Medicines Control Authority of Zimbabwe

MCAZ/LED/GL-17

GUIDELINES ON OPERATING VETERINARY MEDICINES GENERAL DEALERS' (VMGD) SHOP

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Medicines Control Authority of Zimbabwe

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1.0 APPLICATION

These guidelines apply to Veterinary Medicines General Dealers approved by the MCAZ and all persons aspiring to operate VMGD outlets.

2.0 PURPOSE

To define;

2.1 Minimum requirements for the premises meant for use as a VMGD outlet

2.2 Parameters within which Veterinary Medicines General Dealers (VMGDs) are expected to operate

2.3 The range (categories for distribution) of medicines that the VMGDs are allowed to stock for sale as specified in the permit issued by MCAZ.

2.4 How VMGD operators should handle medicines.

3.0 BACKGROUND / INTRODUCTION

The Medicines Control Authority of Zimbabwe (MCAZ) is a regulatory body established by the Medicines and Allied Substances Control Act, Chapter 15:03 (MASCA) and its Regulations, SI 150 of 1991. Part of its mandate is to control the manufacture, importation and sale of veterinary medicines to ensure that only safe, efficacious and good quality medicines are accessible to the animals of Zimbabwe. Therefore MCAZ licenses Manufacturers, Wholesale Dealers, Pharmacies, Dispensing Veterinary Surgeons (or Surgery) or Veterinary Medicines (General) Dealers (VMGDs) with an interest in veterinary medicines.

4.0 DEFINITIONS

4.1 Categories for Distribution

Veterinary medicines fall into three (3) categories for distribution as indicated by their registration details on the labels.

4.1.1 **Veterinary Prescription Preparations (PP (Vet)):** these are medicines that require a prescription from a veterinary surgeon and can only be dispensed or sold from a pharmacy or a licensed dispensing veterinary surgery.

NB. Not to be sold from a VMGD outlet

4.1.2 **Veterinary Medicines (General) Dealer (VMGD):** these are medicines that can only be sold from approved VMGD outlets, pharmacies or dispensing veterinary surgeon.

4.1.3 **Household Remedies (HR (Vet)):** these are medicines that can be sold from any shop with a valid trading licence, including supermarkets.

4.2 **VMGD outlet:** a general dealer's shop, which is licensed as such by the local authority, and that is approved by the Medicines Control Authority of Zimbabwe to sell veterinary medicines in the VMGD and HR (Vet) categories for distribution only.

4.3 Section 2 of MASCA defines **sell** as; sell by wholesale or retail and includes:

4.3.1 Import;
4.3.2 Export;
4.3.3 Advertise, label, prepare, expose, offer or possess for sale;
4.3.4 Smuggle, administer, hawk, supply, barter or dispose of to any person;
4.3.5 Distribute, deliver or transmit by way of gift or sample or in any other way whatsoever;

4.4 **NB.** All persons or businesses intending to sell veterinary medicines are required to be licensed as one of the following;

4.4.1 Manufacturers,
4.4.2 Wholesale Dealers,
4.4.3 Pharmacy,
4.4.4 Dispensing Veterinary Surgeon (or Surgery)
4.4.5 Veterinary Medicines (General) Dealers (VMGDs),

HR veterinary medicines (the lowest risk medicines) can be sold from any shop licensed with a local Authority, e.g. supermarkets. All licensed or approved premises are required to have their licences or permits displayed prominently. *{Reference: Medicines and Allied Substances Control (General) Regulations of 1991, SI 150 of 1991, Section 13 and/or 26}*

5.0 GUIDELINES

REQUIREMENTS FOR THE VMGDS

5.1 Application for a VMGD Permit

5.1.1 A VMGD outlet must be licensed as such, by the Medicines Control Authority of Zimbabwe

5.1.2 The requirements for an application for issue of a VMGD permit are as listed below:

- 5.1.2.1 Completed application form for the issue of a permit to sell Veterinary Medicines (MC11)
- 5.1.2.2 Local authority approval for use or change of use of premises (Trading Licence)
- 5.1.2.3 Proof of citizenship (certified) or residence for the company directors (If applicable)
- 5.1.2.4 Applicable application fee as gazetted
- 5.1.2.5 Memorandum and Articles of Association (if a company)
- 5.1.2.6 Completed CR 14 (if a company)
- 5.1.2.7 Affidavits or police clearance for company directors or proprietors that they have not within the (3) three years preceding the application been convicted of any offence related to medicines or dishonesty.

