



LICENSING AND ENFORCEMENT DIVISION

INSPECTION REPORT FOR A WHOLESALE- NEW

LIMAEEL ENTERPRISES (PVT) LTD T/A LIMAEEL PHARMACEUTICALS, 5 LUCK STREET, FIDELITY LIFE TOWER, HARARE.

Applicant: Limael Enterprises (Pvt) Ltd
Supervisor: Ms. Tinashe Imbayago (*Pharmacist*)
Inspection Date: 5 March 2026
Inspectors: Emmanuel Makotore and Taonga Chakanyuka
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 an 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 unidirectional flow of medicines within the premises which ensure efficient flow of materials. The four warehouse areas (Receiving, Quarantine, Warehouse and Dispatch) were clearly demarcated and labelled. The four areas measured 13.5m², 7.4m², 52m² and 12.1m² respectively. There were five HTC-2 Clock/ Humidity probes placed in random places within the premises. These were not calibrated. The supervisor was advised to get the probes calibrated. There were three (3) air conditioners 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 data loggers in the warehouse.

The staff complement shall include one (1) supervisor: a pharmacist, two (2) sales representatives, one (1) procurement officer, a driver, the Finance Director and an

operations manager.

There were toilet facilities on the floor where the wholesale was located. These were clean and in good working order.

1.2 Receiving Area

The receiving area measured approximately 13.5m² which was considered adequate. The receiving area was physically separated from the other warehouse areas with lockable entrance and exit areas. It was clearly demarcated and labelled. A table and pallets were placed in the receiving area.

1.3 Quarantine Area

The Quarantine area measured approximately 7.4m² which was found satisfactory for the operations of the wholesale. The quarantine area was physically separated from the warehouse areas with lockable entrance and exit areas. It was clearly demarcated and labelled. There were wooden pallets for staging medicines.

1.4 Warehouse

The warehouse measured approximately 52m². This was considered adequate. The warehouse was physically separated from the other three main areas with a lockable entrance and exit areas. The warehouse was clearly demarcated and labelled. There were three (3) air conditioners in the warehouse and HTC-2 Thermo/ Hygrometer probes in this area. There were wooden pallets for staging medicines.

All cold chain medicines shall be stored inside a grey Capri® refrigerator with HTC-2 Thermo/ Hygrometer which was also not calibrated. The supervisor was advised to get the probes calibrated.

1.5 Dispatch

The dispatch area measured approximately 12.1m², which was considered adequate. The dispatch area was physically separated from the other areas with wooden partitions and lockable entrance and exit areas. It was clearly demarcated and labelled. A table and pallets were placed in the dispatch area for staging of medicines.

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 unidirectional flow of medicines.

1.8 Dangerous Drugs

There was a fixed single lockable dangerous drug cupboard in the warehouse for storage of dangerous drugs. There were dangerous drugs registers which were bound and gad serialized pages for recording transaction for dangerous drugs.

1.9 Documentation and Records:

An electronic system Quickbooks Enterprise Solution recording system 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 Quarantine of goods
- iv. SOP for Dispatch of good
- v. SOP for Recalls

The following SOP's could not be availed during the inspection:

- i. *SOP for Storage of returns goods*
- ii. *SOP for Cleaning and maintenance*
- iii. *SOP for cold chain management*
- iv. *SOP for self inspection*
- v. *SOP for trainings*

There was need to have a documented Quality Management System which defines all the processes of the warehouse operations committing to ensuring quality along all the operational processes.

{ref: Good Storage And Distribution Practices For Medical Products In Zimbabwe (MCAZ/LED/GL-08), Section 5.16.1}

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. The four main areas inside had lockable doors and the complex are manned by security 24/7.

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.

Nr	Observations	Ref
	Critical	
	None	
	Major	
	None	
	Minor	
1.	There was need to have a documented Quality Management System which defines all the processes of the warehouse operations committing to ensuring quality along all the operational processes.	Good Storage And Distribution Practices For Medical Products In Zimbabwe (MCAZ/LED/GL-08), Section 5.16.1

3.0 Recommendations

To rectify the noted shortcomings and get all the temperature and humidity probes calibrated before a Wholesale Dealer's Permit can be issued.

Inspector: Emmanuel Makotore
Name

Signature

05/03/2026
Date

Inspector: Taonga Chanyuka
Name

Signature

05/03/2026
Date

Reviewed by: Lewis Mutevera
Name
Date

05/03/2026
Signature