



106 Baines Avenue
Tel: +263 242 736 981-7
708 255 / 792 165 / 0772 145 191/2/3
Email: mcaz@mcaz.co.zw
Website: www.mcaz.co.zw

P.O. Box 10559
Harare
Zimbabwe

REF: B/279/22/417/2025

27th May 2025

Kuponah Investments (Pvt) Ltd
t/a Kuponah Pharmacy,
19 Seke Road
Hatfield
Harare

ATTENTION:

Dear Madam,

**RE: ROUTINE INSPECTION OF KUPONAH INVESTMENTS (PVT) T/A
KUPONAH PHARMACY, 19 SEKE ROAD, HATFIELD, HARARE.**

The inspection of the above premises on the 19th of May 2025 refers.

Appended is an inspection report for your noting and comments. Could we please have your **written** comments on a signed official letterhead, **within 7 working days** of receipt of this letter.

Yours faithfully

MEDICINES CONTROL AUTHORITY OF ZIMBABWE


.....
S. Shambira (Ms.)
For: **DIRECTOR-GENERAL**
/sc



LICENSING AND ENFORCEMENT DIVISION

INSPECTION REPORT FOR RETAIL PHARMACY – RE-INSPECTION

KUPONAH INVESTMENTS (PVT) T/A KUPONAH PHARMACY, 19 SEKE ROAD, HATFIELD, HARARE.

Licensee: Kuponah Investments (Pvt) Ltd
Supervisor: Muwombi Lorraine
Inspection Date: 19th May 2025
Inspectors: Arnold M. Kunaka and Sheila Choga
Type of inspection: Routine Inspection

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 a routine inspection of premises that was last inspected on the 7th of February 2025 and the following shortcoming had been noted;

- i. *The initial floor plan, on which the pharmacy license was granted, indicated the presence of a waiting area for patients inside the pharmacy. However, on the day of the inspection, patients were being served from outside through a window, which deviated from the originally submitted workflow plans. Dispensing through a window also failed to provide adequate privacy for patients during counselling sessions.*

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. Medicines were protected from direct light and moisture. The premises and persons licenses were valid and were displayed. The premises were generally in a tidy condition with suitable and effective means of natural lighting and ventilation. Medicines were protected from moisture and direct sunlight. The premises and person's licences were valid and displayed.

During the inspection, it was noted that the structure of the premises was constructed using a metallic container as the base or main framework. A brick wall was subsequently erected to enclose the container. Inside the premises, the metallic walls of

the container were covered and insulated with wooden material, which was painted white.

A waiting area was created within the premises, as outlined in the originally submitted floor plan. However, the dispensary working space, measured using MCAZ tape #040, was approximately 9.04 m², which was deemed insufficient to ensure effective and efficient workflow. The inspectors also noted that extending the dispensary area into the waiting area would not be viable, as the waiting area measured only 2.40 m². Such an extension would eliminate the waiting area, requiring patients to be served from outside.

(Reference: Good Dispensing Practice Guidelines: Suitability of Premises)

All working surfaces, cupboards, and shelves were finished with smooth, impervious and washable material and maintained in a good state of repair.

The staff complement included one (1) pharmacist and one (1) dispensary assistants.

1.2 Equipment

- i. There was a single stainless-steel sink with separate hand wash basin. There was provision for running cold and hot water.
- ii. There were two (2) plastic measuring cylinders for liquid preparations – one (1) 100ml measuring cylinder for internal preparations and one (1) 100ml measuring cylinder for external preparations. These were labelled with respect to their uses.
- iii. There were two (2) sets of mortar and pestles for preparing extemporaneous preparations. The supervisor was advised to procure another set.
- iv. There were two (2) counting trays with spatulas for counting tablets
- v. There was a digital SF-400 electronic scale for measuring weights. The balance was not yet calibrated, and the supervisor was advised to ensure that the balance was calibrated to ensure accurate measurements.
- vi. There was a functional single single-door Hisense® refrigerator, for storing cold chain medicines. The refrigerator was clean and free of mold. There was an HTC® thermometer for the refrigerator, and this measured 5.5°C which was within the 2-8°C range for cold chain medicines. The thermometer was calibrated and the calibration would expire on 11/11/25.

1.3 Cleanliness and Hygiene

The premises were generally clean and tidy. The floor was smooth and impervious, and the walls were painted with washable cream paint. There was a functional toilet with the premises.

1.4 Control of Materials

No expired medicines were found among the saleable stock. A dispensed medicine label was reviewed, and this captured all details for traceability including batch number, expiry date and manufacturer details. There were no unregistered medicines among sellable stock on the day of inspection. There was a fixed and lockable Dangerous Drugs (DD) cupboard. The physical stocks for Morphine injections and Varigesic® tablets tallied with those recorded in the DD book. The transactions were made within

24hrs and there were no cancellations in the DD book

1.5 Prescription records

There was use of an electronic system, Dispenseware software for recording prescriptions and dispensing purposes. The system had adequate provisions for capturing repeats. Backup of daily transactions was being done on an external flash drive on a daily basis. A dispensed medicine label was written, and this captured all details for traceability including batch number, expiry date and the manufacturer details.

1.6 Reference books

The following reference texts were presented as hard copies:

- a. EDLIZ 2020
- b. Zimbabwe Standard ART Guidelines 2022
- c. British National Formulary, 83rd Edition

1.7 Legislation

The following statutes were present as soft copies:

- i. Medicines and Allied Substances Control Act [Chapter 15:03]
- ii. Medicines and Allied Substances Control (General) Regulations, SI 150 of 1991
- iii. Dangerous Drugs Act [Chapter 15:02]
- iv. Dangerous Drugs Regulations, RGN 1111 of 1971

1.8 Front Shop

There was no front shop.

1.9 Security

There were metal grills on the front and back entrance. There were burglar bars on all windows.

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>Repeat Shortcomings</i>	
	None	
	<i>Critical</i>	
1.	<i>A waiting area was created within the premises, as outlined in the originally submitted floor plan. However, the dispensary working space, measured using MCAZ tape #040, was approximately 9.04 m², which was deemed insufficient to ensure effective and efficient workflow.</i> <i>The inspectors also noted that extending the dispensary area into the waiting area would not be viable, as the waiting area measured only 2.40 m². Such an extension would eliminate the waiting area, requiring patients to be served from outside.</i>	<i>Good Dispensing Practice Guidelines: Suitability of Premises & Medicines and Allied Substances Control Act Section 57(5)</i>
	<i>Major</i>	
1.	None	
	<i>Minor</i>	
	None	

Recommendation

The supervisor is advised to rectify the shortcoming within 90 working days and provide evidence of rectification to the Authority.



Inspector: A. Kunaka 23/05/2025

Name Signature Date

Inspector: S. Choga

Name Signature Date

Reviewed by: C. Kamhoti 27/05/2025

Name Signature Date