5.2 Premises

5.2.1 The building should be free of rodents, vermin, birds, pets and pests.

5.2.2 It should provide protection for the veterinary medicines from contamination and deterioration, including protection from heat, direct sunlight and moisture.

5.2.3 It should be clean and maintained in a good state of repair to prevent ingress of soil and dust and entrance of rain.

5.2.4 The building should have sufficient security to prevent theft of medicines.

5.3 Sale of Medicines

5.3.1 A VMGD outlet is allowed to purchase for re-sale, only registered or approved medicines in the VM (GD) and HR (vet) categories for distribution, from approved or licensed Manufacturers and Wholesale Dealers in Zimbabwe.

5.3.2 VMGD outlets are not approved importers, as such are not allowed to import medicines on their own. *{Reference: Medicines and Allied Substances Control (General) Regulations of, Import and Export Regulations, SI 57 of 2008}*

5.3.3 If a VMGD outlet wishes to procure registered imported medicines, they should approach approved wholesale dealer who can then import the medicines for them.

5.3.4 VMGD outlets should always have on site at least a guideline for operating VMGD outlets, a current updated list or register of approved premises, a current updated list or register of approved veterinary medicines for their reference and to assist in procuring approved medicines from licensed or approved sources.

{Reference: Medicines and Allied Substances Control (General) Regulations, SI 150 of 1991, Third Schedule}

5.3.5 Sale of unregistered medicines is not allowed, except in the case where written permission under the appropriate provisions is given by the MCAZ in terms of Section 75 of the Medicines and Allied Substances Control Act (Chapter 15:03).

5.3.5.1 In this case, a VMGD outlet must have a copy of the authorisation document used to import the product by the Wholesale Dealer supplied together with the products purchased for re-sale;

5.3.5.2 The unregistered medicines should be stored separately from the registered medicines;

5.3.5.3 Sales records of these products should be kept for 5years. This may also include the special conditions imposed by MCAZ on giving the permission to import to the Wholesale Dealer.

5.3.6 Veterinary Medicines must be sold in their unbroken original packs or containers, in good condition and bearing an original label with a batch number, and an expiry date.

5.3.7 Stocks of medicines with broken seals, damaged packaging or suspected of possible contamination must not be sold, instead, they should be returned to the supplier. *Re-packaging and decanting (including re-labelling) of veterinary medicines is not permitted on a VMGD premises*

5.3.8 The sale of expired medicines is not allowed.

5.3.9 Medicines must not be purchased or received for re-sale after their expiry date or within the last six (6) months of their expiry.

5.4 Handling of Products that require refrigeration

5.4.1 Medicines must be kept within the correct environmental storage conditions.

5.4.2 Products requiring refrigeration mainly vaccines must be stored in a cold room or refrigerator at temperatures between +2 and +8°C and must not be frozen;

5.4.3 The cold chain storage facilities must be monitored by placing a thermometer inside cold room or refrigerator and recording temperatures on a tally sheet in the morning and in the afternoon (am and pm temperatures);

5.4.4 VMGDs should ensure they receive only properly packed vaccines and that the cold chain is maintained;

5.4.5 VMGD shops that keep cold chain products should have means of backup power supply in case of power cuts;

5.4.6 When a VMGD is selling cold chain products e.g. vaccines, they must also supply a means of maintaining cold chain e.g. ice packs.

