



LICENSING AND ENFORCEMENT DIVISION

INSPECTION REPORT FOR WHOLESALE - ROUTINE

PHARMLIFE (PVT) LTD T/A PHARMLIFE, 10A SPURRIER ROAD, NEW ARDBENIE, HARARE

Permit Holder: Pharmlife (Pvt) Ltd
Supervisor: Ms Bangeni Patience,
Inspection Date: 10-4-2026
Inspector: Calvin Nyakanda and Tadiwa Tapfumaneyi
Type of inspection: Routine Inspection
Contact details:

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 premises that was last inspected on the 7th of April 2022, and the following shortcomings were noted:

- The quarantine area had products and were not labelled adequately
- The training SOP was not available and initial and ongoing training programmes had never been done
- There was no checklist for checking all the necessary environmental conditions stipulated by the manufacturer, batch number and expiry dates
- The Organogram was not available
- The system for managing recalls was also not available
- The system for managing CAPA and complaint was not available
- Pest control was carried out but not documented
- Temperature mapping was not done

- The thermometer did not have alert systems to notify temperature and humidity excursions

1.1 Staff Compliance

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

1. Mrs. Patience Bangeni

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.

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.

The inspection was conducted in the presence of Ms. Bangeni Patience. The supervisor's technical aptitude, cooperation, openness and drive to continuously improve, set the tone for a successful assessment of the system 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 not smooth.* All the four areas of receiving, quarantine, warehouse and dispatch were physically separated and adequately labelled. The premises were out of reach of the public. *There was no program for rodent and pest control. There were no designated points for the collection of waste and waste was dumped within the warehouse inappropriately.* Toilet and canteen areas were separated from where medicines were kept.

Medicines and Allied Substances Control (General) Regulations, SI 150 of 1991, Section 2(a), Good Storage and Distribution Practices for Medical Products in Zimbabwe, 2021, Section 5.1.3



Impervious floors

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. *However, the quarantine was used for sleeping by personnel, there was a hospital bed which was used for sleeping in the quarantine room.*



Bed used for sleeping in the quarantine room

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 have not been conducted. There were no temperature control mechanisms in place, there were 3 temperature monitoring devices, two which were not working and weren't calibrated.* There were two (2) devices present for monitoring temperature and humidity. *Positioning of the devices was not guided by temperature mapping studies.* On the day of inspection, the devices recorded 25.0°C. The warehouse had a lockable door

LET 01

which restricted access to the warehouse when the supervisor was not around. (*Good Storage and Distribution Practices for Medical Products in Zimbabwe, 2021, Section 5.2.5; Good Storage and Distribution Practices for Medical Products in Zimbabwe, 2021, Section 5.2.1*)

The warehouse ceiling had structural openings that exposed stored medicines to excessive heat, as well as intrusion by rodents, pests, and vermin. Such conditions compromise the integrity, safety, and efficacy of essential medicines, reflecting a critical shortcoming in facility standards and environmental controls that must be addressed to ensure proper storage and public health protection.



Ceiling with openings that possess risk to medicines quality, safety and efficaciousness.

There was a functional Capri® refrigerator for storage of cold chain medicines on the premises. The refrigerator was free of mold; there were no food items in the refrigerator. There was use of a digital Brannan® thermometer which was calibrated. *Temperature records were not availed on the day of inspection for the refrigerator. (Good Storage and Distribution Practices for Medical Products in Zimbabwe, 2021, Section 5.2.1)*

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 not clean and tidy.

1.8 Control of Materials

Stocks were controlled through a computerized system which captured all the required information. There was 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. SOP for receiving
2. SOP for storage of products
3. SOP for cleaning and maintenance
4. SOP for returned products and rejected goods
5. SOP for dispatching goods

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

- *SOP for handling customer complaints, recalls*
- *SOP for training, training calendar*
- *SOP for handling deviations*
- *SOP for CAPA*
- *SOP for self-inspections*

There was no training program in place for training employees. There was no Quality Management Manual. There was no defined procedure for writing SOPs. There was no system for managing CAPA. There was no written procedure for conducting self-audits. (Good Storage and Distribution Practices for Medical Products in Zimbabwe, 2021, Section 5.6.2, 5.6.3; Good Storage and Distribution Practices for Medical Products in

Zimbabwe, 2021, Section 5.4.7; Good Storage and Distribution Practices for Medical Products in Zimbabwe, 2021, Section 5.4.3 (ix))

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.	The floor was not smooth.	Medicines and Allied Substances Control

LET 01

		(General) Regulations, SI 150 of 1991, Section 2(a)
2.	There was no program for rodent and pest control.	Good Storage and Distribution Practices for Medical Products in Zimbabwe, 2021, Section 5.1.3
4	There was no designated point for the collection of waste as waste was being dumped inappropriately.	Good Storage and Distribution Practices for Medical Products in Zimbabwe, 2021, Section 5.1.2
5	Temperature mapping studies have not been conducted.	Good Storage and Distribution Practices for Medical Products in Zimbabwe, 2021, Section 5.2.5
6	There were no temperature control mechanisms in place.	Good Storage and Distribution Practices for Medical Products in Zimbabwe, 2021, Section 5.2.1
7	Positioning of the devices was not guided by temperature mapping studies.	Good Storage and Distribution Practices for Medical Products in Zimbabwe, 2021, Section 5.2.5
8	The following documents were not available and should be submitted for review: • <i>SOP for handling customer complaints, recalls</i> • <i>SOP for training, training calendar</i>	Good Storage and Distribution Practices for Medical Products in Zimbabwe, 2021, Section 5.16.1

LET 01

	• <i>SOP for handling deviations</i> • <i>SOP for CAPA</i> • <i>SOP for self-inspections</i> •	
9	There was no training program in place for training employees.	Good Storage and Distribution Practices for Medical Products in Zimbabwe, 2021, Section 5.6.2, 5.6.3
10	There was no Quality Management Manual.	Good Storage and Distribution Practices for Medical Products in Zimbabwe, 2021, Section 5.4.1
11	There was no defined procedure for writing SOPs.	Good Storage and Distribution Practices for Medical Products in Zimbabwe, 2021, Section 5.4.7
12	There was no system for managing CAPA.	Good Storage and Distribution Practices for Medical Products in Zimbabwe, 2021, Section 5.4.3 (ix)
13	There was no written procedure for conducting self audits.	Good Storage and Distribution Practices for Medical Products in Zimbabwe, 2021, Section 5.4.3 (vi)
	Minor	
	None	

3.0 Recommendations

- The licensee should pay particular attention to the repeat shortcomings as these may affect renewal of their Wholesale Dealers' permit.
- Pharmlife is expected to provide 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:	Calvin Nyakanda		13-5-2026
	Name	Signature	Date

Inspector:	Tadiwa Tapfumaneyi		13-5-2026
	Name	Signature	Date

Reviewed by:	Martha Mwatseteza		20-5-2026
	Name	Signature	Date