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| Format: QMS/FMT/002Revision No: 1Effective 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 |

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| 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 : …../……./……  |

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|   | 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 |

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|  | 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. |  |  |

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|  | 1. **SITE LOCATION APPROVAL**
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|  | **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 |  |  |

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|  | 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*
2. *Incomplete application* ***WILL NOT*** *be accepted.*
3. *Application processes will take 30 working days upon receipt of fully complete documents required.*