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REF:B/279/28/18/2025

4 April 2025

The Supervisor
Curlew Chemicals (Pvt) Ltd
t/a Neomed Pharmaceuticals
No. 129 A. G. Silundika
13th and 14th Avenue
Bulawayo

ATTENTION: Mr Sicelo Ncube

Dear Sir

RE: ROUTINE INSPECTION OF LICENCED PREMISES – CURLEW CHEMICALS (PVT) LTD T/A NEOMED PHARMACEUTICALS, NO 129 A. G. SILUNDIKA, 13TH AND 14TH AVENUE, BULAWAYO

The inspection of the above premises on the 19th of February 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 days** of receipt of this letter.

Yours faithfully
MEDICINES CONTROL AUTHORITY OF ZIMBABWE

Mhatebra
.....
A. Verenga (Ms.)
For: **DIRECTOR-GENERAL**
/bc

INSPECTION REPORT FOR A WHOLESALE- Routine
Curlew Chemicals (Pvt) Ltd t/a Neomed Pharmaceutical, No. 129 A.G. Silundika, 13th and 14th Avenue, Bulawayo

Permit Holder: Curlew Chemicals (Pvt) Ltd

Supervisor: Mr. Sicelo Ncube (Pharmacy Technician)

Inspection Date: 19th of February 2025

Inspectors: T. Samkange and B. Chinhongo

Type of inspection: Routine

Italics: *shortcomings noted during routine inspection (Also summarized in the observations table at the end)*
Bold: **issues noted during re-inspection and sub-headings**
Regular: the rest of the body of the inspection

1. Preamble

Location, activities done and preamble

This was a routine inspection of Curlew Chemicals (Pvt) Ltd t/a Neomed Pharmaceuticals located at No. 129 A.G. Silundika, 13th and 14th Avenue, Bulawayo. followingthe previousinspectionwhich was conducted on the 13th of February 2024. The following shortcomings were noted;

Repeat shortcomings

1. There were inadequate temperature and humidity monitoring devices in the warehouse. There was only 1 (one) Victor® (Model: VC330) digital thermometer and hygrometer in the warehouse.
2. The supervisor stated that temperature mapping studies had been done by 'Gee's Refrigeration and Air Conditioning', however no report was available as proof to show how the studies were conducted.
3. The dispatch trucks used were not qualified and there were no data loggers placed to monitor the temperature conditions in transit.

4. The thermometers and hygrometers did not have alert systems to notify when there were temperature and humidity excursions. The available thermometer and hygrometer had not been calibrated.
5. The receiving of cold chain products did not include checks for transit data loggers and their downloading to check for any excursions.
6. In the absence of pharmaceutical GDP certified delivery trucks, the delivery vehicles were not checked for status of cleanliness during the receiving.
7. The dispatch trucks used were not qualified and there were no data loggers placed to monitor the temperature conditions in transit.

Warehouse

1. There were inadequate temperature and humidity monitoring devices in the warehouse.There was only 1 (one) Victor® thermometer and hygrometer in the warehouse.

2.No Temperature mapping report was available as proof to show how the studies were conducted.

3.The thermometers and hygrometers did not have alarm systems to notify when there were temperature and humidity excursions.

4.There were no refrigerator temperature monitoring devices on the day of inspection.

Training

Training registers for previous trainings were available, however no evidence of evaluation of the trainings was available.

Receiving & dispatch of materials/ consignments

1. The receiving of cold chain products should include checks for transit data loggers and their downloading to check for any excursions. These activities should be adequately recorded and filed.
2. In the absence of pharmaceutical GDP certified delivery trucks, the delivery vehicles were not checked for status of cleanliness during the receiving.
3. The invoice for dispatched medicines did not capture the name of the manufacturer of the medicines.
4. In the 'incoming stock book' they did not capture the batch number, expiry date and the name of the manufacturer of the medicines.

General conduct of the inspection

This was a routine Good Storage Practice/ Good Distribution Practice (GSP/GDP) inspection conducted to encourage compliance and improve quality assurance of medical products in the public sector. The inspection was conducted in a cooperative, transparent and open environment with constructive engagement on risk-based discussion on the quality systems in place.

