PHARMACY AND POISONS BOARD

**Annex IV**

**CHECKLIST FOR INSPECTION OF RETAIL PHARMACY OUTLET**

|  |  |
| --- | --- |
| Date of Inspection | ....................................................................................... |
| Date of Last Inspection | ............................................................................................ |

1. **Particulars of the establishment**

|  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- |
| 1.1 | | Name of Outlet………………………………………………….……………………………………………….…. | | | | |
| 1.2 | | Mailing Address: | | | 1.3 | Physical Address/Location: |
| ……………..…………………………………… | | | | | …………………………………………………... | |
| ……………..…………………………………… | | | | | …………………………………………………... | |
|  | | | | |  | |
| 1.3 | | Telephone No:………………………………...….. | | | 1.5 | Fax No:…………………………………… |
| 1.4 | | E-mail:…………………………………………………………………………………………... | | | | |
| 1.5 | | Ownership:  Sole proprietorship    Partnership    Limited company    Other (specify) | | | 1.8 | Registered premises? Yes No  Reg. No……………………………  Retail License? Yes No  Licenses displayed? Yes No  If yes, are the licenses valid? Yes No  If No, then clarify…………. |
| 1.6 | | **Type of Inspection:**  **Routine**  **Special**  **Follow up**  **Comprehensive**  **Concise** | Comments: | | |

1. **Personnel**

*Licensed person/superintendent:*

|  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- |
| 2.1 | Name: | …………………………………………………………………… | | | | | |
| 2.2 | Designation | …………………………………………………………………… | | | | | |
| 2.3 | Registration/ Enrolment No  (in case of Pharmacist/Pharmaceutical Technologist): | …………………………………………………………………… | | | | | |
| 2.4 | Is the Certificate of Registration displayed? | | Y/N | Is it Valid? | Y/N | Is there a Valid Annual Practice License? | Y/N |
| 2.5 | If there is no authorized person, specify and explain…………………………………………………… | | | | | | |

1. ***Other Persons handling Drugs:***

|  |  |  |
| --- | --- | --- |
|  | 3.1 | 3.2 |
|  | Name | Qualifications |
|  |  |  |
|  |  |  |
|  |  |  |
|  |  |  |
|  |  |  |
|  |  |  |
|  |  |  |

### 4. General condition of premises

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
|  | Is the premises appropriate for the intended purpose of Retail Pharmacy in respect to: | | | |
|  |  | OTC | Dispensary | Other Areas |
| 4.1 | Layout and  Size/Number of rooms |  |  |  |
| 4.2 | Hygiene |  |  |  |
| 4.3 | State of repair |  |  |  |
| 4.4 | Ventilation & Cooling System |  |  |  |
| 4.5 | Lighting |  |  |  |
| 4.6 | Display of drugs |  |  |  |
| 4.7 | Utilities: Running water, hand wash basins, WC |  |  |  |
| 4.8 | In case of non-conformity, explain:  (if space provided is not enough, please use continuation page(s)) |  |  |  |

### Security of premises

|  |  |  |
| --- | --- | --- |
|  | Is the premises secure in respect to: | |
|  |  | Retail Pharmacy |
| 5.1 | External Perimeter security e.g. fencing, gates, walls, windows etc Security features e.g. alarms, CCTV |  |
| 5.2 | Special secure cupboards for restricted drugs e.g. controlled drugs |  |
| 5.3 | Accessibility to unauthorized person(s) |  |
| 5.4 | Documents/records keeping |  |
| 5.5 | In case of non-conformity, explain: | (if space provided is not enough, please use continuation page(s) |

### Storage conditions

|  |  |  |
| --- | --- | --- |
|  | Is the storage condition suitable for the intended purpose in respect to: | |
|  |  | Retail Pharmacy |
| 6.1 | Durability of floor and ease of cleaning.  Condition of walls and ceilings. |  |
| 6.2 | Prevention of infestation by vermin and pests |  |
| 6.3 | Adequate shelving |  |
| 6.4 | Pallets |  |
| 6.5 | Execution of stock rotation/ FEFO/FIFO |  |
| 6.6 | Storage of returned /recalled/expired/quarantined goods |  |
| 6.7 | Cold rooms/refrigerators for the storage of vaccines and/or biologicals |  |
| 6.8 | Are the Products protected from direct sunlight and fire? |  |
| 6.9 | Is there adequate ventilation? |  |
| 6.10 | In case of non-conformity, explain: | (if space provided is not enough, please use continuation page(s) |

