|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| Format: QMS/FMT/002  Revision No: 1  Effective Date: 20 June 2022 | | Department/Division | Food and Drugs Inspection and Safety Monitoring/Food and Drugs Inspection & Compliance | |
| Document Type: **Form** | | | Doc. No | : FDISM/FDIC/FOM/002 |
|  | Title: **Application Form for Premise Licensing of medical products** | | Revision Number | : 1 |
| Revision Date: | : 24/08/2022 |
| Effective Date | : 22/09/2022 |
| Review Due Date | : 21/09/2025 |
| Ref Doc. | : FDISM/FDIC/GDL/005 |

|  |  |  |  |
| --- | --- | --- | --- |
| Name of Premise: | | Application date: / /  *DD / MM/ YYYY* | |
| Domestic Company Registration code: | | Registration date in Rwanda FDA: / /  *DD/ MM/ YYYY* | |
| Physical location:  (Province, District, Sector, Cell) | | Registered Address: | |
| Global Positioning System (GPS) Coordinates | | Name of responsible technician:  (If applicable) | |
| Company e-mail:  Company Telephone: | | Qualification: | |
| Name of Managing Director: | | Email of responsible technician:  (if applicable) | |
| Email of Managing Director  Telephone No: | | Tel of responsible technician: | |
| **TYPE OF PREMISE:**  (Please tick below)  □ Retailer  □ Wholesaler  □ Distributor  □ Manufacturer  □ Hospital Pharmacy  □ Central Medical Stores  □ Health Centres  □ Health Posts  □ Other …….…………………………. | **MAIN ACTIVITY**  (Please tick below)  □ Human retail pharmacy  □ Human wholesale pharmacy  □ Human wholesale of medical device  □ Small scale manufacturer  □ Manufacturer of medical products  □ Veterinary Drug shop  □ Veterinary retail pharmacy  □ Veterinary wholesale pharmacy  □ Veterinary manufacturing facility  □ Vaccine manufacturing facility  □ Herbal drugs wholesaler  □ Herbal drugs retailer  □ Herbal drugs manufacturer  □ Hospital pharmacies  □ Central Medical stores  □ Health posts & Health Centers  □ Orthopedic shop  □ Optical shop  □ Other specify ……………….. …………………………………… | | **TYPE OF APPLICATIONS**  (Please tick below)    □ Site location approval  □ New Application  □ Renewal  □ Variation  □ *Change of ownership*  □ *Change of location&Additional line*  □ *Change responsible technician*  □ *Change of name of the Establishment*  □ *Closure of the business activities*  □ Re-inspection  □ Other specify ……………….… |
| **AFFIDAVIT** | | | |
| I hereby affirm that the statement in this application is true and correct.    **Applicant’s Name and Signature Date (dd/mm/yyyy)** | | | |
| **FOR OFFICIAL USE ONLY:**  Date Received : ……./……./……  Inspection date: … …/……../……..  Approved/ Denial: A / D .  Approval date : …../……./…… | | | |

