



Medicines Control Authority of Zimbabwe

**INSPECTION METRICS REPORT –
GOOD SUPPLY & DISTRIBUTION PRACTICES
JANUARY TO DECEMBER 2025**

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LIST OF ABBREVIATIONS

CAPA	–	Corrective and Preventive Action
GSDP	–	Good Supply and Distribution Practices
MCAZ	–	Medicines Control Authority of Zimbabwe
OOS	–	Out of Specification
PIM	–	Pharmacist-Initiated Medicines
PP	–	Prescription Preparation
SOP	–	Standard Operating Procedure
WHO	–	World Health Organization

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Good Supply and Distribution (Pharmacies) Metrics: 2025

Executive Summary

The Medicines Control Authority of Zimbabwe's inspectorate division inspected 726 pharmacies in 2025 as part of the Good Supply and Distribution Practices inspections. The inspections were conducted with reference to the Medicines and Allied Substances Control Act (Chapter 15:03) and other World Health Organisation Guidelines. The inspections were based on risk-based principles wherein the residual compliance risk from the previous inspection determined the re-inspection frequency.

The colour coded database used by the inspectorate was used as a source of the inspections data. The findings from the inspections were classified as Critical, Major and Minor. As of 2025, there were a total of 1,214 pharmacies in Zimbabwe. A total of 372 supervision inspections were conducted, of which 19 premises were found to be operating without the continuous personal supervision of a licensed pharmacist. A supervision compliance rate of 95% was recorded in 2025, while an observations compliance rate of 73% was achieved.

A total of 253 investigative and enforcement inspections were conducted in 2025. These were mainly inspections of facilities unlicensed with MCAZ and infringing the provision of MASCA.

Table 1: Distribution of Routine Pharmacy inspections across the 10 Provinces of Zimbabwe

Province	Number of Pharmacies	Percentage of Total (%)
Harare	162	45.76%
Bulawayo	74	20.90%
Midlands	38	10.73%
Manicaland	22	6.21%
Mashonaland West	18	5.08%
Mashonaland East	14	3.95%
Masvingo	12	3.39%
Mashonaland Central	6	1.69%
Matabeleland South	5	1.41%
Matabeleland North	3	0.85%
Total	354	100%

1.0 Observations classification

Critical Observations: these are observations that pose a great risk to the general public.

Major Observations: these are observations that pose considerable risk to the general public and may also be departure from statutory and guideline provisions.

Minor Observations: are those observations which pose minimal risk to the public but are still contraventions to the statutory instruments and the guidelines.

Table 2: Deficiencies and their classes

Examples of Deficiencies and their classes	
Critical	
a) Unsupervised Premises	
b) Sale of expired medicines	
c) Sale of unregistered medicines	
d) Significant shortages of Dangerous Drugs, amongst others	
Major	
a) Buying medicines from unauthorised sources	
b) Structural shortcomings	
c) Poor record keeping of Dangerous Drugs	
d) Dispensing Prescription Preparations without a prescription	
e) Selling medicines by wholesale without a wholesale dealer's permit	
f) Malfunctional refrigerator with medicines, amongst others	
Minor	
a) Presence of food items in the refrigerator with medicines	
b) Inaccessible legislation	
c) Failure to display premises and persons licences	
d) Unlockable Dangerous Drugs cupboard, amongst others	

2.0 Compliance

This was defined as the number of pharmacies that were visited for an inspection and were found with minor or no observation noted during the inspection.