The inspection was conducted in the presence of Mr. Sicelo Ncube the supervising Pharmacy Technician. His technical aptitude, cooperation, openness and drive to continuously improve, set the tone for a successful assessment of the system in place.

Key personnel interviewed during the inspection (non-exhaustive) are as follows;

1. Mr. Sicelo Ncube - Pharmacy Technician
2. Michelle Samupunga – Branch Manager
3. Edwin Maziriri – Sales Representative

It was observed that the supervisor was experienced in his roles. This seemed to have positively influenced the smooth flow of many key processes that have an impact on GSP/GDP.

Areas inspected.

1. Review of the quality management system
    a. Quality risk management, deviation, change control, CAPA, Document Control, Data Integrity and the plans to attain ISO19001:2015.
2. The wholesale business
    a. Receiving of stock, quarantine, storage and dispatch
    b. Sanitation and hygiene
    c. Environmental control and monitoring
    d. Equipment- cold rooms, freezers and data loggers, racking system

3. Information Technology
    a. Sage Evolution, a stock management and sales software was being used.
    b. Environmental Monitoring and Control for temperature and humidity in the warehouse areas and cold chain facility.

Personnel / Staff complement

The supervising pharmacy technician had the support of other stores personnel including sales and marketing personnel. The institution was encouraged to have scientific and continuous improvement inspired constructive engagement with the regulatory inspectorate on capacity development.

Suitability of premises

The premises were generally well maintained and in a clean and tidy condition. There was adequate light and ventilation on the premises and the floors were smooth, impervious, and washable. There was unidirectional flow of medicines.

The areas in the wholesale area were properly demarcated and each designated area was labelled. The receiving, quarantine, warehouse, and dispatch areas had locks to keep out other staff members when the supervisor was not around. There were no toxic chemicals kept in the warehouse. The premises was out of reach of the public. There were rodent bait stations in place during the day of the inspection. The premises were designed to minimize accumulation of dust and other contaminants. Waste collection was done at the loading area near the receiving area.

Toilet and canteen areas were separated from where medicines were kept. Visibility was not clear in the whole premises when the lights were switched off, however there was a generator available for power back up to ensure that lights were always on. Medicines were protected from direct light and heat. Medicines were also protected from moisture.

Receiving Area

This area was satisfactory. There was a receiving table provided for and pallets for staging the medicines before clearance for the warehouse. ***The receiving of cold chain products did not include checks for transit data loggers and their downloading to check for any excursions. In the absence of pharmaceutical GDP certified delivery trucks, the delivery vehicles were not being checked for cleanliness status during the receiving.***

{Ref: Good Storage And Distribution Practices For Medical Products In Zimbabwe, 2021, Section 5.8}

Quarantine Area

This area was generally satisfactory, and pallets were available.

Warehouse

This area was satisfactory and there were metallic shelves on which medicines were stored. There were no medicines on the floor. Medicines were packed according to supplier and FEFO was used to ensure stock rotation. There were no unregistered medicines.

There were inadequate temperature and humidity monitoring devices in the warehouse. There was only 1 (one) Victor® (Model: VC330) digital thermometer and hygrometer in the warehouse. A log sheet for recording temperature and humidity readings was available. *Temperature mapping was claimed to have been conducted by Chapleton© however the documents which were presented were invalid. Positioning of the temperature monitoring devices was not guided by temperature mapping studies.*

There was a Hisense® (Model: H130RWH) single door white refrigerator for storing cold chain medicines. The refrigerator was clean and free of molds and there were no food items in it. On the day of inspection there were no medicines in the refrigerator.

Signs of leakage were noted in the warehouse on the day of inspection as depicted in the image below:

{Ref: Medicines and Allied Substances Control (General) Regulations, SI 150 of 1991, Section 7(2c)*}*

{ref: Good Storage And Distribution Practices For Medical Products In Zimbabwe Section, 2021, 5.2*}*

Dispatch
This area was provided for and there was a dispatch table and pallets available.

Cleanliness and Hygiene
The premises were generally tidy and in a clean condition.

Control of Materials
Stocks were controlled through Sage which captured all the required information. There was use of external hard drives to back up the system.

Dangerous Drugs
There were no dangerous drugs on the premises.

