**PART A: Drug Shop Information**

|  |  |  |
| --- | --- | --- |
| 1. NDA Region |  | |
| 1. District |  | |
| 1. Name of the Drug Shop |  | |
| 1. Type of Drug Shop | ○Urban ○Rural | Human ○ Veterinary ○ |
| 1. Physical address of premises |  | |
| 1. GIS coordinates |  | |
| 1. Name of the In-Charge |  | |
| 1. Telephone number |  | |
| 1. Email address |  | |
| 1. Is the license application new or renewal (tick)? | Renewal ○ New ○ | |
| 1. Write previous license number, if renewal   (Indicate N/A for new inspection) |  | |
| 1. Date of inspection |  | |
| 1. Name and address of nearest Pharmacy to premises   Retail Pharmacy: |  | |
| 1. Approximate distance to nearest Pharmacy (m)   Retail Pharmacy: |  | |
| 1. Inspector (Name, Signature and Phone number) |  | |

**PART B: Ownership and staffing**

|  |  |  |  |
| --- | --- | --- | --- |
| 1. Name of owner and Contact |  | | |
| 1. Number and qualification of staff working in the Drug Shop (fill out table below)? | | | |
| **Number of staff** | **Qualification** | **Role (include all roles of staff with this qualification)** | |
|  |  |  | |
|  |  |  | |
|  |  |  | |
|  |  |  | |
|  |  | Name | Qualifications |
| 1. Name and qualifications of personnel dispensing during the time of inspection. | |  |  |
|  |  |
|  |  |
| 1. \*\*Is the person dispensing qualified to dispense? | | **Yes** |  |
| **No** |  |

**PART C: Premises**

|  |  |  |  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| **Indicator** | | | **Location** | | **Acceptable** | | | | | **Needs Improvement** | | **Unacceptable** |
| 1. \*There is a signpost indicating the name and type of business carried out at the premises | | | Drug Shop | |  | | | | |  | |  |
| **Comments** | | | | | | | | | | | | |
| 1. \*Premises not shared with medical clinic, veterinary surgery or any other business | | | Drug Shop | |  | | | | |  | |  |
| **Comments** | | | | | | | | | | | | |
| 1. \*Dispensing area is a separate lockable area without access for the public. | | | Drug Shop | |  | | | | |  | |  |
| **Comments** | | | | | | | | | | | | |
| 1. \*Walls are smooth, clean, impervious and without signs of dampness and degradation, and made of a material that allows for easy cleaning (tiles or oil paint). | | | Dispensary | |  | | | | |  | |  |
|  | | | | | | | | | |
| **Comments** | | | | | | | | | | | | |
| 1. \*\* Roof is in good condition to avoid water penetration. It is without holes or signs that water is running through. There is a ceiling made of appropriate material and in good condition. | | Dispensary | | |  | | | | |  | |  |
|  | | | | | | | | | | |
| **Comments** | | | | | | | | | | | | |
| 1. \* Floors are made of a material that is easy to clean, free of holes and big cracks and the floor appears clean. | | Dispensary | | |  | | | | |  | |  |
|  | | | | | | | | | | |
| **Comments** | | | | | | | | | | | | |
| 1. \*\* The medicines are protected from direct sunlight (painted glass, curtains, blinds or no windows). | | Dispensary | | |  | | | | |  | |  |
|  | | | | | | | | | | |
| **Comments** | | | | | | | | | | | | |
| 1. \* There are no signs of pests, harmful insects or rodents seen. | | Dispensary | | | |  | | |  | | |  |
|  | | | | | | | | | | |
| **Comments** | | | | | | | | | | | | |
| 1. \*The temperature is monitored daily, records maintained and the temperature monitoring device is calibrated. | | Dispensary | | | |  | | |  | | |  |
|  | | | | | | | | | | |
| **Comments** | | | | | | | | | | | | |
| 1. The temperature can be regulated with ventilation, air-condition or by opening windows. | | Dispensary | | | |  | | |  | | |  |
|  | | | | | | | | | | |
| **Comments** | | | | | | | | | | | | |
| **Indicator** | | **Location** | | | | **Size**  **(m**2**)** | | | **Yes** | | | **No** |
| 1. \*Write size (m2) and score. Space requirements:  * Dispensary for Drug Shop ≥ 4m², * Shop area for Drug Shop | |  | | | |  | | |  | | |  |
|  | | | |  | | |  | | |  |
|  | | | | | | | | | | |
| **Comments** | | | | | | | | | | | | |
| 1. The size of the premises is adequate having enough shelves and layout so medicines can be organized systematically. | Dispensary | | |  | | | | |  | | |  |
|  | | | | | | | | | | | |
| **Comments** | | | | | | | | | | | | |
| 1. \* The dispensary is lockable and access limited to authorized personnel. | Dispensary | | |  | | | | |  | | |  |
|  | | | | | | | | | | | |
| **Comments** | | | | | | | | | | | | |
| 1. \*The premises appear clean and tidy. Cleaning of floors is done daily and shelves are dusted weekly. The practices are documented. | Dispensary | | |  | | | |  | | | |  |
|  | | | | | | | | | | | |
| **Comments** | | | | | | | | | | | | |
| 1. Fire safety equipment (fire extinguisher or bucket with sand or water, or big blanket) is available and accessible. | Drug Shop | | |  | | | |  | | | |  |
| **Comments** | | | | | | | | | | | | |
| 1. \*\*Toilet facilities for staff are acceptable (pit latrine, flush toilet);  * hygienic (clean) and well ventilated, * not directly open to any storage area, * Fitted with a sink and have running water. | Drug Shop | | |  | | |  | | | |  | |
| **Comments** | | | | | | | | | | | | |
| 1. \*Hand washing facilities for staff are acceptable;  * hygienic, * functioning, and * soap is available | Drug Shop | | |  | | |  | | | |  | |
| **Comments** | | | | | | | | | | | | |