Table 3: Compliance

Compliance	
Compliant Pharmacies (minor or no observations)	258
Non-compliant (major or critical observations)	96
Total	354

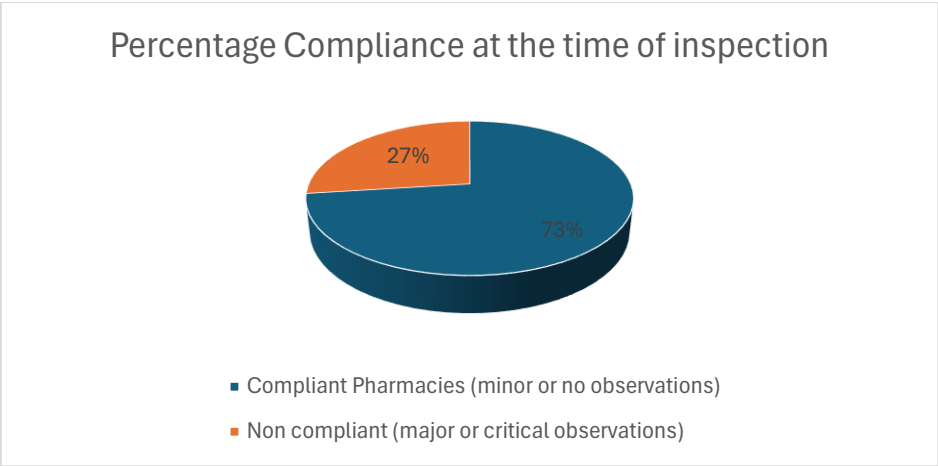


Figure 1: Percentage Compliance at time of Inspection

There was a compliance rate of 73%. This indicated moderate compliance across the retail pharmacy sector, but with persistent systemic weaknesses requiring targeted regulatory strengthening. This compliance rate is mainly attributed to the regulatory systems strengthening by the Authority and self-regulation by the industry.

3.0 Percentage compliance with supervision of premises by licensed persons

Section 55(1)(b) of the Medicines and Allied Substances Control Act [Chapter 15:03] and the subsequent regulations, provide for continuous personal supervision of the premises by a licensed pharmacist. In the period under review, 372 supervision inspections were conducted, and 19 premises (5%) were found without continuous personal supervision. These premises were closed and were only reopened after confirmation of appropriate supervision. A 95% compliance rate with supervision shows good self-regulation and system strength.

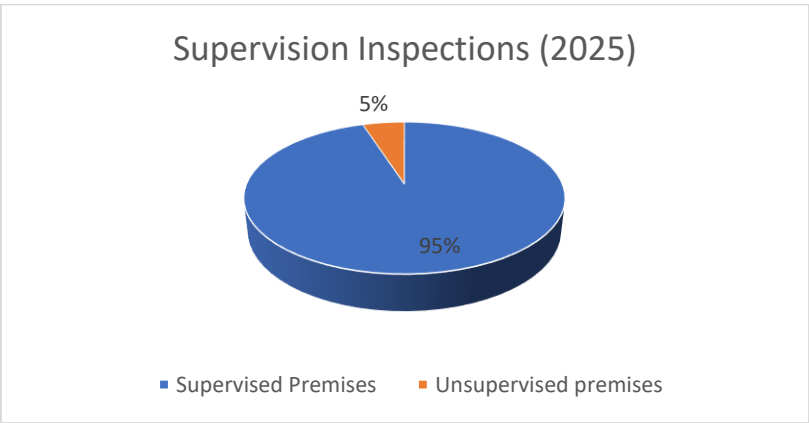


Figure 2: 2025 Supervision Inspections

Table 4: Frequency of Observations from Routine Inspections

Observation	Frequency	% of 354
Incomplete Labels (Pre-pack/Dispensed)	45	12.70%
Inadequate / Missing Equipment (Balances, Mortars, Thermometers)	23	6.50%
Insufficient Capturing of Patient Details	17	4.80%
Temperature Control Deficiencies (Out of Range / No Thermometer / Missing Records)	18	5.10%
Sale of Unregistered / Falsified / Expired Medicines	15	4.20%
Infrastructure / Premises Defects	13	3.70%
Dispensing PP Without Prescription	8	2.30%
No Running Water	8	2.30%
Food Stored in Medicine Refrigerator	7	2.00%
Lack of Physical Barrier (Public Access to Dispensary)	6	1.70%
Dangerous Drugs Mismanagement (Stock/Register mismatch)	4	1.10%
Administrative / System Deficiencies (Licenses, Reference Books, Backup Issues)	5	1.40%