|  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
|  | 1. **REQUIREMENTS FOR PREMISE LICENSING OF MEDICAL PRODUCTS** | | | | **New application** | **Renewal** | **Change ownership** | **Change technician** | **Change location** | **Additional line** | **Additional branch** | **Change of name** | **Closure of business** |
|  | **Premise name:** | **Date:**  **……../…../...….** | | |
|  | **Documents** | **YES** | **NO** | |
| 1 | A dully filled application form for premises licensing of Medical Products- FDISM/FDIC/FOM/002 |  |  | | x | x | x | x | x | x | x | x | x |
| 2 | RDB registration certificate of the domestic company or equivalent certificate /recommendation from local government |  |  | | x | x | x |  | x |  | x | x |  |
| 3 | Architectural plan of the site applicable for manufacturing facility |  |  | | x |  |  |  | x | x | x |  |  |
| 4 | Environment impact assessment report applicable for manufacturing facility |  |  | | x |  |  |  | x | x | x |  |  |
| 5 | Proof of Payment of the prescribed fees (referred to regulation related to Regulatory service Tariff/fees and Fines) |  |  | | x | x |  | x | x | x | x |  |  |
| 6 | List of products to be manufactured applicable for manufacturing facility |  |  | | x |  |  |  |  |  |  |  |  |
| 7 | Lease/rent contract of the premise/house |  |  | | x |  |  |  | x |  | x |  |  |
| 8 | Notarized copy of Degree (and equivalence if applicable) of Responsible Technician  **NB:**   1. **Human Retail Pharmacy:** minimum of 2 months experience in community pharmacy 2. **Human Wholesale Pharmacy:** minimum of 2 months’ experience in supply chain management 3. **Central medical store and the branches:** minimum of 2 months’ experience in supply chain management   **Hospital pharmacy:** minimum of 4 months’ experience in clinical pharmacy |  |  | | x |  | x | x |  |  | x |  |  |
| 9 | Notarized Valid License of the responsible technician to Practice Profession issued by Recognized Professional Councils in Rwanda (if applicable) |  |  | | x | x | x | x |  |  | x |  |  |
| 10 | Notarized degrees of the key personnel to be involved in the manufacturing process, quality control and quality assurance  **NB:** 2 years minimum experience for a Bachelor degree holder; or 6 months minimum experience for a Master degree holder in the relevant field with working experience in a company that has been approved as manufacturer of medical products |  |  | | x |  |  | x |  |  | x |  |  |
| 11 | Professional agreement between the Managing Director/ Director General/ Chief Executive Officer and the responsible technician in case the Managing Director is not the responsible technician |  | |  | x | x | x | x |  |  | x |  |  |
| 12 | The copy of Identity Card/Passport of the managing Director/ Director General/ Chief Executive Officer and the Responsible technician |  | |  | x | x | x | x |  |  | x |  |  |
| 13 | Written commitment of the responsible technician, to respect the laws and regulations relating to the profession and ethics |  | |  | x | x |  | x |  | x | x |  |  |
| 14 | Signed resignation letter/proof of service delivered issued by the last employer of responsible technician, if applicable |  | |  | x |  |  | x |  |  | x |  |  |
| 15 | Copy of Valid contract between responsible technician and Managing Director/ Director General/ Chief Executive Officer |  | |  | x | x | x | x |  |  | x |  |  |
| 16 | A Detailed curriculum vitae of the responsible technician |  | |  | x |  |  | x |  |  | x |  |  |
| 17 | Original authorization of the establishment issued by Rwanda FDA |  | |  |  | x | x | x | x | x | x | x | x |
| 18 | Notarized sales agreement between former and new owner |  | |  |  |  | x |  |  |  |  |  |  |
| 19 | Provide a list of closing stock of medical products and its intended use |  | |  |  |  |  |  |  |  |  |  | x |

|  |  |  |  |
| --- | --- | --- | --- |
|  | 1. **RE – INSPECTION** | | |
|  | **Premise name:** | **Date:**  **……./…../...….** | |
|  | **Documents** | **YES** | **NO** |
| 1 | Re-inspection application letter addressed to the Director General of Rwanda FDA, mentioning the proposed dates. |  |  |
| 2 | The proof of payment of prescribed re-inspection fees |  |  |
| 3 | A Corrective Actions and Preventive Actions (CAPA) report, detailing what has been implemented with respective visual proof and timelines for non-implemented recommendations. |  |  |

|  |  |  |  |
| --- | --- | --- | --- |
|  | 1. **SITE LOCATION APPROVAL** | | |
|  | **Premise name:** | **Date:**  **……./…../...….** | |
|  | **Documents** | **YES** | **NO** |
| 1 | Letter of intent |  |  |
| 2 | Site master plan (indicating the location /plan of the premise and the surroundings activities) |  |  |
| 3 | Environmental impact assessment |  |  |

|  |  |  |  |
| --- | --- | --- | --- |
|  | 1. **ARCHITECTAL PLAN APPROVAL** | | |
|  | **Premise name:** | **Date:**  **……./…../...….** | |
|  | **Documents** | **YES** | **NO** |
| 1 | Approval letter for site location from the Authority |  |  |
| 2 | Architecture plan showing but not limited to the following: |  |  |
| i) Production process flow chart. |  |  |
| ii) Sanitation facilities (Clean water and waste water treatment system) |  |  |
| iii) Mechanical ventilation /Air handling unit /Heat, Ventilation and Air Conditioning (HVAC). |  |  |
| iv) Finishing materials (Production floor and walls shall be seamless, ceiling, doors and windows shall be easy to clean). |  |  |

***INSTRUCTION FOR APPLICANT:***

1. *Ensure that* ***ALL*** *sections of the application form are fully completed before submission. Send completed application form with stated requirements (see above) to the official email* [*:info@rwandafda.gov.rw*](mailto:info@rwandafda.gov.rw)
2. *Incomplete application* ***WILL NOT*** *be accepted.*
3. *Application processes will take 30 working days upon receipt of fully complete documents required.*