



LICENSING AND ENFORCEMENT DIVISION

RE-INSPECTION REPORT FOR A WHOLESALE- NEW

V & S HEALTHCARE (PVT) LTD T/A FIVET ANIMAL HEALTH, 4572 POMONA OF LOT 1, HARARE.

Applicant: V & S Healthcare (Pvt) Ltd
Supervisor: Dr. Linos Mafuvadze (*Veterinary surgeon*)
Inspection Date: 16 June 2026
Inspectors: Emmanuel Makotore and Tavonga Chanyuka
Type of inspection: **Re-inspection of** 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 a re-inspection of new premises after the following shortcomings were noted:

1. There was need for temperature control mechanisms
2. Possible mix up of products from the manufacturing site with goods in the receiving area

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 and wooden 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, however there was need to have direct access to the quarantine area from the receiving area. This will enable quarantine of products that are pending clearance before being placed in the warehouse area. The quarantine and warehouse areas were clearly demarcated and labelled. The quarantine and the warehouse areas measured 22.4m² and 370m² respectively. The receiving and dispatch areas were labelled however they were now properly demarcated.

There are now three single digital thermometer placed in the warehouse area. This is now adequate for effective temperature monitoring of the warehouse considering the size of the warehouse. **Ferns were installed for temperature control for the premises (repeat shortcoming).** The supervisor was recommended to make plans to commence temperature mapping studies to enable efficient and strategic placement of data loggers in the warehouse.

The staff complement shall include one (1) supervisor: a veterinary surgeon, four (4) sales personnel and three (3) stock controllers.

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 99.8 m² and the area is now physically demarcated from the dispatch area. A receiving table and pallets for staging medicines had now been placed in the area. **The manufacturing and receiving area is now physically demarcated to ensure that no mix up of materials can happen.**

1.3 Quarantine Area

The Quarantine area measured approximately 22.4m² 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. The quarantine area was in two parts, one for rejected good and one for general quarantine.

1.4 Warehouse

The warehouse measured approximately 370m². 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 are now three digital probes for temperature monitoring which is regarded adequate considering the size of the warehouse.** *There was no means for temperature control.* There were wooden pallets and metal and wooden shelves for staging medicines.

All cold chain medicines shall be stored inside Coldex® cold chain which had two (2) inbuilt temperature monitoring devices. There was a Easytrack system which gave alerts on mobile telephones in cases of temperature excursions.

1.5 Dispatch

The dispatch area measured approximately 131.716 m² is now physically demarcated. There were other areas (corridor to other offices and the manufacturing unit) accessible to the receiving. The supervisor managed to physically demarcate the dispatch area.

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 no dangerous drugs cupboard. The supervisor advised that they did not intend to keep dangerous drugs.

1.9 Documentation and Records:

An electronic system Dynamics 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 of goods
- ii. SOP for Storage of goods
- iii. SOP for distribution of goods
- iv. SOP for Handling of Quarantined rejected or returned goods
- v. SOP for Rejected or Returned goods
- vi. SOP for Product recalls
- vii. SOP for Mock recalls
- viii. SOP for Training
- ix. SOP for Security of Stocks
- x. SOP for Cleaning of warehouse
- xi. SOP for Pest Control
- xii. SOP for Corrective Action and Preventive Action
- xiii. SOP for Branch internal audits
- xiv. SOP for Complaints and Pharmacovigilance
- xv. SOP for Prevention of Temperature Excursions
- xvi. SOP for SOPs
- xvii. SOP for Lot tracking
- xviii. SOP for in-transit Vaccine Temperature Monitoring

The SOPs are now signed for and approved by Management as single individual SOP. This will enable revisions to be independent arising from different necessities applicable to individual processes.

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

1.10 Legislation

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

1.11 Security

There were roller shutters on the entrance (receiving area) and exit (dispatch area) of 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. There was alarm system and CCTV installed for additional security. There was restricted access to essential areas only accessible via biometric confirmation.

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.

<i>Nr</i>	<i>Observations</i>	<i>Ref</i>
	<i>Critical</i>	
	None	
	<i>Major</i>	
1.		
	<i>Minor</i>	
	None	

3.0 Recommendations

Issue Wholesale dealer's permit

Inspector: Emmanuel Makotore
Name

Signature

16/06/2026
Date

Inspector: Tavonga Chanyuka
Name

Signature

16/06/2026
Date

Reviewed by: Lewis Mutevera
Name

Signature

16/06/2026
Date