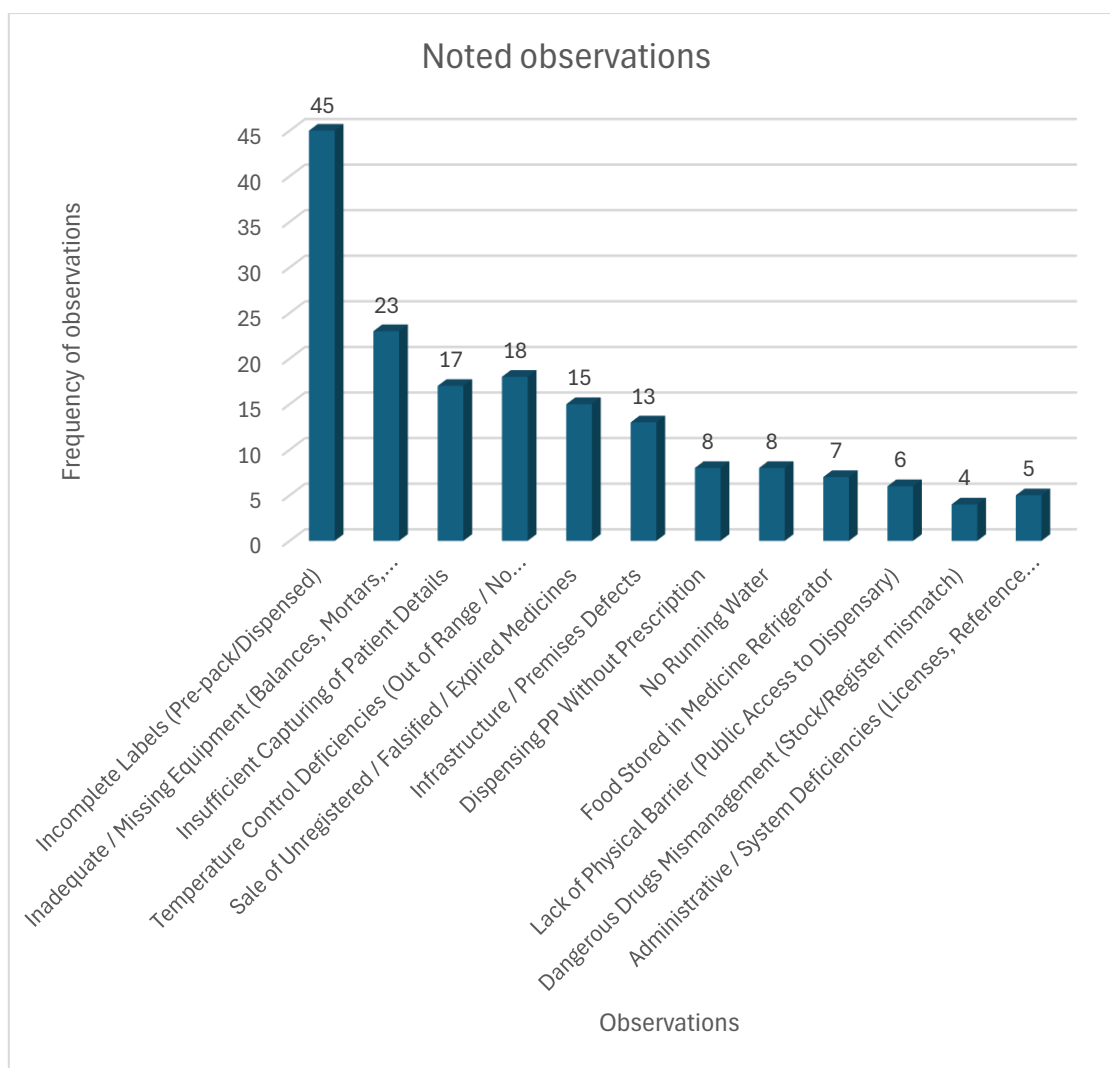


Figure 3: Observation noted during inspections

Table 5: Observations noted during inspections

Observation	Regulatory Concern
a) Incomplete Labels (Pre-pack/Dispensed) The most frequent deficiency involved labels missing manufacturer details, batch numbers, or expiry dates.	Weak traceability, recall complications, and non-compliance with statutory labelling requirements.
b) Inadequate / Missing Equipment (Balances, Mortars, Thermometers) Facilities lacked calibrated balances, adequate compounding equipment, or temperature monitoring devices.	Inaccurate dispensing, compounding, compromised medicine quality, and poor technical oversight.
c) Insufficient Capturing of Patient Details	Weak audit trail, limited traceability, compromised legal defensibility.

Observation	Regulatory Concern
Incomplete dispensing records, missing patient addresses, or use of pseudonyms.	
d) Temperature Control Deficiencies Medicines were stored outside required 2–8°C ranges, or temperature logs were missing/inconsistent and absence of calibrated measuring devices.	Reduced potency of vaccines and cold-chain medicines and direct patient safety risk.
e) Sale/Stocking of Unregistered, Falsified, or Expired Medicines The three most sold unregistered medicines were semaglutide, haloperidol and rabies vaccine.	Severe public health threat, toxicity, sub therapy and resistance
f) Infrastructure / Premises Defects Roof leaks, unsmooth floors, inadequate storage space, or general unsuitability of premises.	Compromised medicine integrity and poor hygiene control.
Dispensing Prescription Preparations Without Prescriptions	Abuse potential, antimicrobial resistance and regulatory breach.
g) No Running Water Facilities lacked hot and/or cold running water for hygiene and compounding.	Poor sanitation standards and infection control weakness.
h) Food Stored in Medicine Refrigerator Staff food was stored alongside cold-chain medicines.	Cross-contamination risk and poor compliance culture.
i) Lack of Physical Barrier to Dispensary Public had unrestricted access to medicine storage areas.	Unauthorized access, theft, tampering risk.
j) Dangerous Drugs Mismanagement Physical stock did not tally with register, or transactions were not recorded within 24 hours.	Diversion risk and potential for abuse
k) Administrative / System Deficiencies Missing licenses, outdated reference books, poor data backups.	Weak governance controls and operational oversight gaps.

Table 6: High Risk Observations

High-Risk Area	Combined Cases	% of 354
Unregistered / Falsified Medicines	15	4.20%
Dangerous Drugs Mismanagement	4	1.10%
Dispensing Without Prescription	8	2.30%
Cold Chain	18	5.10%

