MCAZ Medicines Control Authority of Zimbabwe

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REF:B/279/28/81/2025

01 August 2025

The Supervisor
Milborrow Animal Health (Pvt) Ltd
t/a Milborrow Animal Health
33 Craster Road
Harare

ATTENTION: Mr Magura Naison,

Dear Sir

RE: ROUTINE INSPECTION OF LICENCED PREMISES - MILBORROW ANIMAL HEALTH (PVT) LTD T/A MILBORROW ANIMAL HEALTH, 33 CRASTER ROAD, HARARE

The inspection of the above premises on the 24th of July 2025 refers.

Appended is an inspection report for your noting and comments. Could we please have your **written** comments, on a signed official letterhead, **within 14 days** of receipt of this letter.

Yours faithfully
MEDICINES CONTROL AUTHORITY OF ZIMBABWE

.....
A. Verenga (Ms.)
For: **DIRECTOR-GENERAL**
/bc

LICENSING AND ENFORCEMENT DIVISION

INSPECTION REPORT FOR WHOLESALE - ROUTINE

MILBORROW ANIMAL HEALTH (PVT) LTD T/A MILBORROW ANIMAL HEALTH, 33 CRASTER ROAD, HARARE

Permit Holder: Milborrow Animal Health (Pvt) Ltd
Supervisor: Mr Magura Naison,
Inspection Date: 24-7-2025
Inspector: Brighton Chinhongo and Tavonga Chanyuka
Type of inspection: Routine Inspection

Key

Italics: Shortcomings noted during inspection
Bold: Issues noted during re-inspection and sub-headings
Regular: The rest of the body of the inspection

1. Preamble

This was an inspection of a premises that was last inspected on the 19th of March 2024 wherein the following shortcomings were noted:

- Temperature mapping studies had not yet been conducted
- Delivery vehicles were not being checked for status of cleanliness during receiving as no evidence of checklist or standard operating procedure could be availed
- There was no provision for monitoring and regulation of transportation temperature and humidity conditions during delivery to customers
- There was no provision for humidity monitoring on the premises
- The available thermometers were deficient in that they did not have provision for alert system in case of excursions in temperature.

1.1 Staff Compliance

Key personnel interviewed during the inspection (non-exhaustive) are as follows;

1. Mr Jilani Mahomed (Pharmacist- Managing Director)

Personnel/ Staff complement

Qualified personnel manned all the storage areas. They had the support of other stores personnel including sales and marketing personnel. The institution was encouraged to have scientific and continuous improvement inspired constructive engagement with the regulatory inspectorate on capacity development. On the day of inspection the sales representative had a valid permit issued by the Authority.

General conduct of the inspection

This was a routine Good Storage Practice/ Good Distribution Practice (GSP/GDP) inspection conducted to encourage compliance and improve quality assurance of medical products. The inspection was conducted in a cooperative, transparent and open environment with constructive engagement on the quality systems in place.

Areas inspected

1. Review of the quality management system
   a. Quality risk management, deviation, change control, CAPA, Document Control,
2. The wholesale business
   a. Receiving of stock, quarantine, storage and dispatch
   b. Sanitation and hygiene
   c. Environmental control and monitoring
   d. Equipment- cold rooms, and data loggers, racking system.
3. Information Technology
   a. Inventory stock management system.
   b. Environmental Monitoring and Control for temperature and humidity in the warehouse areas and cold chain facility.

1.2 Suitability of Premises

The premises were generally well maintained in a clean state. There was adequate light and ventilation on the premises. There was unidirectional flow of medicines. The floor was smooth. All the four areas of receiving, quarantine, warehouse and dispatch were physically separated and

adequately labelled. The premises was out of reach of the public. *There was no written procedure for rodent and pest control.* Waste collection was done at different designated points outside the warehouse. Toilet and canteen areas were separated from where medicines were kept.

{ref: Good Storage and Distribution Practices for Medical Products in Zimbabwe, 2021, Section 5.1.3}

1.3 Receiving Area

There was adequate space for conducting receiving operations. There was an overlapping roof to protect medicines from environmental conditions upon receipt of medicines. There was a receiving table provided for and pallets for staging the medicines before clearance for the warehouse.

1.4 Quarantine Area

This area was generally satisfactory, and pallets were available. There was provision for adequately labelling and physically separating different categories of medicines kept in the quarantine room. There were no medicines in the quarantine area on the day of inspection.

1.5 Warehouse

This area was satisfactory and there were pallets and shelves on which medicines were stored. The storage of medicines was adequate to ensure routine inspection of medicines and adequate air circulation. Medicines stored according to FEFO Temperature mapping studies had been conducted. A fan was available for temperature control. Temperature mapping studies had been conducted by Laboserv® from the 3rd of March 2025 to the 12th of March 2025. There were three (3) devices present for monitoring temperature and humidity. Positioning of the devices was guided by temperature mapping studies. On the day of inspection the devices recorded 16.1°C, 16.0°C, and 16.9°C respectively. The warehouse had a lockable door which restricted access to the warehouse when the supervisor was not around.