### Auxiliary items

|  |  |  |
| --- | --- | --- |
|  | Are suitable ancillary items available for the intended purpose in respect to the follow items: | |
|  |  | Retail Pharmacy |
| 7.1 | Hotplate or any other source of heat |  |
| 7.2 | Weighing balance(s) and weights |  |
| 7.3 | Dispensing measures e.g. measuring cylinders, beakers etc |  |
| 7.4 | Source of clean and safe water |  |
| 7.5 | Mortar and Pestle, spatula and dispensing tray |  |
| 7.6 | In case of non-conformity, explain: | (if space provided is not enough, please use continuation page(s) |

### Record-keeping and documentation

|  |  |  |
| --- | --- | --- |
|  | Are record keeping and documentation suitable for intended use in respect to: | |
|  |  | Retail Pharmacy |
| 8.1 | List of Suppliers- all sources and Legality |  |
| 8.2 | Prescription Book |  |
| 8.3 | Poison Book |  |
| 8.4 | Narcotics and Psycho tropics Book |  |
| 8.5 | Written procedures for maintenance of Cold chain product |  |
| 8.6 | Ledger Book or an appropriate Inventory Control System |  |
| 8.7 | Receipts/Invoices |  |
| 8.8 | Copies of delivery notes |  |
| 8.9 | Are the entries accurate |  |
| 8.10 | Endorsement of entries by authorized person(s) |  |
| 8.12 | Written procedures for handling returned, recalled and/or expired drugs |  |
| 8.13 | Written procedures for dealing with complaints and/or adverse reaction reports |  |
| 8.14 | In case of non-conformity, explain: | (if space provided is not enough, please use continuation page(s) |

### The Products- (Physical examination)

|  |  |
| --- | --- |
| Comments on the product suitable for intended use in respect to: | |
|  | Retail Pharmacy |
| Language of labels and package inserts; Labelling requirements; How are the drugs transported?  In case of non-conformity, explain: | (if space provided is not enough, please use continuation page(s) |

### Reference materials

|  |  |  |
| --- | --- | --- |
|  | Are appropriate reference material(s) available? | |
|  | Retail Pharmacy | |
| 10.1 | British National Formulary (Current Edition) | Please indicate edition |
|  |
| 10.2 | Standard Treatment Guidelines |  |
| 10.3 | National Essential Drug List |  |
| 10.4 | Pharmacy and Poisons Act, Cap 244 Laws of Kenya and its corresponding amendments |  |
| 10.5 | Regulations & Guidelines | List the available |
| 10.6 | Others (specify) |  |

|  |  |
| --- | --- |
| **11.** | Any Other Observations |
| (if space provided is not enough, please use continuation page(s) | |

|  |  |
| --- | --- |
| **12.** | Summary of General Observations |
| (if space provided is not enough, please use continuation page(s) | |

### 13. Owner’s/In-charge Declaration

I/we……………………………………………………………..…….in charge/owner of the said premises, certify that, the information and observations made on this sheet during the auditing of the premises to be true and accurate.

|  |  |
| --- | --- |
| Signature……………………………………………….. | Date…………………………………………………. |

### Other staff Declaration

I/we……………………………………………………………..…….in charge/owner of the said premises, certify that, the information and observations made on this sheet during the auditing of the premises to be true and accurate.

|  |  |
| --- | --- |
| Signature……………………………………………… | Date…………………………………………………. |

***14. Inspectors’ declaration***

I/we, the undersigned auditor(s) of the said premises, declare that, the information and observations made on this sheet during the auditing of the premises to be true and accurate.

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
|  | **Names of Inspector(s):** | Designation | Date | Signature |
|  | …………………………………………… |  |  |  |
|  | …………………………………………… |  |  |  |
|  | …………………………………………… |  |  |  |