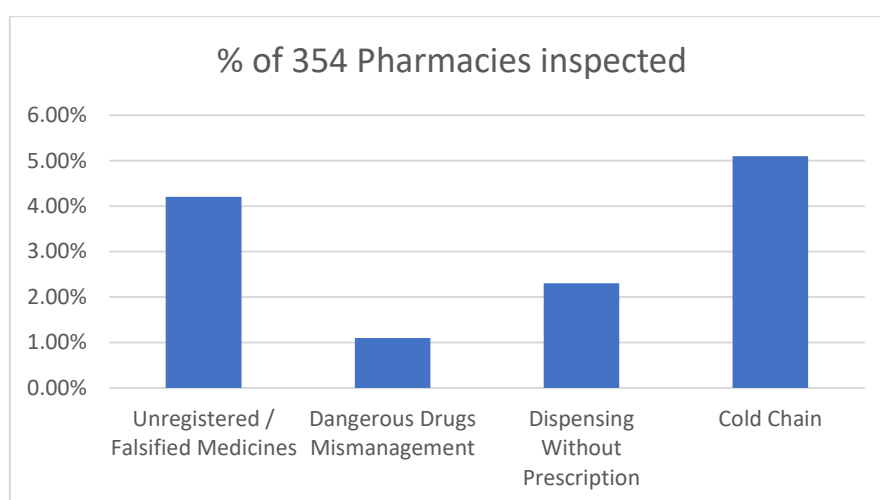


Figure 4: Contraventions as a percentage of pharmacies inspected

4.0 Regulatory Insight

- 4.1 The most frequent issue (labelling) is systemic but low severity.
- 4.2 The most critical issues (unregistered medicines & Dangerous Drugs mismanagement) are less frequent but high impact.
- 4.3 Cold chain and equipment weaknesses reflect technical compliance gaps which can compromise the quality of products.
- 4.4 Documentation gaps show need for sector training and stronger oversight.

5.0 Enforcement Actions

- 5.1 Immediate seizure and formal investigation upon detection of unregistered medicines.
- 5.2 Persons and Premises Licences were cancelled whenever threshold of the point system were surpassed.
- 5.3 Enforcement actions are publicized to deter sector violations.
- 5.4 Introduction of risk-based reinspection schedule for implicated facilities.

Table 7: Enforcement Actions (Sanctions) Issued to Pharmacies and Pharmacists in the Year 2025 (Jan to December)

Sanction	Number
Hearings in 2025 for pharmacies and pharmacists	15
Pharmacists Persons Licences that were cancelled	3
Pharmacy Premises licences that were cancelled	4
Warnings issued to Pharmacists	21
Strong Warning issued to Pharmacists	15
Final Warnings that were issued to pharmacists	20
Warnings that were issued to Premises Licensees	19
Strong Warnings that were issued to Premises Licensees	14
Final Warnings that were issued to Premises Licensees	20

6.0 Conclusion

- 6.1 To improve the year-to-year statistics, the inspectorate shall be tracking the following metrics:
 - 6.1.1 Overall Compliance Rate
 - 6.1.2 Critical Violation Rate
 - 6.1.3 Cold Chain Failure Rate
 - 6.1.4 Labelling Non-Compliance Rate
 - 6.1.5 Unregistered Medicine Incidence Rate
 - 6.1.6 Dangerous Drugs Control Failure Rate
- 6.2 The pharmacy profession is implored for self- regulation in provision of continuous personnel supervision.
- 6.3 Most of the unregistered medicines without registered alternatives should have alternative authorized supply chain approved by the Authority.
- 6.4 Premises with critical observations should be inspected more frequently in line with the risk-based scheduling SOPs.
- 6.5 Pharmacy Professional bodies are encouraged to train their members on safe handling of Dangerous Drugs and effective labelling of medicines.

Good Distribution and Supply Chain Metrics (Public Institutions)

As part of Good Distribution and Supply Chain inspections, MCAZ conducted inspections of a total of 137 public institutions were conducted in 2025. As part of post market surveillance, samples were also collected from these public institutions.

