Format: QMS/FMT/002 Revision No: 1 Effective Date: 20 June 2022	Department/Division/Office/Unit	Food and Drugs Inspection and Safety Monitoring/Food and Drugs Inspection & Compliance
Document Type: **Requirements**		Doc. N° : FDISM/FDIC/CKL/017
RWANDA FDA Rwanda Food and Drugs Authority	Title: **REQUIREMENTS FOR PREMISE LICENSING OF MEDICAL PRODUCTS**	Revision Number : 1 Revision Date: : 24/08/2022 Effective Date : 26/09/2022 Review Due Date : 23/08/2022 Ref Doc. :FDISM/FDIC/GDL/005

	Documents ***(Note: Provide documents corresponding to the service required)***	**New application**	**Renewal**	**Change ownership**	**Change technician**	**Change location**	**Additional line**	**Additional branch**	**Change of name**	**Closure of Approved business**
1	A dully filled application form for premises licensing of Medical Products- FDISMFDIC/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	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:** **Human Retail Pharmacy:** minimum of 2 months experience in community pharmacy **Human Wholesale Pharmacy:** minimum of 2 months' experience in supply chain management	x	X	x	x	X		x	X	

	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									
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	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		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		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 the Valid contract between responsible technician and Managing Director/ Director General/ Chief Executive Officer	x	x		x	X		x	X	
16	A Detailed curriculum vitae of the responsible technician	x			x			x		
17	Original authorization of the		x	x	x	x	x	x	x	x

	establishment issued by Rwanda FDA									
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
RE – INSPECTION										
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.									
	SITE LOCATION APPROVAL									
1	Letter of intent									
2	Land master plan indicating the location and the surrounding activities									
3	Environmental impact assessment									
	ARCHITECTAL PLAN APPROVAL									
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).									

All the above requirements are sent to the following email: info@rwandafda.gov.rw

***Rwanda FDA Accounts**

BNR:1000047658 entitled "RWANDA FDA" in FRW
BNR:1000047666 entitled "RWANDA FDA" in USD
BK:100025143684 entitled "RWANDA FOOD AND DRUGS AUTHORITY" in FRW
BK:100025143765 entitled "RWANDA FOOD AND DRUGS AUTHORITY" in USD

Reference:

Guidelines for Licensing of Public and Private Manufacturers, Distributors, Wholesalers and Retailers of Medical Products Doc N°: ***FDISM/FDIC/GDL/005***

Done at Kigali on ...22.09.2022.

Dr. Emile BIENVENU
Director General

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