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REF: B/279/22/416/2025

19th May, 2025

The Supervisor
Infinity Pharmaceuticals (Pvt) Ltd t/a
Infinity Pharmacy Concession,
2257 Commercial Area,
Amandas,
Concession

ATTENTION: Mr. Clement Dzawo

Dear Sir,

**RE: INSPECTION OF NEW PREMISES – INFINITY PHARMACEUTICALS
(PVT) LTD T/A INFINITY PHARMACY CONCESSION, 2257 COMMERCIAL
AREA, AMANDAS, CONCESSION**

The inspection of the above premises on 15th of May, 2025 refers.

Attached is an inspection report for your noting and comments. May you provide a written response on a signed and dated letterhead **within the next seven (7) working days**.

Yours faithfully

MEDICINES CONTROL AUTHORITY OF ZIMBABWE

.....
S. Shambira (Ms.)

For: **DIRECTOR-GENERAL**
/amk



LICENSING AND ENFORCEMENT DIVISION

INSPECTION REPORT FOR RETAIL PHARMACY – NEW INSPECTION

Infinity Pharmaceuticals (Pvt) Ltd t/a Infinity Pharmacy Concession, 2257 Commercial Area, Amandas, Concession

Applicant: Infinity Pharmaceuticals (Pvt) Limited

Supervisor: Clement Dzawo

Inspection date: 15th May 2025

Inspectors: Arnold Kunaka and Sheila Choga

Type of Inspection: New Premises

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 a new premises after receiving a complete and satisfactory application.

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. Artificial lighting was provided for and adequate. Medicines shall be stored on painted melamine shelves that are washable and protected from direct light, moisture, and excessive heat.

The dispensary working space was measured using MCAZ tape #040 and it measured approximately 8.424m² and this was not sufficient to ensure effective and efficient flow of work. There were wooden cupboards which surrounded the dispensary working area and these created a blind spot which would prevent the supervisor from monitoring front shop activities. Medicines shall be stored safely out of reach of the public.

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

Image showing the dispensary area which was surrounded by wooden cupboards.



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

The staff complement included the supervising pharmacist and three (3) dispensary assistants.

The toilet facilities were within the premises and were in good working order.

1.2 Equipment

The following was noted:

- a) There was a double stainless-steel sink with provision for running cold and hot water.
- b) There were two (2) sets of counting trays for counting tablets and capsules.
- c) There were two (2) 100ml plastic measuring cylinders which were labelled for their intended uses.
- d) There was one (1) set of mortar and pestle which was labelled for its intended use.
- e) There was a functional Virgo® digital balance which was calibrated by Air Zimbabwe. The calibration was traceable to serial number: PF062 and the

next recalibration date was 22/04/2026.

- f) A single-door, black SPJ® refrigerator for storage of cold chain products was available. *There was no fridge thermometer available to monitor the temperature of the refrigerator.*

(Reference: Medicines and Allied Substances Control (General) Regulations, SI 150 of 1991, third schedule, section 2d)

1.3 Dangerous Drugs

There was a fixed and double lockable Dangerous Drugs (DD) cupboard. A Dangerous Drugs Register was available for recording Dangerous Drugs' transactions.

1.4 Cleanliness and Hygiene

The premises were generally clean and tidy, free from accumulated waste and vermin.

1.5 Prescription records

Propharm® software shall be used for capturing prescriptions. *There was no provision for daily backup of prescriptions records. The supervisor was not able to generate a sample dispensed medicines label on the day of the inspection.*

(Reference: Medicines and Allied Substances Control (General) Regulations, SI 150 of 1991, third schedule, section 2e & 60)

1.6 Reference books

The following texts were available on the premises on the day of the inspection:

1. BNF 86th Edition (soft copy)
2. EDLIZ 2020 Edition (soft copy)
3. ART Guidelines 2022 (soft copy)

1.7 Legislation

Soft and hard copies of all the current, relevant, and complete sets of statutes were available.

1.8 Security

The entrance and exit were secured by metal grills and windows were secured with burglar bars. A security guard was available for provision of security from 6pm to 7am.

1.9 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)”

- 2.0 Critical observations are those observations that pose a great risk to the general public
 2.1 Major observations are those observations which pose considerable risk to the public
 2.2 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>The dispensary working space was measured using MCAZ tape #040 and it measured approximately 8.424m² and this was not sufficient to ensure effective and efficient flow of work.</i>	<i>Good Dispensing Practice Guidelines: Suitability of Premises</i>
2.	<i>There were wooden cupboards which surrounded the dispensary working area and these created a blind spot which would prevent the supervisor from monitoring front shop activities</i>	<i>Good Dispensing Practice Guidelines: Suitability of Premises</i>
	<i>Minor</i>	
1.	<i>There was no fridge thermometer available to monitor the temperature of the refrigerator.</i>	<i>Medicines and Allied Substances Control (General) Regulations, SI 150 of 1991, third schedule, section 2d)</i>
2.	<i>There was no provision for daily backup of prescriptions records and the supervisor was not able to generate a sample dispensed medicines label on the day of the inspection.</i>	<i>Medicines and Allied Substances Control (General) Regulations, SI 150 of 1991, third schedule, section 2e & 60)</i>

3.0 Recommendations

The supervisor should rectify the shortcomings in italics. A re-inspection of the premises will be done after payment of 200USD.



Lead Inspector: Arnold M. Kunaka
Name

Signature

16/05/2025
Date

Inspector: Sheila Choga
Name


Signature

16/05/2025
Date

Reviewed by: Lewis Mutevera
Name



Signature

19/05/2025
Date