**PART D: Dispensing**

| **Indicator** | | | | **Location** | | **Acceptable** | **Needs Improvement** | | | | **Unacceptable** |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| 1. \*Appropriate packaging material for tablets and capsules available. | | | | Dispensary | |  |  | | | |  |
| **Comments** | | | | | | | | | | | |
| 1. Tablet counting tray and spatula/spoon are available. Comment if creative trays are used. | | | | Dispensary | |  |  | | | |  |
| **Comments** | | | | | | | | | | | |
| **Indicator** | | | | | | **Location** | **Yes** | | | | **No** |
| 1. Tablets are not counted with bare hands but using a counting tray, spatula or gloved hands. | | | | | | Dispensary |  | | | |  |
| **Comments** | | | | | | | | | | | |
| **Indicator** | | | | **Location** | | **Acceptable** | **Needs Improvement** | | | | **Unacceptable** |
| 1. Check if tablet counting tray and spatula and/or gloves are clean. | | | | Dispensary | |  |  | | | |  |
| **Comments** | | | | | | | | | | | |
| 1. There is provision for cleaning utensils with clean water. | | | | Drug Shop | |  |  | | |  | |
| **Comments** | | | | | | | | | | | |
| 1. \*All tins/bottles that have been opened but are not in use (no current dispensing from it) are covered with a lid. | | | | Dispensary | |  |  | | |  | |
| **Comments** | | | | | | | | | | | |
| 1. Chairs/benches available for customers/patients so they can sit while waiting for their medicines? | | | | Dispensary | |  |  | | | |  |
| **Comments** | | | | | | | | | | | |
| 1. Hand washing facilities and soap available to customer/patient. | | | | Dispensary | |  |  | | | |  |
| **Comments** | | | | | | | | | | | |
| 1. Drinking water (to take tablets) is available to customer/patient (the water should be bottled, purified or boiled). | | | | Dispensary | |  |  | | | |  |
| **Comments** | | | | | | | | | | | |
| 1. \*A dispensing and patient recording system is available. | | | | | | Dispensary |  | | | |  |
| **Comments** | | | | | | | | | | | |
| **Indicator** | | | | **Location** | | **Acceptable** | | **Needs Improvement** | | | **Unacceptable** |
| 1. \*Dispensing recording system includes date, patient number or name, diagnosis, medicine name, prescriber name, amount prescribed and dispensed. | | | | Dispensary | |  | |  | | |  |
| **Comments** | | | | | | | | | | | |
| 1. \*Medicines are labeled correctly. Check if the labeling on the dispensing envelope is proper for 3 patients coming from pharmacy. Fill in the table below with Yes or No.  * Select “Acceptable” if all areas in columns 1)-6) are scored yes. * Select “Needs Improvement” if at least all areas in columns 1) and 4) are scored yes. * Select “Unacceptable” if there is a single “No” score in any area under columns 1) and 4) | | | | | Drug Shop |  |  | | | |  |
|  |  | | | |  |
| **1) Medicine name** | **2) Strength** | **3) Quantity** | **4) Dosage**  **(dose)** | | **5) Patient name** | | | | **6) Facility name** | | |
|  |  |  |  | |  | | | |  | | |
|  |  |  |  | |  | | | |  | | |
|  |  |  |  | |  | | | |  | | |
| **Comments** | | | | | | | | | | | |

