

LICENSING AND ENFORCEMENT DIVISION

CHECKLIST FOR AN INSPECTION REPORT FOR A PHARMACY

Licensee:

Name of Pharmacy:

Address:

Phone Number(s):

Email address (es):

Inspection date:

Name of inspectors:

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

Name of Supervisor (s) of Record:

Name of Supervisor on the day of Inspection:

Other staff members:

.....

(*Pharmacist(s), Pharmacy Technician(s), Dispensary Assistants, Interns, OTC Assistants, etc.*)

Time inspection started:

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

1. Inspection Tablet.....
2. Data Logger.....
3. Measuring Tape.....
4. Raman Spectroscopy.....
5. Other.....(specify)

Inspection Element	Notes	Inspector's Notes
Licenses	1. Were both the persons and the premises license displayed 2. Are both licenses valid	
Premises	1. When standing in the dispensary, can the inspector see all the activities in the front shop?	

	2. Are the premises clean and tidy?	
Natural Lighting	Visibility within the distance of a meter when lights are switched off.	
Artificial Lighting	Visibility within the distance of a meter when lights are switched on.	
Storage of medicines	Protection from heat, light and moisture. Out of reach of the public Any Medicines on the floor	
Category of Medicines	Are there any PIM and PP medicines in the front shop?	
Labelling	Are the prepacks labelled clearly? (<i>capture the batch number, expiry date and pharmacy details</i>)	
Working Space	Is there adequate space for dispensing and compounding?	
Security	Measures in place to protect medicines e.g., Metal grills, alarm system, burglar bars, security guard, etc.	
Measuring cylinders	At least one (1) 50ml or 100ml for internal preparations At least one (1) 50ml or 100ml for external preparations Labelling to indicate use	
Shelving	Washable and painted	

Walls	Painted and washable	
Floor	Smooth and impervious	
Counting trays	At least two (2) counting trays.	
Measuring Balance	Record the type of balance	
Mortar and pestle	At least two (2) sets of mortar and pestle Check if they are labelled for their intended use	
Refrigerator	1. Model, colour, Identification number 2. Is it functional for storing cold chain medicines? 3. Cleanliness and free of mold? 4. Food items in the fridge 5. Temperature monitoring device (note the temperature at the time of inspection)? 6. Are there records for temperature monitoring being filed? Indicate any blank spaces, inconsistencies and temperature excursions.	
Thermometer	Identification Number, calibration status	
MCAZ Data logger	Identification number Time recording started	
Power Supply	Note the backup power supply being used. Indicate if ice packs are	

	available	
Hand wash facilities	Double stainless-steel sink or single stainless-steel sink with separate wash hand basin.	
Water	Running hot and cold water	
Control of medicines	Unregistered medicines/ medical devices	
Storage of unregistered medicines	Dispensary, shelves, boxes, office etc.	
Packaging of unregistered medicines	Medicines or medical devices sold in their original packaging or not?	
Importation	Authorization letters for the unregistered medicines Do the unregistered medicines match those on the authorization letters?	
Proof of clearance for Importation	Check whether the Section 75 authorization letters were cleared by ZIMRA and MCAZ during importation	
Purchase	Check if invoices to account for purchase of the unregistered medicines / medical devices are available at the premises	
Origins of the source	Licensed by MCAZ (<i>If the source is unlicensed collect evidence of sell/ dispensing of the medicines</i>)	
Registers	Human allopathic medicines register Complementary medicines register Premises and Persons register	

Saleable stock	Expired medicines / medical devices. <i>(note the location of the medicines)</i>	
Evidence of sell	Expired medicines <i>(take photographs/ copies of dispensing records. Sales receipt etc.)</i>	
Reference Texts	BNF and or Martindale EDLIZ Antiretroviral Therapy Guidelines. Any other referenced texts	
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,	
Retention for record keeping	Are records being kept for 5 years/ or more?	
Recording system	Microfilm, computer, photocopy or patient profile cards or other approved Check if there is provision for capturing of repeat prescriptions Check the type of back up provided and frequency of back-up	

Stock management system	Traceability of a particular medicine to a particular patient through use of batch number, expiry date, manufacturer of medicine (manual/electronic) Sufficient patient details captured during dispensing PP and PIM medicines	
Dangerous Drug (DD) Cupboard	Fixed and lockable	
DD registers	Bound books Are transaction being recorded within 24 hours Stock tallying with the recorded quantities. If not what are the discrepancies (<i>collect copies or clear pictures of the records</i>) Any cancellations, alterations and obliterations (<i>If yes, collect copies or clear pictures of the records</i>)	
Toilet facilities	Available within the proximity Good working order	
Other	Are there any repeat shortcomings noted in the last inspection? 1. Poor supervision 2. Unregistered medicines 3. Purchasing from unlicensed sources 4. Selling medicines to	

		unlicensed premises 5. Expired medicines 6. Poor recording and stock taking of DDs or Part 1A Psychotropic Substances 7. Incomplete set of statutes 8. Inadequate equipment 9. Failure to notify importation -	
MCAZ loggers reading	Data final	Record the readings from the data logger Time recording ended	

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

Column number	Comments

Time inspection ended:

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

Signature: Date: