Medicines Control Authority of Zimbabwe

LEF 55

LICENSING AND ENFORCEMENT DIVISION

INSPECTION OF NEW PREMISES FOR A WHOLESALE DEALER

1.0 Applicant……

2.0 Trading as ……..……

3.0 Address ……..……

4.0 Contact Phone Number(s)……...……...

5.0 Email address……6.0 Inspection Date……...…….

7.0 Name(s) of inspector(s)…….....……..……..

8.0 Name of Supervisor (s)……..……

9.0 Other staff members……..…….

……..

(Pharmacist, Pharmacy technician, Sales Reps, Telesales, etc.)

10.0 Time Inspection started……

11.0 Equipment used ***(capture the equipment number where applicable***):

11.1Inspection Tablet…….

11.2 Data Logger……

11.3 Measuring Tape……..

11.4 Raman Spectroscopy……..

11.5 Other…….(specify)

12.0 Inspection Element	**Notes**	**Inspector's Notes**
12.1 Premises	Cleanliness and tidiness	
12.2 Natural lighting	Visibility within the distance of a metre when lights are switched off	

12.3 Artificial lighting	Visibility within the distance of a metre when lights are switched on	
12.4 Warehouse areas	The four (receiving, quarantine, warehouse and dispatch) areas should be physically separated, clearly demarcated and labeled	
12.5 Dimensions	Receiving (minimum $10m^2$) Quarantine (minimum $5m^2$) Warehouse (minimum $15m^2$) Dispatch (minimum $10m^2$)	
12.6 Storage of medicines	Protection from heat, light and moisture Out of reach of the public Out of reach of unauthorised personnel in the absence of the supervisor	
12.7 Floor	Smooth and impervious	
12.8 Walls	Painted and washable	
12.9 Direction of flow of medicines	The flow of medicines should be uni-directional	
12.10 Temperature monitoring in the warehouse	Presence of a temperature monitoring device, calibration status Temperature log being kept	
12.11 Tables	To be placed in the receiving and dispatch areas	
12.12 Shelving or pallets	Available in all the four areas of the warehouse	

12.13 Security	Measures in place to protect medicines e.g. metal grills, alarm system, burglar bars, etc.	
12.14 Refrigerator	Model, colour, identification number	
12.15 Thermometer	Identification number; calibration status	
12.16 Legislation	Medicines and Allied Substances Control Act (Chapter 15:03) Medicines and Allied Substances Control (General) Regulations, SI 150 of 1991 Dangerous Drugs Act (Chapter 15:02) Dangerous Drugs Regulations, RGN 1111 of 1975 Import and Export Regulations	
12.17 Registers	Human allopathic medicines register Complementary medicines register Premises and Persons register	
12.18 Recording system	Type of system Provision for capturing batch numbers, names of manufacturers, expiry dates on invoice to customers Back up available and type of back up	
12.19 Documentation	SOPs should be written, have revision dates and be signed by an authorized technical person The following SOPs should be present; Receipt and checking of deliveries Storage of products Cleaning and maintenance Security of stocks	

	Returned products and recall protocol	
12.20 Supervisor	Should be a pharmacist if Dangerous Drugs shall be kept on the premises	
12.21 Dangerous Drug (DD) Cupboard	Fixed and lockable	
12.22 DD registers	Bound books	
12.23 Toilet facilities	Available within the proximity Good working order	

13.0 INSPECTOR'S COMMENTS (WHERE APPLICABLE – USE PROVIDED SPACE, REFERENCE RELEVANT COLUMN FROM ABOVE).

Column number	**Comments**

Column number	Comments

14.0 Time inspection ended: …….

15.0 I …….the supervisor of these premises agree with the findings made during this inspection.

…….…… ……
Signature Date