**PART E: Store management**

|  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| **Indicator** | | **Location** | | **Acceptable** | | **Needs Improvement** | | | **Unacceptable** |
| 1. \* Medicine packs are stored only on shelves and/or in cupboards and they are not stored in disorganized stacks or boxes directly on the floor | | Dispensary | |  | |  | | |  |
|  | | | | | | | |
| **Comments** | | | | | | | | | |
| 1. \*There is a system for inventory management in the Drug Shop. | Drug Shop | | **Yes** | | | |  | | |
| **No** | | | |  | | |
| **Comments** | | | | | | | | | |
| **Indicator** | **Location** | | **Acceptable** | | **Needs Improvement** | | | **Unacceptable** | |
| 1. \*There is a record for expired/damaged medicines and health supplies including name, strength, formulation, batch number, expiry date and quantity (check). | Drug Shop | |  | |  | | |  | |
| **Comments** | | | | | | | | | |

| **Indicator** | **Location** | **Acceptable** | **Needs Improvement** | **Unacceptable** |
| --- | --- | --- | --- | --- |
| 1. \* There is a designated area to store expired/damaged medicines and health supplies away from useable medicine, and the area is clearly marked/ signed? | Drug Shop |  |  |  |
| **Comments** | | | | |

**PART F: Other requirements**

|  |  |  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| **Indicator** | | | **Location** | | | | **Yes** | **No** | | **N/A** | |
| 1. License and Certificate for suitability displayed.   Copies of the Qualification Certificates/Practicing Certificates/Registration Certificates of the Pharmacist and Auxiliary staff available. | | | Drug Shop | | | |  |  | |  | |
| **Comments** | | | | | | | | | | | |
| 1. The latest version of reference material available  * Essential Medicines and Health Supplies List for Uganda * Uganda Clinical Guidelines (current edition) * Uganda National Formulary * British National Formulary * Martindales Extra Pharmacopeia * National Drug Policy and Authority Act and the regulations made under the Act.   (If at least two of the materials are available, check Yes)  Comment if the materials are not available at pharmacy/dispensary | | | | | | Drug Shop | | | **Yes** | |  |
| **No** | |  |
| **Comments** | | | | | | | | | | | |
| **Indicator** | **Location** | | | **Acceptable** | | | | | **Needs Improvement** | | **Unacceptable** |
| 1. Does the drug outlet have written procedures and records for the following  * Dispensing * Receipt and storage of Drugs * Stock management * Cleaning | | Drug Shop | | |  | | | |  | |  |
| **Comments** | | | | | | | | | | | |

**PART G: DOCUMENTATION**

|  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- |
| **Indicator** | **Location** | | | **Yes** | **No** | | **N/A** |
| 1. \*Purchases Records (includes delivery notes) kept for received items. Check for minimum 5 years. | | Pharmacy | | | | | | | **Yes** |  |
| Do the records include: | | | **Yes** | | | **No** | |
| 1. Date of receipt | | |  | | |  | |
| 1. Invoice number | | |  | | |  | |
| 1. Drugs procured | | |  | | |  | |
| 1. Origin (producer/supplier) | | |  | | |  | |
| 1. Quantity received | | |  | | |  | |
| 1. Batch number | | |  | | |  | |
| 1. Expiry date | | |  | | |  | |
| **Comments** | | | | | | | |

**NB: Inspector to summarize the non-conformances on the ‘Addendum to the Inspection Report’ in duplicate and leave a copy at the Drug Shop.**

**PART G: Summary of findings**

**Count the number of “unacceptable “/”No” scores**

|  |  |
| --- | --- |
|  | **Number** |
| **\*\*CRITICAL Indicators with a score of "Unacceptable"/"No"** |  |
| **\*MAJOR Indicators with a score of "Unacceptable"/"No"** |  |
| **MINOR Indicators with a score of "Unacceptable"/"No"** |  |

**Drug outlet falls into the following category (choose *one*) (Adhere to the certification criteria)**

|  |  |  |
| --- | --- | --- |
| **Category of Retail Pharmacy** | **Licensing Criteria** | **Summary**  **(Tick)** |
| **Excellent** | **Licensing without non conformances** |  |
| **Good** | **Licensing with minor non conformances** |  |
| **Satisfactory** | **Licensing with major non conformances after submission of CAPA** |  |
| **Poor** | **Not Licensed with critical non conformances until improvements are made and re-inspection done** |  |

**PART H: Signatures**

**The inspector signing below declares that all the above corresponds with the actual findings in the pharmacy on the day of the inspection.**

**­­­­­­­­­­­­­­­­­­­­­­­­­­­­­­­­­­­­­­­­­­­­­­­­­­­\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_**

**Name of Inspector Designation Signature**

**This is confirmed by the signature of the Head, Drug Inspectorate Services**

**­­­­­­­­­­­­­­­­­­­­­\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ \_\_\_\_\_\_\_\_\_\_\_\_ \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_**

**Name of Head, Drug Inspectorate Services Date Signature**

**NON CONFORMANCES (To be filled in duplicate and a copy to remain at the Pharmacy/Drug Shop)**

|  |  |
| --- | --- |
| Name of the Pharmacy/ Drug Shop |  |
| Physical address of premises |  |
| Date of Inspection |  |
| **Summary of Non Conformances** | |
|  | |
| **Inspector**  **(Name, Signature and Phone Number)** | **Pharmacist/ Auxillary Staff/ Licensed Seller (Name, Signature and Phone Number)** |
|  |  |