5.5 Documentation and Records

5.5.1 Invoices of goods obtained from suppliers (Manufacturers/wholesale dealers) of veterinary medicines must be kept on site

5.5.2 Inspectors may request to see the records to establish that all approved VMGDs are sourcing registered or approved medicines for re-sale from licensed or approved suppliers as is prescribed in section 17A of the SI 150 of 1991,

5.5.3 All VMGDs should have a copy of the Medicines and Allied Substances Control Act, Medicines and Allied Substances Control (General) Regulations SI 150 of 1991, Premises Register and Veterinary Medicines Register either as a soft copy or hard copy on the premises at all times

5.5.4 It is desirable for all VMGDs to have a stock recording system.

5.6 Sale of Counterfeit Medicines

5.6.1 The sale of Substandard or falsified (SF) medicines is prohibited.

5.6.2 If a VMGD operator suspects that a product is substandard or falsified (SF), they should notify the Authority.

5.7 Offences and penalties

5.7.1 In terms of section 67(8) of the MASCA, any person who sells for gain or uses any medicine manufactured, sold or represented as a veterinary medicine for the treatment of any person shall be guilty of an offence and liable to a fine not exceeding level ten or to imprisonment for a period not exceeding one year or to both such fine and such imprisonment.

5.7.2 Any person found selling veterinary medicines without a valid VMGD permit or at a premises not approved by the Authority, is in contravention of sections 80 and 50 of the Medicines and Allied Substances Control (General) Regulations, 1991, SI 150 of 1991, as read with section 106 of the same regulations

5.7.3 Any person who sells an unregistered veterinary medicine, is in contravention of section 29 (1) (a) of the Medicines and Allied Substances Control Act (Chapter 15:03), as read with section 29(1a) of the same Act.

5.7.4 Any person who sells expired veterinary medicines, is in contravention with section 51 of the Medicines and Allied Substances Control (General) Regulations, 1991, SI 150 of 1991, as read with section 106 of the same regulations.

5.7.5 Any person found selling veterinary prescription preparation medicines when approved as VMGD, is in contravention of section 73 of the Medicines and Allied Substances Control (General) Regulations, 1991, SI 150 of 1991, as read with section 106 of the same regulations

5.7.6 In terms of Section 67(1) of MASCA, any person who resists, hinders or obstructs an inspector, in the exercise of his functions in terms of the Act shall be guilty of an offence and liable to a fine not exceeding level five or to imprisonment for a period not exceeding six months or to both such fine and such imprisonment.

5.7.7 In terms of Section 67(5) of MASCA, any person who sells any medicine in a container on or in which he knows or ought reasonably to know there is a false or misleading statement regarding the contents shall be guilty of an offence and liable to a fine not exceeding level twelve or to imprisonment for a period not exceeding two years or to both such fine and such imprisonment.

5.7.8 In terms of Section 67(6) of MASCA, any person who, for the purposes of business or trade, publishes any report or certificate made or issued by an inspector or analyst under this Act shall be guilty of an offence and liable to a fine not exceeding level

four or to imprisonment for a period not exceeding one month or to both such fine and such imprisonment.

NOTE I: VMGD permits should be prominently displayed in the VMGD outlet.

NOTE II: Foreign nationals wishing to operate a VMGD premises in Zimbabwe are required to **produce evidence of competence to understand the English language and comprehension of applicable legislation.**

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

6.3 Application for the Issue of a Permit to Sell Veterinary Medicines- MC11 (**Appendix I**)

7.0 HISTORY

DOCUMENT HISTORY		
Revision Number	Date Approved	N/A
N/A	N/A	

APPENDIX I

MC11

CONFIDENTIAL

MEDICINES CONTROL AUTHORITY

MEDICINES AND ALLIED SUBSTANCES CONTROL ACT [CHAPTER 15:03]
APPLICATION FOR THE ISSUE OF A PERMIT TO SELL VETERINARY MEDICINES

1. Particulars of proposed permit holder

   If an individual: Full names .....

   Address (Business) .....

   Telephone number (Business) .....

   If a company: Name of company .....

   Address .....

   Telephone number .....

   Registered office .....

   Main object of the company .....

   State shareholders and distribution of shares or nominees.....

   .....

2. Particulars of directors

Name	**Address**
1.....	.....
2.....	.....
3.....	.....
4.....	.....

   Position of applicant in the company .....

3. Name under which business is conducted .....

   .....

4. Name(s) of agents, if any

   1.....

   2.....

5. Applicant's general dealer's licence receipt number .....

6. Local authority .....

I am familiar with the regulations and conditions relating to the sale of veterinary medicines.

Date .....

.....

Signature of applicant

**Delete the inapplicable*