



**LICENSING AND ENFORCEMENT DIVISION**

INSPECTION REPORT FOR A WHOLESALE- NEW

**LETHU HEALTH (PVT) LTD T/A LETHU HEALTH, 18- 11<sup>TH</sup> AVENUE, 272A BULAWAYO TOWNSHIP, BULAWAYO.**

**Applicant:** Lethu Health (Pvt) Ltd

**Supervisor:**

**Inspection Date:** 29 January 2026

**Inspectors:**

**Type of inspection:** New Premises

**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

**1.0 Preamble**

This was the inspection of new premises after a complete and satisfactory application was received.

**1.1 Suitability of premises**

The premises were generally in a clean and tidy condition with suitable and effective means of natural lighting and ventilation. There was satisfactory visibility with the lights off. Medicines shall be stored on wooden pallets, as well as metal shelves protected from direct light, moisture and excessive heat.

All working surfaces were finished with smooth, impervious, and washable material and maintained in a good state of repair. The floors were smooth and impervious. The walls were painted and washable. *There was no unidirectional flow of medicines, as medicines which were being received at the premises and those which were being dispatched shared the same entrance, as both doors converged in the reception area. The four warehouse areas (Receiving, Quarantine, Warehouse and Dispatch) were not clearly demarcated and labelled. The dispatch area and the warehouse area were not separate, and there was no door restricting entry into the warehouse from the receiving area.*

The four areas measured 12.6866m<sup>2</sup>, 7.661m<sup>2</sup>, 76.58m<sup>2</sup> and 10.1775m<sup>2</sup> respectively. However the quarantine was located in the warehouse and personnel would enter the warehouse first before reaching the There were two mercury thermometers in the warehouse *which were not calibrated. There was no air conditioner in the warehouse for temperature control.* The supervisor was recommended to make plans to commence temperature mapping studies in the future to enable efficient and strategic placement of

thermometers in the warehouse.

The staff complement shall include one (1) supervisor: a pharmacist, and two (2) sales reps.

There were toilet facilities which were clean and in good working order.

*{Good Storage and Distribution Practices for Medical Products in Zimbabwe, 2021, Section 5.1.6, 5.2.1, 5.3.2}*

## **1.2 Receiving Area**

The receiving area measured approximately  $12.6866m^2$  which was considered adequate. *The receiving area was not physically separated from the warehouse area, as there was no door between the two areas. A table was placed in the receiving area.* *{Good Storage and Distribution Practices for Medical Products in Zimbabwe, 2021, Section 5.1.6}*

## **1.3 Quarantine Area**

The Quarantine area measured approximately  $7.661m^2$  which was found satisfactory for the operations of the wholesale. The quarantine area was however not physically separated from the warehouse as it was located in the main warehouse and was made of movable barriers with no lockable door.

*{Good Storage and Distribution Practices for Medical Products in Zimbabwe, 2021, Section 5.1.6}*

## **1.4 Warehouse**

The warehouse measured approximately  $76.58m^2$  and this was considered adequate. *The warehouse was not physically separated from the dispatch and the receiving area. The warehouse and the dispatch were separated by a table, whereas the quarantine was separated from the warehouse by movable shelves. There was no door between the receiving area and the warehouse area. There were two (2) mercury thermometers in the warehouse, which were not calibrated. There were no temperature control mechanisms installed at the premises.*

All cold chain medicines shall be stored inside a white Capri® refrigerator with its own digital thermometer, *which was not calibrated.*

*{Good Storage and Distribution Practices for Medical Products in Zimbabwe, 2021, Section 5.1.6, 5.2.1, 5.3.2}*

## **1.5 Dispatch**

The dispatch area measured approximately  $10.1775m^2$ , which was considered adequate. The dispatch area was not physically separated from the warehouse as only a table was used as a barrier between the two areas.

## **1.6 Cleanliness and Hygiene**

The premises were generally clean and tidy, free from accumulated waste and vermin.

### 1.7 Control of Materials

*There was no unidirectional flow of medicines as medicines which were being received at the premises and those which were being dispatched shared the same entrance, as both doors converged in the reception area.*

*{Good Storage and Distribution Practices for Medical Products in Zimbabwe, 2021, Section 5.1.6}*

### 1.8 Dangerous Drugs

There was a Dangerous Drugs compartment and a serialized Dangerous Drugs register at the premises.

### 1.9 Documentation and Records:

A manual recording system and stock cards shall be used for capturing all the required information and inventory management. The sample invoice provided captured all the required information including batch number, expiry date and brand or manufacturer's details of the medicines.

The following were available on the day of inspection:

- i. SOP for Receiving and checking of medical products
- ii. SOP for Security of Stocks
- iii. SOP for Recalls
- iv. SOP for returned goods
- v. SOP for cleaning and maintenance

### 1.10 Legislation

All the required legislation were available on the day of the inspection.

### 1.11 Security

There were metal grills on the entrance to the premises and burglar bars affixed to all the windows for security. There was a Fawcett® alarm response system as well as CCTV cameras installed. There was a stainless steel reinforced wooden partition on one end of the facility

### 1.12 General

The premises were generally clean and tidy.

## 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 categories "Critical", "Major", "Other (Minor)"

- 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.

| <b>Nr</b> | <b>Observations</b>                                                                                                                                                                                                                                                | <b>Ref</b>                                                                                    |
|-----------|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-----------------------------------------------------------------------------------------------|
|           | <b><i>Critical</i></b>                                                                                                                                                                                                                                             |                                                                                               |
|           | None                                                                                                                                                                                                                                                               |                                                                                               |
|           | <b><i>Major</i></b>                                                                                                                                                                                                                                                |                                                                                               |
| <b>1.</b> | There was no unidirectional flow of medicines, as medicines which were being received at the premises and those which were being dispatched shared the same entrance, as both doors converged in the reception area                                                | Good Storage and Distribution Practices for Medical Products in Zimbabwe, 2021, Section 5.1.6 |
| <b>2.</b> | The four warehouse areas (Receiving, Quarantine, Warehouse and Dispatch) were not clearly demarcated and labelled. The dispatch area and the warehouse area were not separate, and there was no door restricting entry into the warehouse from the receiving area. | Good Storage and Distribution Practices for Medical Products in Zimbabwe, 2021, Section 5.1.6 |
| <b>3.</b> | There were no temperature control mechanisms installed at the premises.                                                                                                                                                                                            | Good Storage and Distribution Practices for Medical Products in Zimbabwe, 2021, Section 5.2.1 |
|           | <b><i>Minor</i></b>                                                                                                                                                                                                                                                |                                                                                               |
| <b>3.</b> | There were two (2) mercury thermometers in the warehouse, which were not calibrated.                                                                                                                                                                               | Good Storage and Distribution Practices for Medical Products in Zimbabwe, 2021, Section 5.3.2 |

### 3.0 Recommendations

The applicant is required to address the matters in italics before a Wholesale Dealer's Permit is issued. A re-inspection of the premises will be required to verify the rectification of the noted structural shortcomings. A re-inspection fee of USD 200 should be paid prior to the re-inspection.