz.co.zw

4.2 **Category II:** These are medicines that are not yet registered in Zimbabwe but are pending registration. They should be registered in well regulated countries or Stringent Regulatory Authorities (SRA) countries. An application for the registration of the product should be under review and if the product is successfully registered it then moves to Category I. If the application for registration is unsuccessful the importation of the product is banned. For importation of products in this category, the applicant (one who submitted dossier) or wholesale dealer pays as stipulated in the fees schedule authorization/ retainer fee per product per year and the section 75 application fee per product every time an application is submitted to MCAZ.

4.3 **Category III:** These are products that are not registered in Zimbabwe and with no registered alternatives. The value of the products imported per year should not exceed the stipulated fees for Freight On Board (FOB). However, if the market

grows and the FOB exceeds the fee per annum, the product is moved to Category II. If sales remain low and the FOB value remains below the threshold the product is moved to category IV. The industry should prioritize products that were cancelled due to non-payment of retention fees as safety/ efficacy risks would be lower. For new products, wholesale dealer is required to submit prior to authorization:

4.3.1 cGMP certificate of manufacturer

4.3.2 Registration certificate from country of Origin or from other countries to which the product is exported (preferably SRA coutries)

4.3.3 Package inserts or labels for product information

Importing wholesale dealer pays the authorization/ retainer fee per product per year and the section 75 application fee per product every time an application is submitted to MCAZ.

4.4 **Category IV:** These are unregistered products in Zimbabwe with very low volumes FOB << as stipulated in the current fees schedule per annum. Remaining section 75 applications in this category are expected to come from end users (farmers/ veterinary surgeries or hospitals). Products (vaccines) from ONDERSTEPOORT BIOLOGICAL PRODUCTS from the Republic of South Africa fall in this category.

5.0 GUIDELINES

5.1 Applicable application (consignment) fees (to be paid on submission of application) *(use the current fees schedule)*

5.1.1 A wholesale dealer applying to import an unregistered product for resale –payment per product

5.1.2 Veterinary Surgery or Hospital applying to import an unregistered product – payment per product

5.1.3 NGO applying to import an unregistered product – payment per product

5.1.4 Individual/ Farm applying to import an unregistered product – payment per product

5.1.5 Application for authority to import an unregistered game capture product – payment per product

5.2 Stakeholders responsibility in the case of unregistered veterinary medicines imported for a specific end user/ farmer

5.2.1 Role of the farmer

i. To submit their application and accompanying documents to MCAZ

ii. Make the necessary payment of the processing and pay per product on submission of application

iii. Collect authorization letters from MCAZ

iv. Submit the authorization letter to the wholesale dealer who will then import the products

5.2.2 Role of the Zimbabwean Registered Veterinarian

i. Assessing the conditions of animals and determining their pharmaceutical needs
ii. Prescribe medications for the animal.
iii. In cases where the animal requires a medicine that is not registered in Zimbabwe, an application should be made by the farmer with the assistance of the consulting veterinarian to the MCAZ, seeking for authorisation to import the unregistered medicines in accordance with the Act.
iv. Administer or supervise the administration of the medicine, especially if it is a Prescription Preparation.
v.

5.2.3 Role of the Department of Veterinary Services (DVS)

i. Assess all applications for the importation of biological and vaccines
ii. Confirm the presence of the respective strains of disease causing agents and the need for the products by issue of a DVS import permit

5.2.4 Role of the Wholesale dealer

i. To ensure they have authorization letters issued to the farmer
ii. To source for the medicines on behalf of the farm and ensure the quality of the specified products within six (6) months from the date the authorization letter was issued
iii. To present all stamped authorisation letters and invoices to Port Health Officials at the approved ports of entry for scrutiny and clearance
iv. To supply the farmer with the medicines acquired under the authorization letter
v. In the event that the farmer fails to take the consignment the wholesale dealer shall communicate this to MCAZ and indicate the new buyer and if the authority find it satisfactory the wholesale dealer shall be authorized to sell it to the buyer
vi. To return the authorization letter and the medicines that have been cleared
vii. To maintain records of all importations done on behalf of farmers

