LEF 15

LICENSING AND ENFORCEMENT DIVISION

CHECKLIST FOR AN INSPECTION REPORT FOR A WHOLESALE DEALER

1.0 Permit Holder**:** ……..

2.0 Trading as: ……..

3.0 Address: ……..

4.0 Phone Number(s): …….....

5.0 Email address (es): ……...

6.0 Inspection date: …….

7.0 Name of inspectors: ……

8.0 Type of inspection (*delete inappropriate*) ROUTINE / INVESTIGATIVE

9.0 Name of Supervisor (s) of Record: ……

10 0 Name of Supervisor on the Day of Inspection: ……

11.0 Other staff members: ……....

……

(Pharmacist(s), Pharmacy Technician(s), Stores Controller, Pickers, Packers, etc.)

12 Time inspection started: ……

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

13.1 Inspection Tablet…….
13.2 Data Logger…….
13.3 Measuring Tape……
13.4 Raman Spectroscopy……
13.5 Other…… (specify)

14.1 Licences	Wholesale dealer`s permit and persons licences displayed and they are both valid.	
	Sales representatives have valid permits	
14.2 Premises and Grounds	The premises are designed to minimise ingress of dust, soil and other contaminants.	
	Waste is collected in designated points.	
	A rodent and pest control programme should be in place.	
	Medicines are protected from heat, direct sunlight, dust and moisture.	
	Medicines are out of reach of the public.	
	Medicines are out of reach of unauthorised persons when the supervisor is absent.	
	Premises are clean and tidy.	
	The floor is smooth and impervious	
	The four (receiving, quarantine, warehouse and dispatch) areas should be physically separated, clearly demarcated and labelled.	
	The flow of medicines is uni-directional	

	Visibility within the distance of a meter when lights are switched off.	
	Visibility within the distance of a meter when lights are switched on.	
	Toilets, washing and canteen facilities are separated from areas where medicines are kept.	
14.3 Security	Measures in place to ensure that the premises are secure 1. Security guard 2. Metal grills 3. Alarm systems 4. Any other measures	
14.4 Facilities	No medicines are on the floor Adequate shelves and pallets in all the four areas	
14.5 Equipment	Presence of a temperature monitoring device for the wholesale area (Is it placed at the hottest point)	
	Identification number and calibration status of the temperature and humidity monitoring device	
	Temperature and humidity log being kept	
	Temperature and humidity mapping studies done. *(Insert date or period covered and identify the hottest points)*	
	The refrigerator or cold room is clean and free of moulds	
	A functional temperature monitoring device *(take note of the temperature*	

	at the time of the inspection and compare with MCAZ device records)	
	Filing of temperature monitoring records	
	Damaged, expired and returned goods are separated and labelled	
14.6 Quality Management System	Systems for managing returns, complaints and recalls	
	Systems for managing deviations, changes and CAPAs	
	Self-inspections are carried out periodically	
14.7 Personnel	Personnel available (Pharmacists, Pharmacy Technicians and Sales Representatives)	
	Initial and continuous training programmes and certificates for all	
	Organisation chart	
14.8 Stock Handling and Stock Control	System to ensure stock rotation(FEFO or FIFO)	
14.9 Documentation	SOPs should be written, have revision dates and signed by an authorise and technical person The following SOPS should be available 1. Receipt and checking of deliveries 2. Storage of products 3. Cleaning and maintenance 4. Securing of stocks 5. Returned products and recalls 6. Rejected goods 7. Dispatch of goods	

	8. Transportation of medicinal products 9. Handling complaints Purchase Records	
	Distribution Records	
14.10 Importation of medicines	Import permits kept in the warehouse	
	Proof of notification of all consignment (*i.e. completed Form I.E.7 and stamped import permits and supporting documents)*	
14.11 Unregistered Medicines	Proof of authorisation to import unregistered medicines	
	Records of sales are satisfactory	
	Are they stored separately to ensure adequate control of sales	
14.12 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 Import and Export Regulations, SI of 2008 Medicines and Allied Substances Control (Complementary Medicines) Regulations, S.I. No. 97 of 2015.	
14.13 Registers	Premises and medicines registers available or have access to the internet	

14.14 Dangerous Drugs and Part 1A Psychotropics Recording System (If Applicable)	Supervisor is a pharmacist Fixed and lockable Dangerous Drugs cupboard	
14.5 Psychotropics Recording System (If Applicable)	Tallying of physical stock with recorded quantities(if not what are the discrepancies) Any cancellations and obliterations	
14.16 Other Shortcoming noted	Any other shortcomings noted in the last inspection. a) Poor supervision b) Purchasing from un licenced premises c) Selling medicines to unlicensed premises d) Selling of expired medicines e) Poor record keeping and stock of DDs or Part 1A Psychotropic Substances f) Incomplete set of statutes g) Inadequate equipment h) Failure to notify importation	

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

Column number	Comments

16 Time Inspection Ended: ……

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

Signature: ……. Date: …….