7.0 Observation noted during the inspections

- 7.1 Inefficient use of the ELMIS system, e-HR system used during the dispensing of medicines. The electronic systems have not yet been rolled out in some clinics. Efficient rollout of the system and adequate training of clinic staff could help address most of the issues noted, which concern the recording of patient and medicine information, as well as provide a sound basis for inventory management. Integrating the system with dispensing label printing capability is likely to reduce the workload of staff and help to improve efficiency.
- 7.2 There was need of stringent oversight from the district office, especially from hospitals where Dangerous Drugs were being handled, considering that these were being handled by personnel not authorized in terms of the Dangerous Drugs Regulations.
- 7.3 Some of the facilities were had stood the test of time and needed renovations.
- 7.4 There was no electricity in some of the visited facilities.
- 7.5 There were space constraints in some facilities, leading to medicines storage at insecure places, no privacy to patients whilst receiving certain clinic services, as two or more services will be offered in one room and also causing inefficient flow of work.
- 7.6 There was no temperature monitoring in the drug rooms.
- 7.7 Inadequate equipment i.e. measures for accurate measurements of oral liquid preparations such as measuring cylinders.
- 7.8 Dispensing registers were improvised, dispensed labels and stock cards captured insufficient information (missing batch numbers, expiry dates, brands/manufacturers' names).
- 7.9 Expired medicines were not being removed from the facilities, resulting in space constraints.
- 7.10 The nursing staff was overwhelmed with pharmacy roles.
- 7.11 There were major shortages of antibiotics, antipsychotics and antihypertensive medications in some of the clinics.
- 7.12 Medicines which were being ordered through the ZAPs ordering system were not being delivered on time.
- 7.13 Some medicines which were being delivered through Natpharm to the clinics were near expiry and could not all be used before their expiry dates.

Good Supply Chain and Distribution Metrics (Wholesalers)

Executive Summary

The Authority as part of GSDP inspects Wholesale Dealers. In the year 2025, a total of 56 routine inspections were conducted. The risk based standard operating procedure was used. The observations were categorized according to the risk to the supply chain and the public health.

8.0 Frequency of Observations from Routine Inspections

The most common critical observations among the non-compliant wholesalers were predominantly related to **temperature monitoring and storage conditions**, followed by **documentation deficiencies and facility management issues**. These observations highlight weaknesses in **Good Distribution Practices (GDP)** and quality management systems within the inspected facilities.

The most frequent critical observations are summarised below:

8.1 Failure to Conduct or Complete Temperature Mapping Studies (11 Wholesalers)

This was the **most prevalent critical observation**. Wholesalers are required to conduct **temperature mapping studies** to identify the hottest and coldest points within warehouse storage areas. However, **11 of the 14 non-compliant facilities** had not conducted these studies. Without mapping, facilities cannot scientifically justify temperature monitoring locations or ensure appropriate storage conditions for medicinal products.

8.2 Incorrect Positioning of Temperature Monitoring Devices (7 Wholesalers)

Closely linked to the absence of mapping studies, several wholesalers positioned **temperature and humidity monitoring devices arbitrarily**. Without data from temperature mapping, monitoring devices were not placed at critical points within the warehouse, rendering temperature monitoring scientifically unreliable and non-representative of actual storage conditions.

8.3 Missing or Inadequate Documentation and Standard Operating Procedures (4 Wholesalers)

Several wholesalers were cited for **significant deficiencies in quality management documentation**. These included:

8.3.1 Absence of **Standard Operating Procedures (SOPs)** for transportation, complaint handling, and self-inspections.

8.3.2 Failure to maintain records of self-audits and Corrective and Preventive Actions (CAPAs).

These gaps undermine the ability of facilities to maintain a structured quality system compliant with GDP requirements.

8.4 Lack of Rodent and Pest Control Programs (3 Wholesalers)

Three wholesalers were cited for lacking **effective pest and rodent control programs**. In some cases, pest control measures were either absent or insufficient to adequately protect warehouse storage areas and shelving.

8.5 Thermometer Calibration and Temperature Excursions (3 Wholesalers)

Critical observations were also noted regarding **temperature monitoring equipment**:

8.5.1 Two had thermometers that were **overdue for calibration**, raising concerns regarding the reliability of recorded temperature data.