5.2.5 Role of MCAZ

i. Assess application for completeness
ii. Ascertain whether the required medicine is registered in Zimbabwe or not and whether there are registered alternatives available or not
iii. Assess if the application meets the requirements for Category IV above
iv. To issue the letter of authorization within five (5) working days

5.2.6 Role of the Port Authority at the approved port entry

i. To approve for importation only those medicines which comply with the requirements
ii. To return all copies of the authorization letters to the wholesale dealer after clearance of the consignment

5.3 Stakeholders responsibility in the case of unregistered veterinary medicines imported for resale by a Wholesale dealer (Category II and III)

5.3.1 Role of wholesale dealer

i. To submit a complete application to MCAZ
ii. In case of vaccines or biological acquire a DVS import permit and submit it as a part of the application
iii. Pay the necessary application fee on submission of the application
iv. Import the medicines within six (6) months of the authorization by MCAZ
v. Present the authorization letters and stamped invoices to the Port Health Official at the approved port of entry for scrutiny and clearance
vi. To maintain records of all importations made on behalf of farmers
vii. To sell only to approved outlets

5.3.2 Role of the Department of Veterinary Services (DVS)

i. Assess all applications for the importation of biological and vaccines
ii. Confirm the presence of the respective strains of disease causing

5.3.3 Role of MCAZ

i. Assess application for completeness
ii. Ascertain whether the required medicine is registered in Zimbabwe or not and whether there are registered alternatives available or not
iii. Assess if the application meets the requirements for Category II and III above
iv. To issue the letter of authorization within five (5) working days

5.3.4 Role of the Port Authority at the approved port entry

i. To approve for importation only those medicines which comply with the requirements
ii. To return all copies of the authorization letters to the wholesale dealer after clearance of the consignment

NOTE: For control purposes, all products imported for resale in terms of Section 75 of the Act, must have sticker labels showing the distributors details and the reference number of the Authorization letter of that particular consignment.

5.4 List of Approved Ports of Entry

5.4.1 Robert Gabriel Mugabe International Airport
5.4.2 Bulawayo Airport
5.4.3 Beitbridge
5.4.4 Bulawayo
5.4.5 Harare
5.4.6 Plumtree
5.4.7 Forbes

No person shall import any medicine except through these ports of entry in accordance with *Statutory Instrument 57 of 2008*, [CAP, 15:03] *Medicines and Allied Substances Control (Import and Export of medicines) Regulations, 2008 Section 13*

5.5 Contact Details

Address: Medicines Control Authority of Zimbabwe
106 Baines Avenue
P.O Box 10559
Harare
Zimbabwe

Telephone number: 0242 736981-5; 708255; 2901327-31

WhatsApp number: 0718 855 932

Email addresses: mcaz@mcaz.co.zw; licensingunit@mcaz.co.zw

6.0 KEY RELEVANT DOCUMENTS

6.1 Medicines and Allied Substances Control (General) Regulations, SI 150 of 1991

6.2 Medicines and Allied Substance Control Act *(Chapter 15:03)*

6.3 Medicines and Allied Substances Control (Import and Export of medicines) Regulations, 2008

6.3 Guidelines for Licensing of Premises and Persons

7.0 HISTORY

DOCUMENT HISTORY		
Revision Number	Date Approved	Reason for Change and Amendments
0	September 2015	Rolling Review and Documenting the guideline in a standard template **Description of changes from** Reviewed By R T Dzikadza Rev 0_ September 2015- Rev 1_ February 2022 **Changes From Section 1.0** The newly gazetted Medicines and Allied Substances Control Regulations 2012 (No 26) Statutory Instrument 186 of 2012, makes provision for amendments to the importation of Veterinary Medicines and Section 75 application approval procedure. **To: These guidelines apply to all applicants who wish to import unregistered or unavailable veterinary medicines** **From Section 2.2 Category 2** Medicines that are not yet registered in Zimbabwe, but pending registration. They should be registered in well-regulated/SRA countries.

