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REF: B/279/22/93/2025

30th January 2025

Ocean Enterprises (Pvt) Ltd
T/a First Health Pharmacy,
Stand 14589 Cnr S. Muzenda & R.G. Mugabe Road,
Harare

ATTENTION: Mr Tatenda Muswe

Dear Sir,

RE: ROUTINE INSPECTION OF PREMISES - OCEAN ENTERPRISES (PVT) LTD
T/A FIRST HEALTH PHARMACY, STAND 14589 CNR S. MUZENDA & R.G.
MUGABE ROAD, HARARE

The inspection of the above-named premises on the 22nd of January 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 10 working days** of receipt of this letter.

Yours faithfully,

MEDICINES CONTROL AUTHORITY OF ZIMBABWE

.....


A. Verenga (Ms.)

For: **DIRECTOR-GENERAL**

/cm



LICENSING AND ENFORCEMENT DIVISION

INSPECTION REPORT FOR RETAIL PHARMACY – ROUTINE

OCEANS ENTERPRISES (PVT) LTD T/A FIRST HEALTH PHARMACY, STAND
14589 CNR S. MUZENDA & R.G. MUGABE ROAD, HARARE

Licensee: Ocean Enterprises (Pvt) Ltd
Supervisor: Mr Tatenda Muswe
Inspection Date: 22nd January 2025
Inspectors: C. Mberi and R. Ziduche
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 which was licensed in July 2023 and had not been inspected thereafter.

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 licences were valid, but the persons licence was not displayed. The supervisor was advised to always display their licences.

There was a front shop where medicines were reachable to the public because *there was no barrier at the entrance to the OTC*. 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 the supervising pharmacist, and one (1) dispensary assistant.

Ref: Medicines and Allied Substance General Regulations, Third Schedule, Section 2 (a)

1.2 Equipment

- i. There was a double stainless-steel sink. There was provision for running cold water and hot water.
- ii. There was a dispensing bench for performing dispensing duties.
- iii. There were two (2) 100ml plastic measuring cylinders for internal liquid preparations and external preparations. These were labeled with respect to their uses.
- iv. There were two (2) sets of mortar and pestles for preparing extemporaneous preparations, one for internal and the other for external liquids.
- v. There were two (2) counting trays with spatulas for counting tablets
- vi. There was a white electronic SF-400 balance for measuring weights, which was due for recalibration on 26/6/2024.
- vii. There was a functional Univa, white, double-door refrigerator, for storing cold chain medicines. The refrigerator was clean and free of mold. There was a Branaan mercury thermometer for the refrigerator, and this measured 6°C which was within the 2-8°C range for cold chain medicines. There was adequate temperature records maintained at the premises which had no excursions. The thermometer was not calibrated, and the supervisor was advised to ensure that it was calibrated.

1.3 Cleanliness and Hygiene

The premises were generally clean and tidy. The floor was tiled, smooth and impervious and the walls were painted with washable white paint. There was a functional toilet at the back of the premises complex.

1.4 Control of Materials

There were expired medicines that were noted among saleable stock though there was no evidence of sale. Over-the-counter medicine labels captured all details for traceability.

Ref: Medicines and Allied Substances Control Regulations (SI 150 of 1991), Section 53

There was a fixed and lockable dangerous drug cupboard, however, there were no Dangerous Drugs in stock. There was one bound book for recording DDs, which had no loose pages or cancellations.

1.5 Prescription records

There was a Dispenseware® dispensing software installed on the computer for recording prescriptions. The dispensing system was able to trace a given example of medicine to a particular patient. Sufficient patient details were captured during dispensing of PIM and PP medicines. Copies of prescriptions were kept on the premises. The full pharmacy address was shown on the pre-pack and dispensed label. There was provision for backing up the prescription records onto an external hard drive. The supervisor was encouraged to back-up the system daily. Patient details were adequately captured. One (1) dispensed medicine label was printed, it captured all relevant information for traceability.

1.6 Reference books

The following soft copies were found as reference books on the day of inspection

1. ART 2016
2. EDLIZ 2020 (hard copy)
3. BNF 80th Edition (soft copy)
4. Martindale 36th Edition (soft copy)

1.7 Legislation

The following statutes were downloaded and 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 a front shop from which OTC medicines and cosmetics were sold. An OTC counter was present to restrict public access to medicines. There were no PP or PIM in the front shop. There were pre-packed medicines available and these captured adequate information except for manufacturer details.

1.9 Security

There was a roller shutter at the front entrance. There was a functional CCTV and complex security guards were also available for provision of security after hours.

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>	
1.	Expired medicines were among saleable stock	<i>Medicines and Allied Substances Control Regulations (SI 150 of 1991), Section 53</i>
	<i>Major</i>	

	There was no barrier at the entrance to the OTC.	<i>Medicines and Allied Substance General Regulations Third Schedule, Section 2 (a)</i>
	Minor	
	None	

3.0 Recommendations

The supervisor is advised to rectify all shortcomings in italics and provide evidence of resolution.

Inspector: C. Mberi
Name

C. Mberi
Signature

30/1/2025
Date

Inspector: R. Ziduche
Name

R. Ziduche
Signature

30/01/25
Date

Reviewed by: M. Mwatseteza
Name

M. Mwatseteza
Signature

30/01/25
Date