8.5.2 One recorded a **temperature excursion of 30.5°C** in the receiving area, exceeding acceptable storage limits.

8.6 Transportation and Transit Temperature Control Issues (2 Wholesalers)

Two wholesalers were cited for deficiencies in **transportation controls**, including:

8.6.1 Failure to verify **transit temperatures of incoming non-cold chain products**.

8.6.2 Failure to inspect **delivery vehicle cleanliness**.

8.6.3 Use of **unqualified dispatch vehicles lacking data loggers** to monitor product temperatures during distribution.

Graphical Presentation of the observation occurrence

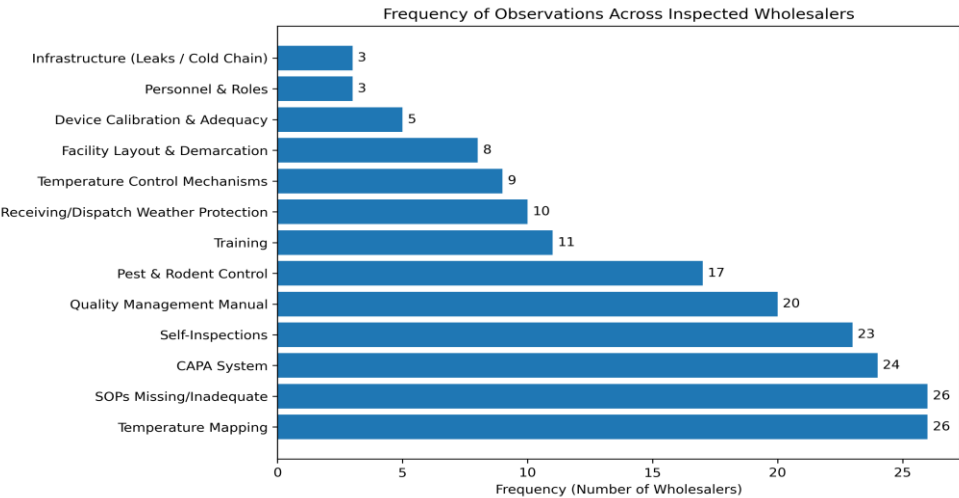


Figure 5: Observation occurrence

9.0 Compliance

Compliant facilities were defined as those that did not have a critical observation at the time of the inspection. For continued licensure, these wholesalers submitted acceptable CAPAs.

Of the 56 facilities inspected, 14 wholesalers had critical observations.

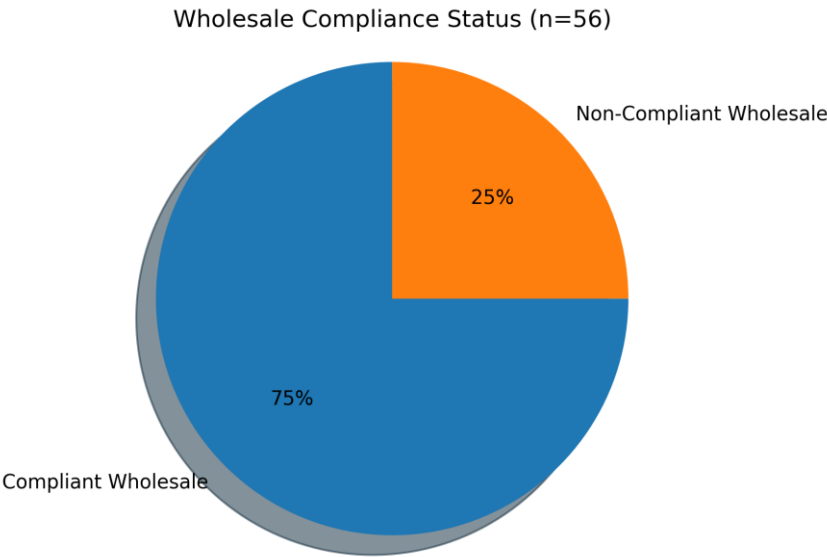


Figure 6: Wholesale compliance status

A percentage compliance of 75% was realized at the time of initial inspection.

Regulatory Recommendations

- 9.1 Strengthen Enforcement of Temperature Mapping Requirements
- 9.2 Strengthen Quality Management System (QMS) Requirements
- 9.3 Enforce Pest Control and Warehouse Hygiene Programs
- 9.4 Strengthen GSDP Requirements for Transportation
- 9.5 Capacity Building and GSDP Training