There was a functional Defy® refrigerator for storage of cold chain medicines on the premises. The refrigerator was free of molds, there were no food items in the refrigerator. There were no medicines in the refrigerator on the day of inspection.

1.6 Dispatch

This area was provided for and there was a dispatch table and pallets available. The invoices contained all the necessary information. There was provision for monitoring and regulation of transportation temperature and humidity conditions of materials during delivery to patients.

1.7 Cleanliness and Hygiene

The premises were generally clean and tidy.

1.8 Control of Materials

Stocks were controlled through a computerized system which captured all the required information. There was the use of external drives to back up the system.

1.9 Dangerous Drugs

There were no Dangerous Drugs (DD) on the premises.

1.10 Documentation and Records

The following documents were reviewed:

1. Dispatch of goods
2. Receiving
3. Cleaning of all areas in the warehouse
4. Dispatch

The following documents were not available and should be submitted for review:

- *SOP for transportation of medicinal products.*
- *SOP for handling of complaints.*

An SOP for training was available however there was no training calendar. No training had so far been conducted in 2025. There was no Quality Management Manual. There was no defined procedure for writing SOPs. There was no system for managing CAPA. There was a procedure for conducting self-audits *however, the procedure was silent on the frequency of the internal audits. The procedure was also silent on follow up inspections as well as CAPA.*

{ref: Good Storage and Distribution Practices for Medical Products in Zimbabwe, 2021, Sections 5.4.1, 5.4.3 (ix), 5.4.8, 5.6.2, 5.6.3, 5.16.1}

1.11 Legislation

Soft copies of all statutes were available at the premises. There was access to the internet hence the registers could be accessed online in real time.

1.12 Security

There was a metal roller shutter at the entrance of the premises. Burglar bars were installed on all the windows. Security guards were available for provision of 24-hour security daily.

2.0 Observations

For the observations the reference numbers given below in the right-hand column refer to the relevant references of the Medicines and Allied Substances Control Act, Medicines and Allied Substances Control Regulations and Good Dispensing or Good Wholesaling Guidelines

Observations are classified into the risk categories "Critical", "Major", "Other (Minor)" and also in accordance with the functions related to GMP/GSP/GDP as provided for in the WHO 986 and WHO TRS 1025.

2.1 Critical observations are those observations that pose a great risk to the general public
2.2 Major observations are those observations which pose considerable risk to the public
2.3 Minor observations are those observations which pose minimal risk to the public but are still contraventions to the statutory instruments and departure from the guidelines.

Nr	Observations	Ref
	Critical	
	None	
	Major	
1	There was no program for rodent and pest control.	Good Storage and Distribution Practices for Medical Products in Zimbabwe, 2021, Section 5.1.3
2	The following documents were not available and should be submitted for review:	Good Storage and Distribution Practices for

	- SOP for transportation of medicinal products. - SOP for handling of complaints.	Medical Products in Zimbabwe, 2021, Section 5.16.1
3	An SOP for training was available however there was no training calendar. No training had so far been conducted in 2025	Good Storage and Distribution Practices for Medical Products in Zimbabwe, 2021, Section 5.6.2, 5.6.3
4	There was no Quality Management Manual.	Good Storage and Distribution Practices for Medical Products in Zimbabwe, 2021, Section 5.4.1
5	There was no defined procedure for writing SOPs.	Good Storage and Distribution Practices for Medical Products in Zimbabwe, 2021, Section 5.4.7
6	There was no system for managing CAPA.	Good Storage and Distribution Practices for Medical Products in Zimbabwe, 2021, Section 5.4.3 (ix)
7	There was a procedure for conducting self-audits however, the procedure was silent on the frequency of the internal audits. The procedure was also silent on follow up inspections as well as CAPA.	Good Storage and Distribution Practices for Medical Products in Zimbabwe, 2021, Section 5.4.8
	Minor	
	None	

3.0 Recommendations

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Milborrow Animal Health is expected to provide a comprehensive Corrective action and preventive action, CAPA to all the identified shortcomings within 14 days of receipt of this report. The CAPA should as much as possible clearly highlight;

a. The root cause of the shortcoming
b. The corrective action
c. The preventive action
d. Whether the shortcoming has been closed or the plans and targeted date of completion.

Inspector:	Brighton Chinhongo Name	 Signature	28/7/25 Date
Inspector:	Tavonga Chanyuka Name	pp  Signature	28/7/25 Date
Reviewed by:	**Clive S. Kamhoti** Name	pp  Signature	**31/07/2025** Date