Documentation and Records:

The following SOP were submitted for review:

1. Receipt of goods
2. Storage of products
3. Cleaning of the warehouse
4. Stock Security
5. Self-inspections and self-audits
6. Product recalls
7. Products received from clients
8. Dispatching to clients
9. Handling complaints

There was no training program and there was an obsolete SOP for training. SOP for self-inspections was available however the procedure was not being adhered to. There was no Quality Management Manual, and there was no defined procedure for writing SOPs. There was no system for managing CAPA and there were no records for any self-inspections which had been conducted at the premises.

{Ref; Good Storage And Distribution Practices For Medical Products In Zimbabwe, 2021, Section 5.4}

Legislation

Soft copies of statutes were available. They had access to the internet hence they could access online medicines and persons registers in real time.

Security

There was a metal roller shutter door on the dispatch and the receiving areas. Burglar bars were installed on windows. Security guards were said to be available from 1700hrs to 0800hrs. There was an alarm system which was responded to by Fawcett Security. CCTV cameras were available for provision of extra security.

Part 3: Summary of shortcomings

Observations are classified into the risk categories "Critical", "Major", "Other (Minor)" and also in accordance with the functions related to GMP/GSP/GDP as provided for in the WHO TRS 986 and WHO TRS 1025.

Critical Observation: An observation that has produced, or may result in a significant risk of producing products that are harmful to the user

Major Observation: A non-critical observation that:

- has produced or may produce a product that does not comply with its specifications; and/or
- indicates a major deviation from the GSP/GDP guide; and/or
- indicates a failure to carry out satisfactory procedures for the release/ dispatch of batches; and/or
- indicates a failure of the person responsible for QA/QC to fulfil his/her duties; and/or
- consists of several other deficiencies, none of which on its own may be major, but which may together represent a major deficiency and should be explained and reported as such

Other Observation: An observation that cannot be classified as either critical or major, but indicates a departure from GSP/GDP.

A deficiency may be classified as "other" either because it is judged as minor, or because there is insufficient information to classify it as major or critical

Nr	*Observations*	*Ref*
	Repeat Shortcomings: *1.* There were inadequate temperature and humidity monitoring devices in the warehouse. There was only 1 (one) Victor® (Model: VC330) digital thermometer and hygrometer in the warehouse. *2.* The receiving of cold chain products did not include checks for transit data loggers and their downloading to check for any excursions. In the absence of pharmaceutical GDP certified delivery trucks, the delivery vehicles were not being checked for cleanliness status during the receiving.	Good Storage And Distribution Practices For Medical Products In Zimbabwe Section, 2021, 5.2 Good Storage And Distribution Practices For Medical Products In Zimbabwe, 2021, Section 5.8
	Critical	
	1. There were inadequate temperature and humidity monitoring devices in the warehouse. There was only 1 (one) Victor® (Model: VC330) digital thermometer and hygrometer in the warehouse. *2.* Temperature mapping was claimed to have been conducted by Chapleton© however the documents which were presented were invalid. Positioning of the temperature monitoring devices was not guided by temperature mapping studies.	Good Storage And Distribution Practices For Medical Products In Zimbabwe Section, 2021, 5.2
	Major	
1.	**Facility** 1. Signs of leakage were noted in the warehouse on the day of inspection **Documentation** 1. There was no training program and there was an obsolete SOP for training. SOP for self-inspections	Medicines and Allied Substances Control (General) Regulations, SI 150 of 1991, Section 7(2c)

	There was no system for managing CAPA and there were no records for any self-inspections which had been conducted at the premises.	
	Others	
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Recommendations

- The licensee should pay particular attention to the repeat shortcomings as these may affect renewal of their Wholesale Dealers'permit.
- Neomed is expected to provide a comprehensive Corrective action and preventive action, CAPA to all the identified shortcomings within 14 days of receipt of this report. The CAPA should as much as possible clearly highlight;
    a. The root cause of the shortcoming
    b. The corrective action
    c. The preventive action
    d. Whether the shortcoming has been closed or the plans and targeted date of completion.

Inspector:	T. Samkange Name	 Signature	2/4/25 Date
Inspector:	B. Chinhongo Name	 Signature	2/4/25 Date
Reviewed by:	M. Mwatseteza Name	 Signature	4/4/25 Date