		An application for registration of the product is under review, and MCAZ to finalize within (12 months) and if successfully registered, product moves to Category 1. If the application for registration is unsuccessful, importation is banned. For this category, the applicant (who submitted dossier) or wholesale dealer pays the stipulated fees for authorisation fees per product per year, plus section 75 application fees every time an application is submitted to MCAZ **To: These are medicines that are not yet registered in Zimbabwe but are pending registration. They should be registered in well regulated countries or Stringent Regulatory Authorities (SRA) countries. An application for the registration of the product should be under review and if the product is successfully registered it then moves to Category I. If the application for registration is unsuccessful the importation of the product is banned. For importation of products in this category, the applicant (one who submitted dossier) or wholesale dealer pays US$ 150 authorization/ retainer fee per product per year and the section 75 application fee per product every time an application is submitted to MCAZ.** **Changes Form Section 2.3 Category 3** Medicines that are not registered in Zimbabwe and with no alternatives registered. Value of the product imported per year is less than the stipulated fees Free on Board (FOB). The importing company tries to grow the market to ≥the stipulated fees FOB p.a. If FOB exceeds the stipulated fees, the product is moved to category 2.

		If sales remain less than fees FOB, the product is moved to category 4. Industry should prioritise products that have been cancelled due to non-payment of retention fees as safety / efficacy risks would be lower <u>To:</u> **These are products that are not registered in Zimbabwe and with no registered alternatives. The value of the products imported per year should not exceed the stipulated fees of Freight On Board (FOB). However, if the market grows and the FOB exceed the fee per annum, the product is moved to Category II. If sales remain low and the FOB value remains below the threshold the product is moved to category IV. The industry should prioritize products that were cancelled due to non-payment of retention fees as safety/ efficacy risks would be lower. For new products, wholesale dealer is required to submit prior to authorization:** **4.3.1 cGMP certificate of manufacturer** **4.3.2 Registration certificate from country of Origin or from other countries to which the product is exported (preferably SRA coutries)** **4.3.3 Package inserts or labels for product information** **Importing wholesale dealer pays the authorization/ retainer fee per product per year and the section 75 application fee per product every time an application is submitted to MCAZ.** <u>Changes From section 2,4 Category 4</u>

		Unregistered in Zimbabwe with very low volume <<as stipulated in the fees schedule FOB p.a. Remain section 75 products and applications are expected to come from end-users (Farmers/Veterinary Surgeries). Products (vaccines) from ONDERSTEPOORT BIOLOGICALS Republic of South Africa also fall in this category. To: **These are unregistered products in Zimbabwe with very low volumes FOB << per annum. Remaining section 75 applications in this category are expected to come from end users (farmers/ veterinary surgeries or hospitals). Products (vaccines) from ONDERSTEPOORT BIOLOGICAL PRODUCTS from the Republic of South Africa fall in this category.** Changes From Section 3.0 **3.0 Applicable Application Fees** ***(to be paid on submission of application)*** **3.1** Wholesale Dealer applying to import an unregistered product for resale per product. **3.2** Veterinary Hospital/Surgery applying to import an unregistered product per product **3.3** NGO applying to import an unregistered veterinary product per product

		3.4 Individual/ Farm applying to import an unregistered veterinary product per product **3.5** Application for Authority to import an unregistered game capture product per product *{REF: Medicines and Allied Substances Control (General) Regulations, 1991, First Schedule}* **NOTE 1:** All applications for authority to import unregistered vaccines should be accompanied with a permit from the Department of Veterinary Services (DVS) **To 5.1** 5.1.2 **A wholesale dealer applying to import an unregistered product for resale –payment per product** 5.1.3 **Veterinary Surgery or Hospital applying to import an unregistered product – payment per product** 5.1.4 **NGO applying to import an unregistered product – per product** 5.1.5 **Individual/ Farm applying to import an unregistered product – US$ 10 per product** 5.1.6 **Application for authority to import an unregistered game capture product – US$ 10 per product**

		KEY RELEVANT DOCUMENTS 6.1 Medicines and Allied Substances Control (General) Regulations, SI 150 OF 1991 6.2 Medicines and Allied Substance Control Act