



LICENSING AND ENFORCEMENT DIVISION

INSPECTION OF NEW PREMISES FOR A WHOLESALE DEALER

Applicant.....

Trading as

Address

Contact Phone Number(s)

Email address..... Inspection Date.....

Name(s) of inspector(s).....

Name of Supervisor (s).....

Other staff members.....

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

Time Inspection started..... Time Inspection ended.....

Table with 3 columns: Inspection Element, Notes, Inspector's Notes. Rows include Premises, Natural lighting, Artificial lighting, and Warehouse areas.

Dimensions	Receiving (minimum 10m ²) Quarantine (minimum 5m ²) Warehouse (minimum 15m ²) Dispatch (minimum 10m ²)	
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	
Floor	Smooth and impervious	
Walls	Painted and washable	
Direction of flow of medicines	The flow of medicines should be uni-directional	
Temperature monitoring in the warehouse	Presence of a temperature monitoring device, calibration status Temperature log being kept	
Tables	To be placed in the receiving and dispatch areas	
Shelving or pallets	Available in all the four areas of the warehouse	
Security	Measures in place to protect medicines e.g. metal grills, alarm system, burglar bars, etc.	
Refrigerator	Model, colour, identification number	

Thermometer	Identification number; calibration status	
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	
Registers	Human allopathic medicines register Complementary medicines register Premises and Persons register	
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	
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	
Supervisor	Should be a pharmacist if Dangerous Drugs shall be kept on the premises	

Dangerous Drug (DD) Cupboard	Fixed and lockable	
DD registers	Bound books	
Toilet facilities	Available within the proximity Good working order	

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

Column number	Comments

Ithe supervisor of these premises agree with the findings made during this inspection.

Signature.....

Date: